DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2017

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

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

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PART 6

	Page
National Institutes of Health	**1**
Department of Education	**167**
Centers for Disease Control and Prevention	**215**

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2017

WEDNESDAY, MARCH 16, 2016.

NATIONAL INSTITUTES OF HEALTH

WITNESSES

HON. FRANCIS S. COLLINS, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DOUGLAS LOWY, M.D., ACTING DIRECTOR, NATIONAL CANCER INSTITUTE

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

RICHARD J. HODES, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING

NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. COLE. Good morning. It is my pleasure to welcome you to the Subcommittee on Labor, Health and Human Services, and Education to discuss the fiscal year 2017 National Institutes of Health budget request. We are looking forward to hearing the testimony of Dr. Collins, and his colleagues, I know, will be brought in for questions along the way.

I would like to publicly thank Dr. Collins and the staff at the NIH for hosting me and other subcommittee members for a briefing and a tour at the NIH campus a few weeks ago, the second of what I hope becomes an annual trek out to NIH by this committee. We all left NIH with a deeper appreciation of the exciting work your staff do every day to find ways to save lives.

I am proud that last year this Congress was able to increase NIH funding by $2,000,000,000, and I am confident that through these efforts, one day we will find cures for diseases like cancer and Alzheimer's. I was, therefore, especially disappointed to see the proposed budget cut to the National Institutes of Health this year by the administration.

A proposal to divert $1,000,000,000 of biomedical research funds to the mandatory side of the budget ledger and rely on new and possibly unlikely authorizations to continue the advances that we have made in increasing the research funding is disheartening. Frankly, I do not plan to let the $1,000,000,000 cut stand. We need to ensure a sufficient basic biomedical research base is sustained to pave the way for these long-term advancements.

Proposing new one-time mandatory spending that may never materialize is not the path to do this. I look forward to discussing the effects of the President's proposed discretionary budget cuts on your research this morning.

I also want to stress how important it is to ensure that we continue to focus on the next generation of investigators. We know how long it takes for a new drug or treatment to make it from the lab to the patient. So without a pipeline of young researchers committed to following the process, we won't be able to find the cures we seek.

I will be asking some questions this morning about a variety of issues like Institutional Development Awards, Alzheimer's disease, and the Cancer Moonshot. I hope to learn more this morning on how the increases we provided for the NIH this year are being used to move us forward toward cures of these diseases that cause so much suffering in our Nation.

So without much further ado, I want to welcome Dr. Francis Collins, the NIH Director, to the subcommittee. Dr. Collins is accompanied by four of his institute directors who can assist in answering specific Member questions. They are Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases; Dr. Richard Hodes, the Director of the National Institute of Aging; Dr. Doug Lowy, the Acting Director of the National Cancer Institute; and Dr. Nora Volkow, the Director of the Institute on Drug Abuse.

As a reminder to the subcommittee and our witnesses, we will abide by the 5-minute rule. But before we begin, we have been joined by both the big chairman, as we like to call him, and our ranking member. And so I am going to defer first to the chairman for any remarks he would like to make.

Then I am going to move to Mrs. Lowey, and then I will move to my good friend and ranking member, Ms. DeLauro. And then we will move to the testimony.

So, Mr. Chairman.

Mr. ROGERS. Mr. Chairman, thank you.

Mr. COLE. And may I add, the 5-minute clock does not apply to you. [Laughter.]

Mr. ROGERS. That means I have got to keep it under 1 minute.

Well, welcome, all of you, to this hearing, and thank you, Mr. Chairman, for the courtesy.

Through all of our work together, Dr. Collins, you have exhibited the highest level of professionalism and dedication. And during a time of so much groundbreaking research in addiction science, Alzheimer's, cancer, NIH surely has the right man at the helm, I think, to meet the challenges that we face.

The emergence of the Zika virus throughout the Western Hemisphere, one of those challenges that you are undertaking, underscores the importance of NIH's mission to gain and apply knowledge to enhance health, lengthen life, and to reduce illness and disability. Since most of its recent emergence in Brazil 10 months ago, Zika, of course, has spread to dozens of countries. And although CDC does not anticipate any widespread outbreak in the U.S., we have had 193 travel-associated cases reported thus far.

The chairman and I and others just returned from a visit to South America night before last. We met leaders, health officials about—talking about the virus. We are interested to hear your thoughts on the role NIH can play and are playing to develop vaccines and therapeutics based on existing and future research to limit Americans' exposure going forward.

We met with various officials on that trip, particularly in Brazil, and explored what they are doing to try to tamp out the exposure—and others in the region.

Given the importance of NIH research, I am proud that we were able to work in a bipartisan fashion to increase your budget in fiscal 2016 by $2,000,000,000 to fund more groundbreaking medical research. This year, the NIH budget request prioritizes basic foundational research, precision medicine, and applying big data to improve health outcomes.

In addition to the public health benefits that accompany your work, the economic impact of medical research should not be underestimated. NIH research dollars not only impact research facilities and researchers, but they also help get new drugs and devices to the marketplace.

Through these funds, we have established a strong relationship between NIH and Kentucky, the Markey Cancer Center, a National Cancer Institute designated cancer center at the University of Kentucky, and the UK Center for Clinical and Translational Science, that continue to perform transformative research benefiting the entire region and country. We look forward to continuing our work together to bring an end to these devastating diseases.

That being said, funding toward that goal must come through regular discretionary channels that allow us to respond to needs as they arise. I am disappointed to see the request cuts NIH discretionary funding by $1,000,000,000, including $57,000,000 from the National Institute on Drug Abuse, NIDA, and then backfills the hole with over $1,800,000,000 in mandatory money.

However, I look forward to meeting your requirements through the regular appropriations process. We don't like mandatory spending. It has grown completely out of control. We have had to cut discretionary spending the last 5 years by some almost $200,000,000,000 in real cuts. In the meantime, the mandatory entitlement side of the budget is soaring out of control.

When I came to Congress, we appropriated two-thirds of Federal spending. Now it is one-third. Entitlements were one-third. Now they are two-thirds and growing. And unless we deal with it, we can't even pay the interest on the debt with discretionary funds.

So that is why we are so dead set against mandatory increases. We need to keep control of the spending that takes place. It is the only accountable way under the Constitution.

I am pleased to see Dr. Nora Volkow with us again this year. She has been a champion for advancing the science of drug abuse and addiction as the Director of the National Institute on Drug Abuse for 13 years now. Beyond her personal expertise in cutting-edge brain imaging, she has been with us since the beginning of our battle against drug abuse in southern and eastern Kentucky, where it really got its start.

I am anxious to hear about your recent efforts regarding the abuse of prescription medications. As you well know, this epidemic now runs rampant across our Nation. I hope you will update the committee on your work with pharmaceutical companies to evaluate the risks associated with the long-term use of opioids and what NIH is doing to research abuse-deterrent medications and opioid alternatives.

I am also pleased that you have both once again committed to sharing these insights at the National Prescription Summit in Atlanta in a few weeks, and we are excited about your being there for this one. And we are hopeful the chairman and others on the subcommittee will be able to make that fifth annual summit as well.

Secondly, I look forward to hearing from you today about your pursuit of the Adolescent Brain Cognitive Development Study. I believe collecting extensive data on the effects of marijuana and other drugs on a young person's brain will help us finally appreciate the harm these substances can do over time.

Federal law is clear. Yet States continue to rush to decriminalize or legalize marijuana, despite the lack of sufficient scientific data about its use. This study will help close that gap and, hopefully, shift public perception back to reality.

We appreciate this very esteemed panel being with us today. We look forward to working with you during the year to make sure that you are doing what the country expects of us.

Thank you, Mr. Chairman.

Mr. COLE. Thank you, Mr. Chairman.

We want to move next to our ranking member of the full committee, the distinguished lady from New York, Mrs. Lowey.

Mrs. LOWEY. And I thank you, my distinguished chair. And thank you for holding this very important hearing. Pleasure to be with you and Ranking Member DeLauro.

This is one of the most exciting hearings I attend every, every appropriations session, and I would like to welcome Dr. Lowy, Dr. Fauci, Dr. Hodes, Dr. Volkow, and of course, Dr. Collins. I would also like to thank each of you for your service, and it is because of your vision and your dedication the National Institutes of Health are providing a bright future for millions of Americans suffering from illness and disease.

I am very pleased you are here to discuss important investments in biomedical research and the health of our Nation. Thank you.

And I must say I was thrilled, as I always am, to meet with many of you at the NIH 2 weeks ago. During our meetings, I saw firsthand the lifesaving breakthroughs you are leading, including gene therapies to treat patients with advanced cancer; ultra high field MRI machines to get the clearest look at an aging brain to date, allowing for advances in Alzheimer's and other brain diseases; and clinical studies that are improving mental health and reducing suicides and so much more.

These breakthroughs and the need for additional research into hundreds of other diseases is why this committee fought to increase funding for the NIH by $2,000,000,000 in the fiscal year 2016 omnibus spending bill. NIH has the world's best physicians, researchers, technology at our disposal, and I worry that even a

$2,000,000,000 investment will not go far enough to ensure that the NIH can compete against foreign research initiatives. It does not serve our national interests if there are not enough grants to support young researchers or if researchers are lured away to foreign countries to develop medical breakthroughs abroad.

That is why last year, although I was pleased with the $2,000,000,000 increase, I called on this committee to once again commit to doubling funding for the NIH. I was here when that bipartisan effort was made, and I do call on my colleagues, both sides of the aisle, to double the funding for the NIH.

We can't afford to let some of these brilliant researchers not get the support they need. Your fiscal 2017 budget request would be a positive step toward that end. Your budget includes targeted investments, such as the Cancer Moonshot, increases in the Precision Medicine Initiative, the BRAIN Initiative. In addition, it would result in 600 additional research project grants.

These investments not only fund research that eases suffering, they would greatly reduce ballooning costs associated with treatment down the line. By the way, I must say I had the opportunity to visit Watson, the IBM research center in my district, just last week. And in fact, I am not sure I understood everything they were explaining to me, but what I paid particular attention to was the coordinative efforts between Watson and other research facilities and your precision brain initiative.

It is so amazing to me that precision medicine and the research that is being done at the NIH is coordinating with many facilities. And I understand in my follow-up Watson isn't the only place. So, Dr. Collins, I would love if you would touch on that as well, the coordination that is going on and the amazing work to think that someone could get their cancer analyzed at the NIH and all the facilities out there in a machine such as Watson that could certainly help lead us to new discoveries and new cures.

Let me say, however, while representing a net increase of $825,000,000, your budget will result in a $1,000,000,000 cut in discretionary funding for NIH. And I assure you that this chair and ranking member and the big chair, who I think is still over there, and I will just not let that happen. As an appropriator, the department's request for substantial sums in mandatory funding is of concern.

Finally, in addition—and if you can get it, good luck to you. I mean, that would really be great.

Finally, in addition to your budget request, the NIH is also awaiting congressional action on the emergency supplement to combat Zika. The world is looking to the United States to lead, and I am concerned that delaying consideration of the emergency supplemental is leaving the American public, particularly women who are pregnant or could soon be pregnant, at severe risk.

And I know you are doing additional research, Dr. Fauci. I still am not satisfied that only pregnant women can suffer from Zika. So I know we have touched on that in our discussions.

But the bottom line is we are already behind. We must act. I urge this committee and Congress as a whole to meet this need without delay.

And thank you, Mr. Chairman.

Mr. COLE. Thank you.

We now to go to my good friend, the ranking member of the subcommittee, the gentlelady from Connecticut.

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

And if there are any Yankee fans in this audience, you will know the term "murderers' row," which was Babe Ruth, Tony Lazzeri, Lou Gehrig, and others. I want to look at this group this morning as "survivors' row" and Volkow, Lowy, Collins, Hodes, and Fauci. And you are, indeed, allowing people to survive.

As I have said many times in the past, you give the gift of life, and we are so honored really to have you here this morning and to listen to you and have the opportunity to have a discussion.

So, Mr. Chairman, again, I want to welcome everyone. And as we discuss the budget, the NIH is the leading biomedical research entity in the world. And with each scientific discovery, each medical breakthrough, its research advances human knowledge to improve the quality of our life and saves lives.

Funding this research has the power to do more good for more people than almost anything else within the purview of our Government, and last year we were able to provide a significant increase of $2,000,000,000 for the NIH. I want to say a thank you to Chairman Cole, and to all of the members of the subcommittee, for their bipartisan work to support NIH research. The additional funds are helping NIH accelerate research to find cures for cancer, Alzheimer's, and help them move forward with exciting new programs like the Precision Medicine Initiative and the BRAIN Initiative.

However, I was disappointed to learn that funding for HIV/AIDS research is not increasing in fiscal year 2016. In its 2016 budget request, NIH had proposed an additional $100,000,000 for HIV/AIDS research in order to advance its work on a universal vaccine to prevent HIV infection. I think it is a mistake to change course, and I hope to see NIH support that research this year, and it is something that I will advocate for.

NIH plays an integral role in responding to emergency public health threats. In 2014, as Ebola raged in West Africa, NIH accelerated its work to create an Ebola vaccine. More recently, NIH has been working to develop a vaccine to address the looming Zika crisis, which poses an urgent and serious threat, as my colleague Mrs. Lowey said, to pregnant women and their babies.

If you take a look at yesterday's New York Times, "Pregnancies Shadowed by Fears of Zika." This is real in the minds of men and women, and women particularly.

I look forward to hearing from Dr. Fauci about the current status of Ebola vaccine candidates, as well as progress on moving Zika vaccine candidates toward clinical trials. Some of my colleagues have expressed a desire to shift unobligated funds that Congress provided for Ebola to respond to Zika. I strongly oppose that idea.

I would be anxious to know what activities we would have to forego if we shift funds away from Ebola to Zika. We need to be able to respond to multiple public health threats at the same time, which is why in this Congress and the last Congress I proposed funding a public health emergency fund that mirrors the Disaster

Relief Fund, which would enable the Federal Government to immediately respond to public health threats.

I would also urge the NIH to use its statutory authority to respond to the rising cost of prescription drugs. As you know, when taxpayer-funded Federal research results in a drug patent, NIH may require the patent holder to license the resulting intellectual property to third parties, resulting in competition that drives down drug prices.

It is outrageous that drugs invented under taxpayer-funded grants can cost sick Americans hundreds of thousands of dollars over the course of a year. The public pays at the front end, and they pay at the back end.

I must note that while NIH is now funded at $32,100,000,000, thanks to the $2,000,000,000 increase, that funding has not kept pace with the rising cost of biomedical research. NIH's fiscal year 2016 funding level remains $7,500,000,000 below the 2003 level, adjusted for biomedical inflation.

Fifteen years ago, NIH funded about one in three meritorious research grants. Today, the rate has fallen to about one in five, a slight improvement over recent years, but still low by historical standards. We are missing opportunities to work toward cures for life-altering diseases affecting far too many people.

That brings us to today's topic and today's discussion, the 2017 budget request. So much good in the proposal, and I applaud the ambitious proposal to increase cancer research by $680,000,000 in 2017. As a 30-year survivor of ovarian cancer, you have heard me say it before, I am alive because of the grace of God and biomedical research.

I am pleased to see proposed increases of $100,000,000 and $45,000,000 for the Precision Medicine Initiative and the BRAIN Initiative. These initiatives have the potential to revolutionize our understanding of a disease, as well as our understanding of long-term physical and mental health.

I think we can do better. This budget is clearly constrained by sequestration and arbitrarily low budget caps. As I said earlier, I think we need to boost funding for HIV/AIDS research and not relent until we have developed a universal vaccine. This would save countless lives, as well as save billions of dollars in treatment costs in future years.

We need to continue to develop new antibiotics or risk the devastating consequences of antibiotic-resistant bacteria to our public health and our entire public healthcare system. I want to note my concern over mandatory funding for NIH in this budget. It is the responsibility of this committee to fund the NIH.

An increase to this subcommittee's allocation is the straightforward and responsible way to support NIH research, rather than to rely on mandatory funding that will not materialize. We should also continue to uphold the longstanding tradition of scientific independence in setting Federal research agendas rather than override scientific judgment with congressional preferences. That ability to allow scientific independence has been a hallmark of this subcommittee.

I had the opportunity to introduce a bill last year that would enable our committee to increase NIH funding by 50 percent over 5

years by providing a cap adjustment. Just like what we do in a cap adjustment for program integrity funding, we have a model. We do it there. We ought to be able to do this for the NIH. That would ensure proper funding for research without robbing other vital programs to do so.

Thank you again for everything that you do. Biomedical research is one of the most important investments that we can make as a Nation. As I said, it gives the gift of life.

Thank you. I look forward to your testimony and to our discussion.

Mr. COLE. Thank you.

DR. COLLINS OPENING REMARKS

And now, Dr. Collins, we will go to your opening statement.

Dr. COLLINS. Well, good morning, Chairman Cole, Ranking Member DeLauro, Chairman—from the full committee—Rogers, and ranking member of the full committee, Mrs. Lowey.

My colleagues and I are delighted to appear before you today, and we were honored very much to host you at NIH with several of your committee members. And by all means, let us do it again next year. I think that was extremely helpful for us to have you on our campus.

In this hearing on the last budget proposal of this administration, I plan to reflect more broadly in my opening statement here than usual on NIH's contribution to the Nation's health. So I am going to break with tradition and make some predictions.

PROGRESS 10 YEARS FROM NOW

Ten areas in which I believe we can expect to see major progress 10 years from now, given a sustained commitment of resources for NIH. So this is 10 for 10. So here we go.

First, the long arc of scientific discovery must begin with basic science. Experiments that are going on, excuse me, right now in labs across this Nation contain the seeds of breakthrough discoveries that will transform medicine.

ONE: ANALYSIS OF INDIVIDUAL HUMAN CELLS

Let us fast forward to 2026 and the first of these 10 breakthroughs, and I think that will be advances in analysis of individual human cells. Cells are the unit of life. Cells are for biology like atoms are for chemistry.

And yet during the long history of medical research, we haven't really had the technical ability to study individual cells. We have had to deal with millions of cells, maybe billions. With new technologies just invented in the last couple of years, that is all changing.

As just one example, we can now decode the process by which individual immune cells attack and destroy healthy tissue in autoimmune disorders and transform the ways that we approach lupus, rheumatoid arthritis, multiple sclerosis, and many other diseases.

TWO: BRAIN INITIATIVE

On to breakthrough number two. In 10 years' time, tools developed through the BRAIN Initiative will have identified hundreds of different types of brain cells and, more than that, major circuits responsible for motor function, vision, memory, and emotion, all functioning at the speed of thought.

As a result, we will be able to diagnose conditions earlier and more precisely, and we will have new targets to explore for prevention and treatment of conditions like autism, prescription drug addiction, traumatic brain injury, schizophrenia, Parkinson's disease.

THREE: NEW IMAGING TECHNIQUES AND DISCOVERIES

Number three, aided by the BRAIN Initiative's new imaging techniques and discoveries made with our private sector collaborators, I believe we will be able to identify individuals at high risk for Alzheimer's disease even before any symptoms appear and provide them with effective therapies aimed at slowing or preventing the disease. Personal and family tragedies will be delayed or averted, and the economic savings from this alone will add up to hundreds of billions of dollars.

FOUR: TREATMENT FOR SPINAL CORD INJURIES

Number four, I predict that 10 years from now, we will have developed an effective treatment for spinal cord injuries. Already, groundbreaking NIH research has allowed four young men paralyzed from the waist down to walk by the use of electrical stimulation that bypasses the severed cord.

If resources are available to follow up this proof of concept study, we can give freedom of movement back to victims of car accidents, sports injuries, and other spinal trauma.

FIVE: SAFE AND EFFECTIVE ARTIFICIAL PANCREAS

Number five, we will see the introduction of a safe and effective artificial pancreas. For those with diabetes, such a device will continually track changes in blood glucose levels and provide precise doses of insulin, significantly improving the management of their disease and preventing countless complications.

SIX: OPPORTUNITIES FOR ORGAN TRANSPLANTATION

Number six, hope is also on the horizon for heart failure, a major cause of death in this country. The development of induced pluripotent stem cells, iPS cells, derived from a skin biopsy, has opened up profound new opportunities for organ replacement. Early experiments suggest that a patient's heart could even be rebuilt using his or her own iPS cells. This personalized rebuilt heart would make transplant waiting lists and anti-rejection drugs obsolete.

SEVEN: NEW VACCINES

Number seven, new vaccines will be readily available. Universal flu vaccines will protect against all strains of the virus, preventing a worldwide pandemic, saving millions of lives and eliminating the

need for an annual flu shot. Early clinical trials are already underway, and we are in active collaboration with industry.

I am also optimistic that an effective vaccine for HIV/AIDS will be available by 2026, giving us the opportunity to, at long last, bring an end to this most frightening and costly global epidemic.

EIGHT: TREATMENT FOR PAIN

Number eight, genomics, neuroscience, and structural biology will unveil entirely new targets for the treatment of pain, allowing researchers in the public and private sectors to develop highly effective, non-addictive medications for pain management, turning around the current alarming trend of massive numbers of Americans becoming addicted to opiates.

NINE: TAILORED APPROACH TO MEDICINE

Number nine, we will have tailored approaches to medicine that acknowledge not all people are the same, thanks in large part to the Precision Medicine Initiative and the more than 1 million volunteers in the national research cohort that we aim to enroll by 2019. The willingness of these participants to share a wide variety of their health-related information will ensure that major new insights emerge and Americans from all walks of life will be healthier than ever 10 years from now.

TEN: PREVENTIVE STRATEGIES AND TARGETED THERAPIES FOR CANCER

And last, but certainly not least, I predict that a decade from now, hundreds of thousands of individuals will be thriving who without NIH's research efforts would have succumbed to cancer. Powerful new prevention strategies and targeted therapies will arise from research, accelerated by the Vice President's Cancer Moonshot proposal.

If that sounds bold, consider what is happening right now. Seven months after President Jimmy Carter revealed that melanoma had spread to his brain and that he was beginning a course of therapy to boost his immune system's ability to destroy his cancer cells, last week he announced he is cancer free and no longer needs treatment.

Our Nation needs a lot more stories like this. With the sustained efforts of this subcommittee, I think it is possible. With a strong, stable trajectory for support of NIH research, the world can look forward to a healthier and happier future, whether 10, 50, or even 100 years from now.

Thank you, Mr. Chairman. My colleagues and I welcome your questions.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2017 Budget Request

Witness appearing before the

House Appropriations Subcommittee on Labor, HHS, Education, and Related Agencies

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

March 16, 2016

Good morning, Chairman Cole, Ranking Member DeLauro, and distinguished Members of the Subcommittee. As you know, I am Francis S. Collins, M.D., Ph.D., and I am the Director of the National Institutes of Health (NIH). It is an honor to appear before you today to present the Administration's fiscal year (FY) 2017 budget request for the NIH, and provide an overview of our central role in enhancing the nation's health through scientific discovery.

Before I discuss our diverse investments in biomedical research and the exciting scientific opportunities on the horizon, I want to thank this Subcommittee for the recent $2 billion boost in the FY 2016 Omnibus Appropriation bill. This investment comes at a time of unprecedented scientific opportunity and we are truly grateful for your leadership.

As the nation's premier biomedical research agency, NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems, and to apply that knowledge to enhance human health, lengthen life, and reduce illness and disability. I can report to you today that NIH leadership, employees, and grantees continue to believe passionately in our mission.

As a federal research agency, we are acutely aware that in order to achieve our mission we must be effective and efficient stewards of the resources we have been given by the American public. In December 2015, we released the *NIH-Wide Strategic Plan, Fiscal Years 2016-2020: Turning Discovery into Health*, an overarching, strategic plan that reflects the rapid progress in bioscience. This plan ensures our agency remains well positioned to capitalize on new opportunities for scientific exploration and address new challenges for human health. Developed after hearing from hundreds of stakeholders and scientific advisers, and in collaboration with leadership and staff of NIH's Institutes, Centers, and Offices (ICOs), the plan is designed to

complement the ICOs' individual strategic plans that are aligned with their specific congressionally mandated missions.

The plan focuses on four essential, interdependent objectives that will help guide NIH's priorities over the next five years as it pursues its mission and optimizes return on public investment. The objectives are to:

1) advance opportunities in biomedical research, from basic science to prevention and treatment;
2) use all available information to set NIH priorities nimbly and wisely;
3) enhance stewardship of the resources provided by the American people; and
4) excel as a federal science agency by managing for results.

Our strategic plan concludes with a bold vision of advances we will strive to deliver over the next five years including: enhanced survival of cancer patients from applications of precision medicine, critical steps toward universal flu and HIV vaccines, and crucial progress on the artificial pancreas that will lead to better management of diabetes. NIH will pursue these and many other forward-looking measures to enhance our role as a visionary steward of the resources entrusted to us by the American people. Such actions will ensure that the U.S. biomedical research enterprise remains on the pathway to a bright and sustainable future.

Today, I want to share with you a few of the many promising opportunities before us that will lead to that healthier future for all. First, of all, many recent breakthroughs stem from our nation's commitment to investing in basic science research. Basic science lays the foundation for advances in disease diagnosis, treatment, and prevention by providing the building blocks for clinical applications. Basic science is generally not supported in the private sector, and NIH's focus on understanding fundamental biological processes not only has led to no less than 145

Nobel Prizes to our grantees, but fosters innovation and ultimately leads to effective ways to treat complex medical conditions.

A compelling example of how we are trying to unravel life's mysteries through basic science is with the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, which continues to address basic neuroscience questions. We are grateful to this subcommittee for its support of this initiative since its launch in FY 2014, and we look forward to ramping this up further in FY 2017. This bold, multi-agency effort to revolutionize our understanding of the human brain will enable the development and use of innovative technologies to produce a clearer, more dynamic picture of how individual cells and neural circuits interact in both time and space. By measuring activity at the scale of neural networks in living organisms, we can begin to decode sensory experience and, potentially, even memory, emotion, and thought. Ultimately, the technologies developed under the BRAIN Initiative may help reveal the underlying pathology in a vast array of brain disorders and provide new therapeutic avenues to treat, cure, and prevent neurological and psychiatric conditions such as Alzheimer's disease, autism, schizophrenia, epilepsy, traumatic brain injury, and addiction.

Scientific advances are also accelerating progress toward a new era of personalized medicine. President Obama announced the Precision Medicine Initiative (PMI) in January 2015, and we are thrilled to have a lead role in this multi-agency effort. As a long-term goal of this Initiative, NIH is building a national research cohort of one million or more volunteers who will play an active role in how their genetic, environmental, and medical information is used for the prevention of illness and management of a wide array of chronic diseases. Capitalizing on the alignment of scientific opportunities created by advances in genomics, the widespread adoption of electronic health records, the recent revolution in mobile health technologies, and the

emergence of computational tools for analyzing large biomedical data sets, precision medicine is poised to usher in a new era in how we treat and diagnose disease. Ramped up funding in FY 2017 will support several activities that are critical to the scope of the PMI Cohort Program, including enrolling and consenting participants, core phenotyping, expanded informatics, building a biorepository, and incorporating the use of wearable sensors.. A cohort of this size will capture data on a wide range of diseases and be large enough to detect genetic and environmental effects that are difficult to discern from research on smaller groups. Scientists will be able to use data from this cohort to identify trends and understand health and disease on a much larger scale, and that will lead to new ideas for diagnostic tests, treatments, and prevention strategies.

A final area of exceptional scientific opportunity I want to highlight today involves one of our nation's most feared killers: cancer. During his 2016 State of the Union Address, President Obama announced the establishment of the National Cancer Moonshot—a bold initiative to tackle this often life-threatening disease. Too many American families know all too well the devastation cancer can bring. More than 1.6 million new cases of cancer will be diagnosed and cancer will kill an estimated 600,000 Americans in 2016. With passionate and principled leadership from Vice President Biden, and in partnership with the Food and Drug Administration (FDA) and other Federal agencies, NIH's National Cancer Institute (NCI) is launching a bold and promising cancer research initiative to accelerate research to prevent, diagnose, and treat cancer. In FY 2017, $755 million in mandatory funds for new cancer-related activities are proposed at the Department of Health and Human Services (HHS). Within NIH, investments of $680 million will support cutting-edge opportunities, such as prevention and cancer vaccine development, early cancer detection, cancer immunotherapy, genomic analysis of

tumor cells, enhanced data sharing, and new approaches to pediatric cancer. Our sister agency, the FDA, proposes a new Oncology Center of Excellence to speed progress in approval of new diagnostics and therapeutics that will be safe and effective. We are at an inflection point in cancer research, and the science is ready for the concerted new effort this initiative will bring.

While all of these exciting research efforts and scientific opportunities are leading to a much deeper understanding of health and human disease, much more work needs to be done.

To this end, the President's FY 2017 budget request for the NIH is $33.136 billion, $825 million or 2.5 percent above the enacted FY 2016 level. This budget request reflects the President's and the Secretary's commitment to improving the health of the nation and to maintaining our nation's leadership in the life sciences. The request highlights investments in innovative research that will advance fundamental knowledge, and speed the development of new therapies, diagnostics, and preventive measures to improve public health, including an additional $100 million to ramp up the PMI Cohort Program to a total of $230 million, an increase of $45 million for the BRAIN Initiative, bringing the total to $195 million, and $680 million for the National Cancer Moonshot.

The FY 2017 budget request will enhance NIH's ability to support cutting-edge research and training of the scientific workforce. Within this budget, we will increase Research Project Grants (RPGs), NIH's funding mechanism for investigator-initiated research. NIH expects to support 36,440 total RPGs in FY 2017, an increase of 600 above the FY 2016 estimate. The budget request allocates resources to areas of the most extraordinary promise for biomedical research, while maintaining the flexibility to pursue unplanned scientific opportunities and address unforeseen public health needs.

I have provided you with examples of how investments in biomedical research through NIH are advancing human health, spurring innovations in science and technology, stimulating economic growth, and laying the groundwork for the future of the United States biomedical research enterprise. We have never witnessed a time of greater promise for advances in medicine than right now. With your support, the future of medicine can be very bright.

This concludes my testimony, and I look forward to answering your questions.

Mr. COLE. Thank you very much, Dr. Collins.

ORDER OF QUESTIONING

Just for informational purposes for the Committee, I am going to ask my questions. Then we are going to go to the chairman of the full committee and the ranking member of the full committee, and then my good friend, the ranking member of the subcommittee. And then we will proceed in questions in order of arrival.

IMPACT OF $1 BILLION CUT TO NIH BUDGET

As I mentioned, Dr. Collins, in my opening statement, although the administration budget appears to request an increase, that increase is sought through the mandatory side of the budget, which is, of course, outside our jurisdiction as a committee. The administration's request before this committee actually proposes a $1,000,000,000 cut in the area that we actually have jurisdiction over, discretionary spending.

If we were to appropriate exactly what the administration has requested in your budget on the discretionary side, again a $1,000,000,000 cut below current levels, what would the impact on biomedical research in general be and on research into diseases like Alzheimer's and cancer specifically?

Dr. COLLINS. Thank you for the question. And obviously a very sobering scenario that you portray and one that we very much hope will not happen.

Certainly, the impact would be severe. It would be felt across every aspect of what NIH supports. All of my colleagues here and the other 23 Institute and Center directors would have to cut severely back in their programs. New initiatives would not be able to get started. Whether you are talking about cancer or diabetes or heart disease or Alzheimer's disease, this would represent a very significant slowdown.

Again, I am just a simple doctor to the country. So the idea of how you divide up appropriations between discretion and mandatory is a little over my head. We are certainly pleased in the President's budget proposal for an increase and very gratified by your words, Mr. Chairman, and by others of the intention of this Committee to figure out how to maintain the trajectory that you started this year with the $2,000,000,000 increase.

I can't tell you what a shot in the arm it has been for our biomedical research community. The morale, the enthusiasm, the willingness to take risks and start new projects, which had been pretty much at a slowdown for about a decade, is back. And we want to be able to see that continue and appreciate your support for that.

NIH'S USE OF ADDITIONAL FUNDS

Mr. COLE. Great. Let me ask you a sunnier, more upside of a question now that we have gotten that out of the way because I can assure you—and I have talked, obviously, to the Chairman of the Full Committee, and the Ranking Member certainly made her feelings known—this Committee is not going to cut $1,000,000,000 of discretionary funding from the NIH. Just not going to happen.

So in that sense, you don't need to worry about that in front of you. But let us say last year the President proposed a $1,000,000,000 increase, which was very welcome. This committee actually, working in a bipartisan fashion, was able to double that.

Dr. COLLINS. Yes.

Mr. COLE. Let us assume that we were able to go beyond what the President asked for, beyond the $32,800,000,000, roughly. If we were able to give you extra money, where would you direct it? What do you think the most promising use of additional funds might be if we were able to do it?

Dr. COLLINS. What a wonderful question. Certainly, in my professional judgment, there are a lot of areas that are ripe for expansion, and the opportunity to be able to go even faster on those would be welcome, indeed.

As you know, a great deal of the research that we support are ideas that come to us from investigators all over the country. It is their bright brains that push forward the envelope, and we would want to be sure to do something to encourage even more of those grants to be fundable. As you know, we are still under 20 percent for that success rate.

And that would have effects across the board. Antimicrobial resistance would have more resources. Alzheimer's research could move faster with additional resources. Cancer research—even beyond the Moonshot, so many things are possible now. Opioid abuse and other issues of drug abuse, and I could go on. Diabetes, autism, all of these conditions, which right now are scientifically poised for rapid advances, all of them would have their opportunities lifted by the kind of wonderful scenario that you portray.

THE STATE OF ALZHEIMER'S RESEARCH

Mr. COLE. Well, that is wonderful. Let me move to another area of particular interest to the committee and certainly to me. I saw a recent Time magazine article on Alzheimer's that highlighted some of the early stage clinical trials based on what I understand to be NIH-supported basic research.

In my visit at NIH a few weeks ago, it was very interesting to learn how increased support from Congress over the last 3 years has expanded peer review science on Alzheimer's disease and other dementia and has helped move the ball further. So if you could, and this will probably go to Dr. Hodes, I am sure, right away—and I don't have a lot of time—but sort of tell us where you are at and what you see the prospects are in Alzheimer's and other dementia.

Dr. HODES. Well, thank you for the question. And first of all, thank you very much for the increased funding this year, which has made an enormous difference.

Fortunately, the good news is that the scientific opportunities, what we are learning about the brain and Alzheimer's disease, have expanded enormously so that resources are really applicable to research that is well thought out, well prioritized. In preparation, for example, in particular for the bypass budget that we submitted for the first time last year at congressional direction, we underwent a very extensive planning process in which national and international experts came together to identify priorities.

These got translated into milestones, *i.e.*, what we had to achieve to accelerate goals such as the establishment of an effective intervention in the nearest possible terms. This meant that with the additional funds, we were poised to act on this full spectrum of well-defined priorities and milestones.

And for example, the initiatives that this year we were able to embark upon include a spectrum: from looking at the most basic biology and genetics to understanding new targets for intervention, new clinical trials that take advantage of the most promising of those interventions, and ways to intervene with people who already have disease and the caregivers who take so much responsibility in caring for those who have Alzheimer's disease.

In health disparities, epidemiology, et cetera, across this broad spectrum, we have seen a huge increase of applications, from scientists who have been inspired by the availability of resources. And across this whole trajectory, we see a very bright future of accelerated progress thanks to the support of Congress.

Mr. COLE. Well, thank you. I have violated my own rule and asked you a tough question too near the end of my own time. So I apologize to the committee for that.

And I want to move next, if I may, to the Chairman of the Full Committee for whatever questions he cares to ask.

PRESCRIPTION DRUG ABUSE

Mr. ROGERS. Thank you, Mr. Chairman.

Dr. Collins and Dr. Volkow, thank you for both actively engaging the issue of prescription drug abuse. We lose 100 Americans a day from overdoses of prescription medicine and heroin. We need a holistic, multipronged approach to the epidemic that CDC says we have.

Before we get to the pills themselves, let me explore a sizable part of the problem, oversupply of opioids. As you know, over 250 million prescriptions are written each year for opioids, many of which need not be written at all. And thanks in part to deceptive marketing practices and reckless overprescribing, these drugs have become a default solution, it seems, for any pain rather than the severe pain for which they were intended.

Doctors should appropriately target pain with appropriate and proportionate medicines. Moderate measures for moderate pain, more powerful opioids for those who really need them. What are we doing to address the lack of effective non-opioid treatment for chronic pain?

PAIN MANAGEMENT

Dr. COLLINS. Mr. Chairman, I want to thank you for your leadership in this area over these years, and again, I think many of us looking forward to the summit that you are bringing us together for in a couple of weeks.

I am going to ask Dr. Volkow, though, to tell you about some of the things that are being explored in other areas of pain management.

Dr. VOLKOW. I would like to thank you for your leadership in this whole area that has been very devastating. Research on pain exists

across multiple institutes at the NIH, and there is a pain consortium that actually aims to integrate these efforts.

So as it relates to the development of new strategies for the management of pain, there are several approaches. One of them is the one that helping develop abuse-deterrent formulations of opioids that cannot be tampered with. That is one of the approaches.

Another approach is the development of analgesics that are potent that are not based on opioids and, therefore, are not going to be rewarding.

There is a third approach that aims to the use of stimulation technologies in the—that will affect the impulses in nerves and in the brain to control and regulate pain. And that relates to tools like transcranial magnetic stimulation, or electrical direct current, that allows you to either inhibit certain areas of the brain or stimulate them.

There is also research in terms of evaluating behavioral and cognitive interventions that can improve the outcomes in patients suffering from chronic pain. So there is a wide variety of approaches to try to address the lack of effective interventions that are safe for management of chronic pain.

NEW CDC GUIDELINES FOR OPIOIDS

Mr. ROGERS. Yesterday, CDC announced new prescribing guidelines for opioids. There are 12 recommendations, but I think here is the bottom line.

Doctors should avoid using powerful opioids as the first line of defense against pain, saying the risks from such drugs far outweigh the benefits for most people. With respect to the dosage, CDC says start low and go slow.

Do you think doctors are likely to follow the recommendations that the CDC has put forward? And what steps can we take to get the medical community more engaged in the problem?

Dr. VOLKOW. Yes, and indeed, the CDC guidelines are actually a step forward in helping improve the prescription practices as it relates to the use of opioid medications, particularly for the management of chronic pain. And again, the CDC guidelines were excluding patients that lead to cancer pain or hospice care pain.

The guidelines put a frame of reference that is based on one hand on the current knowledge, but also on experiences. There is not sufficient scientific evidence on how to properly use opioids, and as a result of that and added with the fact that there is an increased awareness that current prescription practices of opioids cannot continue the way they are doing right now—it is unacceptable—that that education on the healthcare system and also in the public, along with guidelines like the one of CDC, will facilitate the changing of practices of how we prescribe these medications for the management of chronic pain.

While at the same time, I think, because that is the other aspect of it, providing adequate care for those patients that suffer from chronic pain, which can be very devastating.

ROLE OF PHYSICIANS IN PRESCRIBING DRUGS

Mr. ROGERS. You know, we fought for years, you and the Congress and others have fought for years to get the pharmaceutical

companies to develop abuse-deterrent formulations, to make opioids so they could not be crushed and take away the time release of the drug in just a split second. And now we have got, I think, five abuse-deterrent opioid pills on the market, but doctors are not prescribing them.

I don't know whether they don't know about them or don't care about them or whatever. But the bottom line is they are not using what we have developed as an abuse-deterrent strategy. What do you think about that?

Dr. VOLKOW. Well, it is likely there are different reasons why doctors may not be using them, but one that is important for us to be aware of is that we have to be certain because these abuse-deterrent formulations require development. They tend to be more expensive than the old opioid medications.

So we want to be mindful that there are insurances that when a physician prescribe it, the patient will be reimbursed for the cost associated with it. So we have to create a system that incentivizes the utilization of these abuse-deterrent formulations that by default are going to be in general more expensive.

Mr. ROGERS. And insurance companies are reluctant to pay the increased cost because they say the regular opioids are cheaper, and therefore, we are only going to cover the lower cost. How can we deal with the insurance companies not paying for the abuse-deterrent feature?

Dr. VOLKOW. I am going to call on Dr. Collins. I am just a pure scientist, and that is above my pay grade. [Laughter.]

Mr. ROGERS. I am way over time here, but can you answer that one quickly?

Dr. COLLINS. Well, it is a complicated ecosystem you are talking about in terms of what we need to do to educate physicians about their role, and I think most physicians—I am a physician, the people at this table are also—are focused on trying to deliver the right care to patients.

But things take some time to filter down, and we need to speed up that process of translating now what we know. And I think the CDC guidelines are intended to achieve that.

In terms of the economics, however, that really comes down to whether insurance companies can, in fact, be talked into this kind of reimbursement if they are given a strong reason. I think we have got a stronger case, yet, that needs to be made about moving where we have been from drugs that are so abuse prone to things that are safer.

Mr. ROGERS. Well, if there is any insurance companies listening, they would be very wise to allow coverage of these abuse-deterrent featured drugs because they don't want to know what would happen if they don't.

Thank you.

Mr. COLE. Thank you, Mr. Chairman.

And with that, we will go to my good friend, the ranking member of the full committee, the gentlelady from New York.

CANCER MOONSHOT

Mrs. LOWEY. Thank you very much, Mr. Chairman. And I want to say we are all with our big chairman over there on this issue.

But I want to get back to the Cancer Moonshot because when you look at the numbers and you think of the number of people, I am sure, in this room whose lives have been touched with a loved one who is suffering from cancer, I am thrilled that we are focusing on this issue. In 2015, there were nearly 1.7 million cases of cancer diagnosed in the United States. So I am very pleased to see this focus of the President and the NIH.

Dr. Lowy, could you provide specific examples of what the Cancer Moonshot hopes to achieve that current research and the Precision Medicine Initiative do not address, and how would the Cancer Moonshot target cancers that to date have been difficult to detect and treat, such as kidney cancer and pancreatic cancer?

Dr. LOWY. Thank you, Congressman Lowey.

We really appreciate your strong support, the support of the Subcommittee, and the support of the Congress not just for 2016, but also the long-term support that has gotten us to this point where incidence and mortality rates from cancer are going down. But as you point out, not only is the incidence high, but in addition, close to 600,000 people in the United States will die this year from cancer.

The Moonshot is designed to look at many different aspects of cancer and to take advantage of the enormous opportunities that we have in this area. Two areas of focus are not just areas of treatment, but also for prevention and screening.

In prevention, looking to develop vaccines not just against targeted material from infectious diseases, but also abnormalities in cancer. And then in addition, for screening, taking advantage of new technology, such as Dr. Collins mentioned for single cell analysis in peripheral blood, and we can—we can make these changes looking at the blood and other fluids to try to screen for early detection of pre-cancer and cancer.

These are just two of the highlights in the Moonshot.

CAUSE OF AUTISM

Mrs. LOWEY. Well, thank you. And I have a little time left.

Estimates, and I have been very concerned with the numbers in my own district, that 1 in 68 children will have an autism spectrum disorder. This is one of the reasons I am such a strong supporter of the BRAIN Initiative, which could provide deeper understanding of how the brain works and unlock treatments for autism, as well as a host of other disorders. And I think all of us here appreciate the work that you are doing on Alzheimer's disease as well.

If you could tell us what has the research told us to date about the cause of autism, both in genetics and environmental factors, and how would the fiscal year 2017 budget request bolster these research initiatives both under the BRAIN Initiative, as well as other institutes throughout the NIH?

Dr. COLLINS. Well, thank you for that question because we are enormously excited about what is possible now in terms of research on the human brain, probably the most challenging frontier in all of biomedical research, the most complicated structure in the known universe. There are 86 billion neurons in the brain. Each of those have about 1,000 connections, and we are just bold enough

to think we might be able to understand how those circuits work and do the amazing things they do over the course of the next 10 years in a very well laid out blueprint for that research, which is guiding the BRAIN Initiative and which is now in its third year.

And thank you, the Congress, for supporting it, and we hope that will continue to be able to ramp up to its full funding.

Autism is clearly a complex heterogeneous collection. If anybody thought we were going to come up with just one simple molecular explanation, that chance has long gone by. It does now seem that with careful analysis of DNA, looking at the genome information, that something in the neighborhood of 20 to 25 percent of those with autism—and it tends to be in the more severe end of the spectrum—do, in fact, have genetic changes that happen for the first time in that child. Not in the parents, but it was a mutation that arose during the course of spermatogenesis or oogenesis.

And those have an interesting set of features when you look to see what genes are involved. They are mostly genes that code for proteins that are active at the synapse, the place where neurons talk to each other, and that kind of makes sense that autism is a circumstance where the communication systems in the brain are not functioning in the normal way.

But, that gives us hope that we could begin with that unifying theory of what is happening in autism, begin to develop even better ways of introducing new therapeutics. But, this will be one of the many consequences, I think, of the investment in the BRAIN Initiative, which is, itself, a basic science effort to understand the brain.

But, it builds a foundation upon which we can apply all kinds of other research to understand autism, Alzheimer's disease, Parkinson's disease, traumatic brain injury, drug addiction, all of which have, of course, roots in the brain's circuits that sometimes don't function the way they should.

So, it is an enormously exciting time for us to push this forward. It has resulted in the recruitment of a really fascinating array of people coming from different disciplinary perspectives. The BRAIN Initiative has lots of technology and lots of engineering and lots of neuroscience and nanotechnology, all those things folded together.

Mrs. LOWEY. Thank you very much.

And thank you, Mr. Chairman.

Mr. COLE. Thank you.

And we will next go to my good friend, the ranking member of the subcommittee, the gentlelady from Connecticut.

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

SEX BALANCE IN PRECLINICAL RESEARCH

Dr. Collins, last year we talked about NIH's relatively new policy to require applicants to report their plans for the balance of male and female cells and animals in preclinical studies in all future applications. As you know, this is an issue that Congresswoman Lowey and I have been working on since we first came to the Congress.

In our discussion last year, you noted that Institute Directors were in the process of finalizing their guidelines for all grantees. Let me note a recent analysis in Nature magazine. It is a March

3rd article, which showed that as recently as 2014, only 53 percent of research papers recorded both the sex and age of the animals used in the studies.

I realize the analysis looks at research papers that predate the implementation of NIH's policy about sex balance in preclinical research. Can you provide an update on NIH's efforts to ensure that research includes both male and female animals in preclinical studies, and can you update us on NIH's efforts to ensure that preclinical research includes both male and female tissues and primary cells?

Dr. COLLINS. Well, thank you for the question.

As you can see in the visual that I put up, this is something that NIH has gotten very interested in and committed to, and this article that Janine Clayton and I wrote in Nature about a year and a half ago, very much points out that from NIH's perspective, that you are right. And Mrs. Lowey, you are right, and all those who have made this case are right that we have not been taking enough attention as we should to balancing males and females in preclinical research.

And in the process, because many animal experiments, particularly with mice, have focused solely on males, we have been missing out on important differences of biological significance that might very well be things we need to know for human medicine. We are determined to change all of that.

I saw the article that you mentioned in Nature, and I am happy to say I don't think you would see that article being written in another year or so. We did, in fact, put out a notice back in June, and it went in effect on January 25th. From now on, if you are an NIH-funded grantee and you are doing experiments involving animals, you need to include males and females.

If you have some idea that you are not going to do that, you have to justify it. If you are studying prostate cancer, you can probably get away with sticking just to males. But for most other things, it is going to be absolutely required, and it will be a condition of the review and the grant award.

Ms. DELAURO. And that is true with male and female tissue and primary cells as well?

Dr. COLLINS. And I think that has been a real wake-up call as well, that people thought, well, a cell is just a cell. But a cell has a sex, too, and we are actually losing out on information if we don't take account of that. And that has now become part of the norm of the way in which we want to fund research.

Ms. DELAURO. Okay. Thank you very much.

Dr. COLLINS. Thank you.

DRUG COSTS

Ms. DELAURO. Taxpayers provide more than about $30,000,000,000 annually for NIH's research. Dr. Collins, you have said that NIH conducts the basic science that "fosters innovation, ultimately leads to effective ways to treat complex medical conditions."

And yet, in so many cases, taxpayer-funded research leads to drugs that are sold back to the taxpayers at exorbitant prices. Example. UCLA led to a patent for Xtandi, a drug to treat prostate

cancer. The drug now costs patients $129,000. The same costs patients in other countries about a third of that amount.

Look, I realize the pharmaceutical companies invest their resources. They bring a new drug to market. They should profit from that innovation. But what I want to know is why U.S. taxpayers are getting gouged for drugs that wouldn't exist without the significant investment of U.S. taxpayers.

Can you better explain why U.S. taxpayers are paying for biomedical research on the front end and paying exorbitant prices at the back end? And I will just say that 50 of my colleagues and myself have sent a letter to you and to Secretary Burwell, requesting that the NIH and HHS assert March-in rights when taxpayer-funded research leads to a patented product that is not available to the public on reasonable terms.

What are reasonable terms? A drug shouldn't cost $129,000 for people to get access to it.

Dr. COLLINS. Well, I know this is a topic of great interest, and well it should be. And certainly, my heart goes out, as all of us do, to patients who are in need of a therapeutic which is outside of their financial means to be able to gain access to, and that really ought to be the thing that drives us trying to come up with better solutions.

I would say with regard to March-in rights, we read the letter carefully. You saw the response from Secretary Burwell. NIH does, in fact, have the ability to march in if reasonable terms are not being met and if we have intellectual property that is attached to that particular product.

Ms. DELAURO. What is a reasonable term?

Dr. COLLINS. Well, that is very much where it gets down to the nitty-gritty, doesn't it? And we have looked at that situation several times in the past, and have not felt like we reached reasonable terms. But we are totally open to considering that on a case-by-case basis, and we will be glad to do that with other products that are brought forward for our consideration.

We get it that this is a serious issue.

Ms. DELAURO. And let us have further conversation. And I have gone over my time.

I thank you, Mr. Chairman.

Mr. COLE. Absolutely. Next, operating on the order of arrival, Mr. Harris, you are recognized for whatever questions you care to pose.

Mr. HARRIS. Thank you. Thank you very much.

And good to see all of you again. It was a great visit I guess last month up to see what is going on. And you know, meeting with Dr. Rosenberg and the patients just reminded me of, you know, why I went into medicine. And what am I doing in politics? Anyway——

[Laughter.]

VACCINE DEVELOPMENT

Mr. HARRIS [continuing]. Let me ask a couple of questions. First of all, with regards to the strategic plan, you know, Dr. Collins, you had mentioned that one of the 10 things on your predictions, you know, is an HIV vaccine. And you know, part of what is addressed in the strategic plan is that nonstatutory set-aside for research.

And when you look at the investment by objective, vaccines or a vaccine accounts for less than $400,000,000 out of a total of what I assume is now almost $3,000,000,000.

So my question is specific. With the additional $2,000,000,000 that was appropriated last year, how much of that went into the vaccine development since that—it really is—I mean, because you address, you know, the cost, if you can bring that down to zero. But the only way to bring it down to zero really is we are going to have to develop a vaccine.

So you are already spending only about 15 percent of the budget on the vaccine on HIV. So is it—so the additional monies, how much went into vaccines? How much went into non-vaccine HIV programs?

Dr. COLLINS. Well, I appreciate the question, and you and I have talked about this issue. And it has been very helpful to have your perspective and that of other Members.

I am glad you mentioned the strategic plan. I hope people have read. There is a copy of this at your place. This was something you, the Congress, asked us for, and we put it forward in a way that we thought could be very helpful in terms of defining how we set priorities. So, please, have a look if you have not looked at it previously.

With regard to HIV/AIDS, what we have decided is that it is time, just as you have said, to focus on the most important priorities to end this epidemic, and the vaccine is right at the top of that list. There are other things on that list as well.

And as a result, we have looked at our entire HIV/AIDS portfolio this year, and we have identified projects which were going to come back for competing renewal which we no longer think fit into those highest priorities, four of them. And as a result, the dollars that would have gone to renewing those programs is becoming open for competition for things that are high priority, and vaccine development is very much on that list.

We will, in the course of probably the next couple of weeks, announce how we are moving $66,000,000 out of areas which were good science, but they don't seem to be high priority for HIV/AIDS, into the areas that are. And a substantial fraction of that is going to go to vaccine preparation.

Mr. HARRIS. I would urge that you do that. I mean, there is a line here. You know, $100,000,000 a year for basic behavioral and social science research. I mean, honestly, I would much rather see the $100,000,000 going to accelerating the development of that HIV vaccine.

I just returned from Kenya, around Lake Victoria. Look, the solution is we are going to have to vaccinate people in the end. I mean, I am becoming convinced that you have treatment penetration of only 50 percent. Until we can vaccinate, as with other infectious disease, we are really not going to cure it.

MARIJUANA USE

Dr. Volkow, let me just ask you a question because the Chairman of the Full Committee, who has left already, you know, mentioned marijuana. And there is a—you know, SAMHSA surveys, and they

survey by State. And they—you can find charts that look at the increased use of marijuana.

And it is interesting to look at what happened in Colorado between the 2002–2003 survey for 18- to 25-year-olds and the 2013–2014 survey for marijuana use in the past month for 18- to 25-year-olds. And past month is not just I have used it once. I mean, I have used it recently.

It went from 21 percent to 31 percent. 18 to 25, by my understanding of the potential adverse effect of marijuana on brain function and development, is probably the worst interval. Maybe not, maybe even younger use would be bad. But certainly up to age 25 is a bad interval.

The national use, by the way, in that age group went from 17 percent to 19 percent. So pretty clearly, and I think, you know, what happened in Colorado is you legalized the drug. Bottom line, you legalized the drug.

And there is a lot of misinformation out there about what happened when you legalized the drug, but honestly, a change from 21 percent to 31 percent use in a highly vulnerable population is of concern to me. Is it of concern to you?

Dr. VOLKOW. How can it not be? I think that actually——

Mr. HARRIS. Well, Doctor, I will tell you that the advocates for legalization say we shouldn't be concerned about the usage figure. So I am interested in what your opinion is.

Dr. VOLKOW. Indeed, we are very concerned, and we are particularly concerned by the very high rates of abuse of marijuana not just on 18 to 25, but actually on teenagers 12 to 18 years of age. And Colorado has the highest rates in the whole country of the use of marijuana in that age bracket.

We are particularly concerned because cannabinoids, actually marijuana is a cannabinoid, interfere with the normal formation of synapses, the connections between neurons, how they talk to one another. And that process of connections is happening from the moment you are born, actually before you are born, until you are in your mid twenties.

So cannabinoids, our own endogenous cannabinoids regulate that formation. So when you are smoking marijuana, you are interfering with this very carefully orchestrated process by which biology, nature ensures that our brain develops into the most complex organ so far.

So, yes, indeed we are very concerned specifically because of the potential developmental adverse effects that exposure to cannabis may have in young people.

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

Mr. COLE. Thank you very much. The chair is struggling to enforce the clock even on himself, which I think shows how much interest there is here. So I just would ask Members to try and do the best they can in that regard.

With that, I will go to my good friend, the gentleman from Pennsylvania, for whatever questions he cares to pose.

UPDATE ON BRAIN INITIATIVE

Mr. FATTAH. Well, I resemble that remark, Mr. Chairman. I see you said that right before you came to me.

But let me thank Dr. Collins and our guests. I authored some language that created the Interagency Working Group on Neuroscience at NIH, along with the National Science Foundation co-chair. Simultaneous to this hearing, the National Science Foundation is on another side of the Capitol giving a hearing, and these two things are inextricably intertwined. That is the science and the work at NIH together is how we are going to make disruptive progress, I am convinced.

Now, we also have now in my other bill put some language in creating an interagency working group on imaging, and I know that NIH is at the—very engaged in this. What I am interested in now is I see the numbers for this year's budget. Dr. Collins, if you could talk to the committee for a minute about what the 12-year cost is on the BRAIN Initiative so that we can see it in totality?

I spent some time out at Stanford with Dr. Newsome and some of his people, but I think it would be helpful. This is I know we say the administration's initiative. In truth, it is a partnership between the Congress and the Administration, and I think that we need to make sure that we have a good understanding of how the road—how the runway is out in front of us in terms of what we want to achieve.

Dr. COLLINS. I appreciate the question because this is certainly an area of great excitement. How do we figure out how those circuits in the brain do what they do? That is a picture of a recent diffusion tensor MRI showing you the ways in which all the wiring works in the normal brain. That was taken on a perfectly healthy individual who is quite awake at the time this was done, new technologies that we didn't really have the ability to do until fairly recently.

Yes, the BRAIN Initiative was, in fact, conceived of as an effort that would result in a lot of technology development in order to be able to do these measurements on circuits in real time in the human brain, but then to move into applications in its second 5 years. The overall budget for this was to ramp up, beginning in the first year, fiscal year 2014, at $46,000,000, and then ramping up to something like $400,000,000 a year, which we hope to get to in the next year or two.

The overall budget over 12 years from—going from fiscal year 2014 to fiscal year 2025 is $4,500,000,000 in the proposal that was put together. This was an effort that was led by Cori Bargmann of Rockefeller and Bill Newsome of Stanford and an amazing dream team of neuroscientists who put together this plan over more than a year and a half.

And that blueprint is out there and very much worth studying and, of course, will be revisited as technology develops. I would say right now we are ahead of our schedule.

Mr. FATTAH. Thank you, Doctor.

Let me say that the Chairman and our ranking member, along with members of the committee, we were very pleased to do the $2,000,000,000 increase last year. And I know that the chairman made some comments about the administration's proposal and where we are on that, and I would join in the Chairman's view that that is not acceptable.

I want to put this in some context. For a good part of the years that we have been in Afghanistan, we have been spending about $2,000,000,000 a week on average. So, just as a country, when we think about all of the lives that are affected by the diseases and disorders that you are seeking to cure, you know, a $2,000,000,000, even though it is very significant and it was some heavy lifting, in perspective, this is a nation that can do more in terms of research in science and in medicine that will make a difference for tens of millions of Americans. It is just a matter of political will.

UPDATE ON ZIKA VIRUS

So I want to make sure that we are clear that the $4,000,000,000 is where we have to get to to do the work that we want to do. And if you could, I will conclude with my last comment, which is Zika virus, is there anything more that we need to be helping you do in that regard?

Thank you, Mr. Chairman. I yield back on time.

Dr. COLLINS. Dr. Fauci.

Dr. FAUCI. Thank you very much for that question.

There is something that the Congress can do. As you know, the President asked for a $1,900,000,000 supplement to enable NIH, the CDC, FDA, and others, a variety of other agencies to respond to Zika. We need that money urgently.

NIAID has already started a major program in Zika research, particularly toward the development of a Zika vaccine, and we are doing that with no new funds. And that is not going to last very long because in order to prepare for the next phase of studies—that would be the efficacy studies of a vaccine—we plan to go into a Phase I trial for safety by the end of the summer or early fall. We could not take it beyond these studies if we do not have the supplemental funding.

Mr. FATTAH. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. Absolutely. We now go to the gentlelady from Alabama for any questions she cares to pose.

RESULTS GAINED FROM NATIONAL CHILDREN'S STUDY

Mrs. ROBY. Thank you, Mr. Chairman.

Dr. Collins, as a mother of two young children, I am very interested in the health of the youth of our Nation. And specifically, it has come to my attention that NIH has spent an estimated $1,500,000,000 on the National Children's Study, NCS, since 2000. This effort was halted in 2014 based on your recommendation.

NIH conducted a shutdown of the Children's Study in fiscal year 2015 and fiscal year 2016. And last year, the Omnibus provided $165,000,000 for the Children's Study follow-on. The President's fiscal year 2017 budget requests level funding for this program.

In your fiscal year 2017 budget justifications, you mention that NIH will use these funds on a new program, the Environmental Influences on Child Health Outcomes—ECHO, I believe is what you are calling it—which is designed to study a wide range of pediatric conditions.

The budget justification also states that the ECHO program is designed to take advantage of existing resources left over from the

now-defunct Children's Study. So, what I want to know is can you begin by describing first the results that we gained from the $1,500,000,000 that we spent on the entirety of the Children's Study? If you will start there, and then I have some follow-up questions.

Dr. COLLINS. So I appreciate your raising the issue because this has been an area of intense interest for myself and my colleagues. The National Children's Study, originally authorized by the Congress 15 years ago, over the course of time developed a number of features about its design that began to look as if they had not kept up with the technology developments and the other opportunities.

It was painful to look at this a couple of years ago and conclude that we needed a different approach, that we didn't want to continue to expand a program that clearly had deficiencies. It was not going to be as successful as we had once hoped. And that was the reason, with much advice from experts, that we decided it was time to close down the National Children's Study and come up with another strategy.

There are many samples and data available from the individuals who were enrolled in the National Children's Study, although it was a modest number. It was all pilot programs, and those are available to researchers who are starting to mine through them and see what data can be derived.

But, I think at this point, we very much turned our attention to how could we achieve the same goals of understanding, what are the environmental influences on children's health, and how could we get those answers now in 2016 in ways we couldn't have imagined possible 15 years ago?

HOW WILL ECHO BENEFIT FROM NCS INVESTMENT

Mrs. ROBY. But explain to us how that $1,500,000,000 investment will carry over into ECHO as specifically as you can? What can we take from all of that investment and know that now, with this additional money, the $165,000,000 that is requested for fiscal year 2017, how can we know that that $1,500,000,000 is not time and money wasted?

Dr. COLLINS. Well, it is not time and money wasted in the sense that there are these pilot efforts that were run that have research samples available that people can study, which will help us guide what kind of decisions we want to make with the new program ECHO in terms of what kinds of lab measurements and environmental exposures are going to be most important.

If I can, ECHO is focused, in fact, on four areas, which seem to be particularly compelling, based on what we learned through the study of the National Children's Study—namely, upper and the lower airway, asthma; obesity; pre-, peri-, and post natal outcomes; and neurodevelopment, including autism. That is where we want to go now.

But in a way that I think will be more efficient. It will result in more meaningful data. It will get there quicker, and it will involve many more data access opportunities for researchers around the country who have good ideas about how they will learn from these, how we can do a better job of keeping our children healthy.

UPDATE OF ECHO REPORT

Mrs. ROBY. And the report that was required, in the language in the omnibus said that you should submit a spending plan on the next phase of the study no later than 90 days of the enactment of this act. Where are we on that? Can you give us some highlights?

Dr. COLLINS. I would be glad to. We are planning to submit that report a few days late because we are right now at a very formative place for ECHO.

What we are doing with ECHO is to invite those who have been running cohorts of children where they have already collected a fair amount of data to join this effort—and we will make it possible for them to have additional laboratory measures added to what they were already doing—and create a whole that is greater than the sum of the parts, with perhaps 70,000 or 80,000 individuals, children, on whose follow-up information we can add further data.

That is going to be, I think, something we will learn about fairly soon. The applications are due on April 15th for the cohorts to come in and say they want to be part of it. We hear a lot of noise out there about that.

I am in the process of recruiting a director for this effort and have a very exciting candidate lined up. So there is going to be a lot to report about how we are spending this money. We are grateful to the Congress for your confidence that this was something you wanted to continue and provide the resources for, and I actually think, although we have gone through a difficult transition here, we are on the path to do is going to be much more successful than I would have thought possible 5 years ago.

Mrs. ROBY. Thank you. I yield back.

Mr. COLE. Thank you.

We will now go to my good friend, the gentlelady from California, Ms. Roybal-Allard.

UPDATE ON ECHO ADVISORY PANEL

Ms. ROYBAL-ALLARD. Okay. Thank you, Mr. Chairman.

And I would like to follow up on the questioning of Mrs. Roby with regards to ECHO. I think that you said that you are putting together that 10-year plan and that you will include, I assume, milestones and funding estimates in that plan. And when do you expect that the recommended advisory panel with outside experts to be established?

Dr. COLLINS. Those are highly appropriate questions. At the moment, the plan is for a 7-year effort. We would very much want to see how we do in 7 years, but expanding to 10 would be the hope if this project is going well because it should continue to yield up new information as we follow these children over time.

The advisory committee is being put together. It will be formed as a working group of our Council of Councils. That is important because this ECHO program involves multiple institutes at NIH. You might guess particularly the Environmental Health Sciences Institute and the Child Health Institute, but others as well. And we, therefore, need to have this positioned in a place where we have advice from expertise across many different disciplines. That

is where our Council of Councils comes in, and that is where we are going to position the advisory panel for ECHO.

ECHO ACTIVITIES

Ms. ROYBAL-ALLARD. The congressional justification mentions about six research activities for which NCS funds were directed in fiscal year 2015. Are these the existing cohorts that will be used going forward, or are you still identifying cohorts to include in the ECHO initiative?

And then also I want to throw in one more question because of time. Will the array of cohorts include broad population samples and measures that are specifically designed to compare the study cohorts to known national samples, such as the National Health and Nutrition Examination Survey?

Dr. COLLINS. Great questions. In terms of what cohorts will be involved, we have decided this was best handled as a competition. So we put out a Funding Opportunity Announcement and are waiting, as I said, for April 15th to come when we see who comes in to apply to take part. And we expect many of these cohorts will be very interested in taking part because it gives a chance for their work to become even more meaningful. We will want to see that happen.

And certainly, we will want to take full advantage of NHANES, the national study that has much data in it about environmental exposures and a variety of other measures of health and nutrition, to do comparisons with what we see in these cohorts. It is wonderful that we have that kind of foundation from other studies to do this with.

I might say there is one other aspect of ECHO that deserves mention, and that is an effort to set up in the IDeA States, the States that do not currently have a research-intensive university setting, a pediatric research network. There are so many things that we could be doing in terms of pediatric clinical research in those States, but we are not currently set up to do so.

And so this is a proposal to build upon the expertise. It is happening in those IDeA States through other programs to create a pediatric research network and enhance our ability to understand what are the influences in children's health that we don't know about yet.

STATUS ON NCS ACTIVITIES

Ms. ROYBAL-ALLARD. Okay. And just one final question on this, in this area. Your congressional justification also states that the NCS-A will be assessed starting in fiscal year 2017, and that this could drive its future direction significantly. When will that assessment begin, and who will be involved in doing it?

Dr. COLLINS. So, again, we will very much count on our advisory group that is being put together. In fiscal year 2017, we will have these cohorts now funded and assembled together. There will need to be a coordinating center to try to be sure that all of this is working in the most effective and comprehensive way.

So fiscal year 2017 will be the point at which we will have an assessment to see whether this model is working and producing all the data that we believe it should.

Ms. ROYBAL-ALLARD. Okay. Thank you.

Mr. COLE. We will next go to the gentleman from Tennessee, my good friend Mr. Fleischmann.

PMI ACTIVITIES

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And may I say to the chairman and the ranking member, it is truly a privilege to be on this committee. When we see what the NIH and the related agencies are doing, it is tremendous that we see the great cooperation and efforts made in this critical subcommittee, and I am privileged to be part of it.

Dr. Collins, let me thank you and your distinguished panel again. Your efforts in combating the maladies which face us on the health front are difficult, and again, I thank you for your successes and your continued efforts.

I have got a three-part question, which I will read through in the interest of time. Dr. Collins, I would like to take a moment to address the Precision Medicine Initiative. My first question is regarding the direct volunteer portion of the research cohort.

As you know, Vanderbilt University is playing a leading role in piloting the direct volunteer portion of the research cohort. Can you elaborate further on how that pilot program will inform the initiative going forward?

The second part of my question is regarding the approaches NIH is using for recruiting and retaining people in the PMI. While I am pleased to see NIH adopting novel practices, including the use of social media, to attract these volunteers, I would like for you to address some concerns that have been presented to me by the scientific community.

Specifically, can you address NIH plans to interpret and understand the inherent biases the approach presents, particularly given that many people do not use social media at all?

Finally, is the NIH working with the NCHS or other Federal partners that fund or conduct large representative surveys to understand the biases in the PMI million-person cohort?

Thank you, sir.

Dr. COLLINS. Well, great trio of questions, and let me answer quickly because I know we are under a time constraint.

The Precision Medicine Initiative is getting launched this year. Many of us are working 24–7 to get this up and going and are very excited about its potential. Again, the goal is to enroll by 2019 a million Americans as full participants in a study that will collect information from them, including electronic health records, laboratory data, genome sequences, environmental exposures, their own reports of medical experiences.

Allow us to really, with a very large-scale longitudinal study, understand what are the factors that are involved in health and disease. We have never had anything like this before, and everybody who has heard about it is pretty excited about the kind of inferences we could learn from this initiative.

Yes, you are right. Vanderbilt is right out of the blocks a major part of our first launch year because they just received an award actually in partnership with Google, which is now called Verily, to set up the effort to do a pilot effort to recruit direct volunteers. And

I say "pilot" intentionally because we need to learn more about how to do this.

Your concerns about social media being a biased way of involving people have certainly been apparent to us, and we don't want to depend solely on that. But at the same time, with a partner like Google and Vanderbilt working together, we do believe we should be able, just in a few months, to learn more about what is it that volunteers are interested in, what makes it appealing to them to join this effort, and what things are they turned off by. We want to get that really clear before we launch.

Now admittedly, we have two different ways that people can come into this. One is by a direct volunteer route, which is going to be open to any American starting sometime this summer. But, also, we are asking those health provider organizations that already are running large cohorts to come in as our partners because they already have access to patients and information about them.

And that will be a very substantial part of the effort, and that won't depend on any social media concerns. All of these individuals will need to be asked their permission, and if they decide to consent, then they will become participants in this historic undertaking.

We are also reaching out to the traditionally underrepresented groups by working through community health centers with our partners at HRSA to be sure that those individuals also have a chance to take part. And certainly, we are also very interested in working with NCHS and NHANES as we get into this to be sure that the kind of data we collect will be generalizable to the population.

We don't want a set of individuals that are so different than the population at large that we can't do that generalizing, and that will be important then to talk about with those experts at NCHS, which we have already been doing.

So, I guess you can tell I am pretty excited about this. This is really something many of us have dreamed about for more than a decade. We really appreciate Congress' support in getting it started this year, and the appreciation for the consideration of expanding it even further next year as we really launch this initiative.

Mr. FLEISCHMANN. Thank you, Dr. Collins.

It looks like my time has expired, Mr. Chairman. I will yield back.

Mr. COLE. Thanks very much.

We will next go to my good friend from Pennsylvania, Mr. Dent.

COLORECTAL CANCER

Mr. DENT. Thank you, Mr. Chairman.

Good morning to the whole panel, and again, thanks for having us up at the NIH a few weeks ago. I really enjoyed that opportunity.

Dr. Collins, I have been very involved in working on obviously the fight against cancer, but including encouraging screening for colorectal cancer. In fact, you will see a lot of those folks up on the Hill today in their blue shirts.

The NIH's NCI, cancer institute, is pursuing new cancer research to prevent, diagnose, and treat. What are some promising areas of

cancer research in this area of colorectal? I don't know if somebody can talk about that?

Dr. COLLINS. I am going to turn to my colleague Dr. Lowy, the Acting Director of NCI, to answer your question.

Dr. LOWY. Thank you very much, Mr. Dent.

As you probably are aware, March is Colorectal Cancer Awareness Month, and part of the Vice President's Moonshot initiative involves screening, which you also are vitally involved in and to try to use molecular analysis in fluids for making this more realistic so that we can have higher uptake of colorectal cancer screening.

One of the big problems with colorectal cancer screening is that many people don't follow the screening guidelines, and it is really important to try to implement what we already know works while we are also doing research to develop better tests and more specific tests.

I can report to you that the incidence of colorectal cancer is going down, as is the mortality, as a result of the screening that we have to date.

SUPER BUGS

Mr. DENT. Thank you for that answer.

I will also move to the issue of superbugs. What is the latest information on how NIH is working with the CDC on treating and curing these antibiotic-resistant bacteria? And what advancements have been made in this effort and if you have any results you could share?

Dr. COLLINS. Dr. Fauci.

Dr. FAUCI. Thank you very much for that question.

The NIH is part of a multi-agency approach towards addressing of problem of antimicrobial resistance. This effort is led by the White House, which, had an executive order and a related initiative on Combating Antibiotic-Resistant Bacteria, or CARB. NIH is a major part of the CARB activities.

As you know, the CDC is involved in surveillance and detection of antibiotic resistance and in providing guidelines for the use of antibiotics. The NIH component is research to address antibiotic resistance.

And in that regard, we are responsible for determining at the molecular level the basis of the emergence of resistance, number one. Number two, we conduct early screening for new types of antibiotics. For example, there has been recently discovered the teixobactin antibiotic, which is a soil antibiotic. This discovery has the potential to open up the door to a whole new class of antibiotics for gram-positive microorganisms, particularly methicillin-resistant *Staphylococcus aureus*.

In addition, we have a clinical research network, which we have modeled on the clinical networks that we built years ago for HIV/AIDS, to test promising antibiotic compounds. And then, finally, the most important issue about all of this is diagnosis.

In order to really circumvent the problem of antimicrobial resistance, you have to be able to make the diagnosis right on the spot. We have been working on very sensitive point-of-care diagnostics to determine if you have a viral infection versus a bacterial infection—because one of the biggest challenges is the prescribing of

antibiotics for a disease that isn't even a bacterial disease. And so improving diagnostic tests for bacterial infections is one of the things that we have been working on.

We are also working on point-of-care diagnostics that can determine the resistance profile of an infection. You put all of those research activities together, along with the work of CDC and others, and you have a rather comprehensive program. In addition, we are participating in a diagnostic prize. We have a $20,000,000 prize that we, the NIH, are partnering with BARDA, the Biomedical Advanced Research Development Authority, in order to develop a sensitive diagnostic to be able to quickly diagnose infections and determine their resistance profiles.

FUNDING CLIFF

Mr. DENT. Thank you. Thanks, Dr. Fauci, for that.

And finally, I just want to mention in my remaining time, I know the NIH funding cliff through mandatory spending has been raised. We are all concerned about it, and I am concerned that there is a decrease in discretionary funding at NIH and that an increase in mandatory funding, which is obviously going to be problematic.

Last year, you know, we did the $2,000,000,000 increase in discretionary funding. This will create a funding cliff for NIH, and how will NIH be impacted if the authorizers don't act to provide mandatory funding?

Dr. COLLINS. Well, it would be pretty devastating if we were to lose $1,000,000,000. Chairman Cole asked the same sort of question at the outset of the hearing, and I guess I painted a pretty gloomy picture, and it was not just because I was feeling gloomy. It is because it would be, in fact, devastating.

We would lose 1,000 grants that would otherwise have been spent, would have been supported. We would, I think, have really done terrible damage to the momentum that has been started here in fiscal year 2016, thanks to the Congress. It would be a terrible step in the wrong direction, comparable only to the sequester in terms of the harm that it might do.

Mr. COLE. That was a very sneaky way because you knew I would like that question. [Laughter.]

Mr. COLE. Very smart.

Mr. DENT. Anything to suck up to the chairman.

Mr. COLE. Yes. Well, we will next go to my good friend from Idaho, Mr. Simpson.

IMPACT OF GOVERNMENT SHUTDOWN

Mr. SIMPSON. Thank you, Mr. Chairman.

And thank you all for being here today, and thanks for hosting us out to the NIH a couple of weeks ago. I always come back—I have been out there several times over the years that I have been in Congress, and I always come back both amazed and inspired.

It almost makes me feel guilty of having you all come up here and testify because you have got actually much more important things to do than testify before this committee. But obviously, getting out what you do and what NIH does is part of what is necessary.

But as we took a tour, you took us around and visited some patients, a young man and his wife. The young man had melanoma. And you talked to us about the treatment that he was getting, and so forth and so on, and what you were trying to accomplish.

And somebody, I can't remember which Member it was, asked a pretty simple question that I would like you to respond to for the record. And that was what did the Government shutdown do to you?

Because we sit here, and you know, most people see it visibly as, gee, you didn't get into the national park, or something like that, you know? Okay, go next week. I know you travel a long ways, et cetera, et cetera, et cetera, but it is not life threatening.

What did the Government shutdown for 16 days do to you, and what happens if that occurs again, regardless of whose fault it is? And we could argue that from now until the cows come home?

Dr. COLLINS. So I have been at NIH for 23 years. Those 16 days were just about the darkest that I can recall ever going through. The laboratories where graduate students and postdoctoral fellows and other remarkably talented scientists were working were all dark. We had to tell everybody to go home.

They were under threat of criminal prosecution if they came onto the campus. Experiments that had been set up that needed to go for several weeks were basically ruined and had to be started all over again later on, if they got started at all.

But our clinical center, our largest research hospital in the world, also very much affected by this. We were allowed to continue the care of patients who were already there, but we were not allowed to admit any new patients during those 16 days.

Those were people who had planned to come to NIH, their last chance, many of them. We are the house of hope for people where medical research is needed because there is no real answer for what afflicts them. And we had to turn them away, hundreds of them. And I personally had to oversee that.

The only exception was people who were at imminent danger of death, and we were allowed to have a few, one or two or three per day, with very high-level approval in order to do that. And people couldn't understand this. How could this be that something like this could have happened?

So I appreciate your asking the question. I hope and pray we will never go back to that situation again. It was very hard to preside over that kind of dark 16-day period and feel good about the Government.

Mr. SIMPSON. I appreciate that answer, and because it is the real effects of what happens that people don't see out there. As I said, they can see the obvious. Trash didn't get picked up on the way to Mount Vernon and stuff or by the Park Service or whatever, you know? And they don't really think about the life-threatening implications of some of these decisions that we make that we make too light-heartedly, frankly.

So I appreciate that answer. I could ask about a lot of the other stuff that you have got going on, but I am not smart enough to ask it. What I would say is that I appreciate this strategic plan that you have given, and what I would encourage the Members to do is

to look at the last page. A few bold predictions for America's future. Interesting.

If you think of the work that is being done out at NIH, as I have said many times, it is the best-kept secret in America and best-kept secret in Washington. That is both the good news and the bad news.

And somehow we need to get the American people to understand what goes on at NIH and how much of the research that is done at universities and extramural programs and stuff are done and funded by the taxpayers so that they know what they are getting in return for the investment that they are making. And quite frankly, we are politicians. We respond to the public. And when there are public demands that we invest in these types of things, that is when it happens.

So I appreciate you all being here today. I am sorry that I have wasted your time instead of doing the important things that you do.

Thank you.

Thank you, Mr. Chairman.

Mr. COLE. Well, I don't think my friend wasted anybody's time, and I think that is something that needed to be heard broadly, and I appreciate him doing that.

With the consent of the committee, we are going to move to 3 minutes so we can try and give as many people as possible an opportunity to go. But not before Mr. Rigell gets his full 5 because you actually finish out the first order, but in the second round, we will move to 3 minutes. But you get 5.

ALZHEIMER'S DISEASE

Mr. RIGELL. Thank you, Mr. Chairman.

And I regret that I wasn't able to be here at the start. I was, of course, at another hearing.

Dr. Collins and the full panel, thank you for being here. We just really appreciate the good work that you do.

I have a little window into, I guess, growing old because I have been blessed. My two parents are still doing well at 93 and 88, and you know, I speak to them every week. And there is a sad part, though, because they will generally take me through some of my childhood friends' parents that I knew growing up, and they will just kind of walk through that so many of them have Alzheimer's.

And of course, I knew them growing up, and that is just my little window into this profound challenge. You know, we have done a real good job I think generally of lengthening life, but the quality of life side is lagging a bit.

And as it relates to Alzheimer's, and I don't have all the quantitative data that I want right now. I am kind of working in that direction. But I think that as we have increased the funding sharply on a bipartisan basis, which I think is a real win, but I wonder and I wrestle with this, that even though we are in a great fiscal stress and that has my full attention, it seems to me that this particular area warrants sharply increased funding.

I mean, like this is a major national priority for a host of reasons. And some of them, in all candor, are economic. I mean, just

the fact if we could get a hold of this. And so would you comment on that, please?

And also how much funding could we—in a perfect world, if you could have more—you know, at some point, you get diminishing returns. You just can't put it all to good use. I mean, you hadn't had that problem yet.

But how much do you think you could absorb and really, really leverage the dollar and get the most out of it? And I want to give you time to respond.

Dr. COLLINS. I am going to ask Dr. Hodes, who is the Director of the National Institute on Aging, as our lead on Alzheimer's disease, to answer your question.

Dr. HODES. Well, thank you. Thank you for the question.

It is certainly true that just about everyone has had their lives touched by loved ones, family members, who have suffered from Alzheimer's disease. And with the great success of the biomedical enterprise and the public health enterprise of increasing life span, the projections are that unless we are able to intervene better, there is just going to be more and more of this. So it certainly is an area, among many you have heard about today, which is in dire need of further research and support.

In terms of the very direct question about whether a given level of funding can be wisely used, it is a critical question. It is not enough to have simply an urgent public health imperative. We also have to have confidence that there is a scientific opportunity behind it.

And one of the opportunities to test that has actually come with the congressional request or requirement of NIH to deliver a bypass budget each year—last year was the first one—which asks us to estimate the degree of increased funding that would be needed to maximally pursue an efficient spending in support of research towards the goal, an end.

And we have taken this very seriously. When we have composed that bypass budget, which was first released last July for the 2017 budget, we began by convening groups of experts. Last year, a summit of several hundred national and international experts told us what the opportunities were, what the priorities were. We translated that into milestones, all of which are available in as much detail as people would like in an online database.

And this was the real scientific estimate of what we could accomplish or level of funding as an increment we could use in fiscal year 2017. We knew when that budget was submitted that there was a possibility, of course, that accelerated funding could come in 2016, but we were not sure. And we thank you ever so much for the fact that money was forthcoming.

What that money allowed us to do was to carry out the very thoughtful plan accelerating what we proposed could be done with increased funding in 2017 and using it in 2016. Now in July of this year, we will be forwarding—Francis Collins on behalf of NIH—the fiscal year 2018 bypass budget, which really, I think, appropriately calls us to do just what you are asking, to account for what level of research could be done to ensure that we can have research supported efficiently without any compromise in its quality with the resources available.

Mr. RIGELL. So within NIH, I mean, there is—and I think I have got about 20 seconds left here. But I mean, there is, I am sensing here, just a true recognition that this is not to the exclusion of other diseases and other things that are afflicting us in our human journey, but this particular challenge is getting increased recognition as one that really needs to be addressed.

And Dr. Collins, perhaps you can close it out here?

Dr. COLLINS. If I may? I think we are not limited by ideas about interventions that might be successful. We are not limited by talent of scientists, all the way from basic to clinical, who are really fired up about tackling this disease.

So resources are, in fact, much appreciated, and we have nowhere near hit the point where we don't know what to do with them. And again, the bypass budget is a great way to sort of see if resources were available, what could we do? We could go faster, and goodness knows, we need to. The cost of this economically, over $200,000,000,000 every year.

Mr. RIGELL. I thank you all.

Thank the chairman for the additional time.

NATIVE AMERICAN HEALTH

Mr. COLE. Thank you.

And again, we will move to 3 minutes, and I just do want to add parenthetically, it was extraordinarily helpful to this committee to have access to that kind of data in our decision-making last year. So I would encourage you to continue that.

As you know, Dr. Collins, I have got a particular interest in Native American issues, and just quickly, I know you look at particular populations, and not everybody is the same. Obviously, there are gender differences, racial differences, all sorts of things. Can you give us an update on what the NIH is doing specifically to address Native American health issues?

Dr. COLLINS. Well, we are very concerned about all populations in the United States, and American Indians are a special group, both in terms of their history, their culture, and their tribal sovereignty, which has a major effect in terms of participation in research that we need to be very respectful of, and we aim to do that in every way.

Actually, thanks to the leadership of my Principal Deputy, Dr. Tabak, NIH initiated a Tribal Council Advisory Committee, bringing representations of the American Indian community to NIH to listen carefully to what they see as priorities that we should be focused on and to engage with them in topics like the Precision Medicine Initiative.

And there are sensitivities there, particularly about what kind of information is being derived about ancestry, what kind of access to the information will be provided to people outside of the community. As you know, there have been experiences in the past that American Indian communities have gone through that causes them to be somewhat less than completely confident that researchers are always working in their best interests—the Havasupai example, for instance.

So we really need to understand that. In that context, I think we do have a number of important programs that have been ongoing

for a while. I think of the Strong Heart effort that is looking at heart disease, for instance, in Indian Country that has been conducted by the Heart, Lung, and Blood Institute.

And on a particular project that I have just recently read about that we are supporting, which is aiming to try to deal with high-risk pregnancies in the Native American community and particularly providing resources to women who are about—early in their pregnancy about how to maintain a situation that will result in a good outcome, with a very impressive outcome of that particular pilot project that has now been implemented across many different tribes across the U.S.

So we are always looking for ways that we can do research that is acceptable and embraced by the community, but very sensitive to the special nature of those concerns in those communities.

Mr. COLE. Thank you very much for that and appreciate it very much.

And in the interest of time, I will move directly to my good friend, the Ranking Member of the Full Committee.

Mrs. LOWEY. I am going to talk very quickly, Mr. Chairman.

First of all, I want to say, Dr. Collins, your 7 years of service have left an indelible mark, and I hope you continue your work because we really appreciate you.

Thank you.

Secondly, "even the lab rats are all male" has been a great laugh getter at cocktail parties, but it is really serious. And I hope that will continue because it is unacceptable.

Third, Dr. Volkow, I appreciated Dr. Harris' comments. I don't think the majority of people in this country understand the serious impact of marijuana on the brains, 12 to 18, 18 to 25, and I do hope you can be aggressive in getting this message out.

VACCINES

And I thank you, Dr. Harris.

And lastly, my friend Dr. Fauci, the Zika vaccine. We know the seriousness of dengue. We know the seriousness of chikungunya, and I wonder, if there are any seconds left, whether the Zika vaccine, they all come from mosquitoes, same areas, will certainly have an effect on chikungunya and dengue?

Dr. FAUCI. Thank you for the question, Congresswoman Lowey.

We have a vaccine for dengue, one that has been approved in Mexico and the Philippines and Brazil. It is not as effective as we would like. It is about 67 percent effective.

The NIH started in January a Phase III trial for an NIAID-developed dengue vaccine in Brazil in association with the Butantan Institute. For chikungunya, we have data from a Phase I trial of a vaccine we developed that shows the vaccine is safe and induces a good immune response. We have had some trouble, and I don't think we are going to have much more trouble, in getting pharmaceutical partners to work with us for the advanced development of this vaccine candidate.

I think the Zika outbreak has really emphasized the urgency of responding to these outbreaks because we now have pharmaceutical partners who are interested in working with us on a chikungunya vaccine. Importantly, for Zika, although there are al-

ways challenges in the development of a vaccine, we desperately need a Zika vaccine to protect pregnant women because they are the most vulnerable to negative outcome from Zika. If you get infected during your pregnancy, there is a disturbing percentage of fetal abnormalities.

We will start a phase I trial of a Zika vaccine candidate likely in September of 2016 based on the expertise that we have developed over a decade or more in working with vaccines for similar viruses. And I want to thank you and the committee for supporting the work we have been doing and our ability to respond rapidly to emerging infectious diseases.

We have about six Zika vaccine candidates that are in the queue. The one that is the furthest ahead, we had a meeting 3 or 4 days ago with the FDA to discuss plans for the Phase I trial that I mentioned would likely start in September, and then transition into a Phase II trial likely by the beginning of 2017.

How fast we get an answer on whether the vaccine is safe and effective will depend on two things. One, how effective it is. And two, how many infections there are.

If there still is a big outbreak in 2017, we will get an answer much more quickly. If the number of infections go down—it will be good for the public health—but it may take longer to get an answer on the vaccine's effectiveness. But we are vigorously pursuing Zika vaccine development.

Mrs. LOWEY. And I just want to say, Mr. Chairman, I appreciate your leadership and our Ranking Member and the whole Committee in getting the extra $2,000,000,000 and I appreciate this extraordinary panel and all the work you are doing.

And I look forward to working with you so we can say the chairman of this committee has doubled once again in a bipartisan way money for the National Institutes of Health because I can't, frankly, think of a more important investment. And thank you so much for all the really important work you do and your leadership.

Let us do it, Mr. Chairman. We will go down in history.

Thank you.

Mr. COLE. Are you advocating for my budget, or are you just pressuring me? [Laughter.]

Mrs. LOWEY. A little bit of both.

Mr. COLE. A little bit of both. With that, we will go to my good friend Mr. Simpson again. Members are advised we are at the 3-minute limit.

NIH AND DOE RELATIONSHIP

Mr. SIMPSON. They have already started timing, and I just barely got—no, quick question. The Cancer Moonshot that the President announced in his State of the Union and, by the way, which I think was great. I support it. Republicans don't always criticize everything the President does.

I think this is a good start. It is Government wide. I chair the Energy and Water Development Subcommittee. The Department of Energy is going to have a role in this also. They are getting more and more involved in the biological sciences and stuff. And when I ask them about it, they say, well, you know, we were originally involved in the biological sciences because of radiation and the can-

cer caused by radiation from weapons development and other things over the years and stuff like that.

What is the relationship between NIH and the Department of Energy? What are we looking at in the future? What will be that relationship, do you know?

Dr. COLLINS. Well, I will start by saying there is a task force at the highest level, which was appointed to support this effort across Government with the Vice President's leadership, and that very much includes the Department of Energy, as well as FDA, NIH, strong input from NSF, and a variety of other parts of the Government that are involved here, including Commerce because of IP issues.

But I will turn to Dr. Lowy, who could tell you something about a direct involvement that is already ongoing between DOE and the Cancer Institute.

Mr. SIMPSON. And when you answer that, could you also talk a little bit about radio—or the medical isotopes, and with the Canadian reactor shutting down, are we going to have access to the medical isotopes that are necessary?

Dr. LOWY. Thank you, Dr. Simpson.

First, with regard to the Department of Energy, we have initiated very recently three pilot projects with them in cancer research, and they will form a key part of the Moonshot, and we are continuing to have ongoing extended discussions with people from the Department of Energy, including Secretary Moniz, about further extending this because largely they have extraordinary computing power and also machine learning, which is able to do things that really would be extraordinarily helpful in the cancer research area.

Given the time, let me get back to you for the record in terms of the isotope issue.

Thank you.

[The information follows:]

MEDICAL ISOTOPES

Thank you for the question, Congressman. We do expect to have access to the medical isotopes we need in the United States, both for medical research purposes, and for their use in medical imaging needed to diagnose and monitor cancer and other conditions outside of the research setting. The critical isotope is known as molybdenum–99 (Mo99), which is processed into generators that make technetium–99m (Tc–99m), which is widely used for cardiac and bone scanning, as well as scans of the thyroid. The enactment of the American Medical Isotopes Production Act of 2012 positively supported reliable supplies of Mo–99 produced without highly enriched uranium (HEU), and NCI and others no longer need to rely on the Canadian reactor for their supply of Tc–99m. NCI also participates in an interagency effort led by the Department of Energy's National Nuclear Security Administration and the Office of Science and Technology Policy to continue to support sustainable means of producing Mo–99 without using HEU.

Mr. SIMPSON. Thank you, Mr. Chairman.

Mr. COLE. Thank you.

With that, we will go to the Ranking Member of the subcommittee, my good friend from Connecticut.

PRECISION MEDICINE AND CANCER RESEARCH

Ms. DELAURO. Thank you, Mr. Chairman. I am going to talk fast.

On antibiotic research, I just came from an Ag Committee hearing. I just will say this to you. Seventy percent of antibiotics sold in the U.S. are bought for livestock production. There is industry guidance today that is voluntary through the FDA.

I don't know what collaboration you have with USDA, with FDA, but it is critical. We should not be in silos here. You talked about 23,000 deaths. If we know what is going on, let us get their research, your research, and look at how we can cut that number in half, as you said last year, Dr. Collins, that we could do.

So it truly is unbelievable, and it is voluntary. We need to think about guidance—not guidance, voluntary guidance. We need to think about how we tell people that and the pharmaceutical companies that in a mandatory way, in my view.

Let me move to the Precision Medicine Initiative, and I will just cut to the chase. I was alarmed by a New York Times article that raised concerns about the lack of success in utilizing genetic testing to identify personal treatment for breast cancer patients.

Just Dr. Lowy, Dr. Collins, what is the clarity on this issue and guidance to practicing breast cancer physicians or patients?

Dr. LOWY. Thank you very much, Ms. DeLauro.

I think that this area really exemplifies both the strengths and the limitations that we have of any clinical test. You do a clinical test, and for some people, it is enormously helpful. And for other people, the results are ambiguous.

The genetic tests that we have can be enormously helpful in pointing people with cancer in the right direction in terms of treatment, but not for all of them.

Ms. DELAURO. But is it accurate in terms of the success that has been in other areas other than breast cancer? Is breast cancer a specific disease that is not responding to PMI, or am I—or is this article off base? But help us.

Dr. LOWY. There have been—there have been specific inhibitors. For example, Herceptin, which was the first targeted inhibitor, was specifically for breast cancer, and EGF receptor inhibitors. So there are specific inhibitors for breast cancer. The problem is that when you get an abnormality, not all of them are clearly actionable, and not all of them are going to be responsive.

Ms. DELAURO. I would like to continue this conversation to look at breast cancer particularly. And I might just ask you to take a look at the Wall Street Journal this week. Bristol, and this is Bristol-Myers Squibb bets against Precision Medicine. I would ask you to take a look at it and tell us, you know, what Bristol-Myers Squibb is thinking about or talking about when we are trying to move in this direction.

ZIKA

Ah, I have got 4 seconds left. La-da-da. All I will just say is, and this is to Dr. Fauci, if, one, I want to make sure that any vaccine that we deal with for Zika is going to be available and affordable for people. This is this reasonable terms issue.

But secondly, I will just offer my view. I think it is critical for us to deal with supplemental emergency resources in order to address this issue and this problem. You are right. I will tell you that

we are now sending blood products to Puerto Rico in response to a Zika outbreak.

What happens when we are looking at a blood supply that is potentially going to be difficult or people are not going to understand the safety of a blood supply with regard to Zika, and what kind of problems that is going to cause here in the U.S.? And let me just tell you, American women are not going to—they are going to be outraged if we are not doing something about them and about their ability to be pregnant and to bring a child to term.

So thank you for the great work that you are doing in this area.

I have another question, but that is okay.

[Laughter.]

Mr. COLE. Well, I am not sure that was a question, but it was——

Ms. DELAURO. Genetically modified mosquitoes. Are they—is it—genetically modified mosquitoes?

Mr. COLE. I am going to ask the gentlelady to take that one for the record.

Ms. DELAURO. Okay. All right. Thank you.

[The information follows:]

RESARCH ON MOSQUITOES

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports a wide variety of vector research that aims to reduce the spread of infectious diseases, including research focused on the mosquitoes that carry flaviviruses such as Zika. NIAID supports research on mosquito biology, host-virus interaction, novel vector control methods, new insecticide targets, and vector competence studies to understand the replication and transmission of flaviviruses and other pathogens. Currently, NIAID is supporting research on methods to reduce the population of the Zika virus vectors, *Aedes aegypti* and *Aedes albopictus*, including studies to evaluate the efficacy of *Wolbachia* bacteria as a vector control strategy against these mosquitoes. NIAID is in discussions with researchers pursuing a variety of novel approaches to vector control, including the development of several genetically modified mosquito approaches currently under investigation for control of infectious agents, including Zika virus. Evidence regarding the impact of transgenic mosquito technology on disease still needs to be generated. It is possible that the use of transgenic mosquitoes over a large area may not be sufficient and that other supplementary vector control methods may need to be used as well. One example of a company NIAID is currently discussing transgenic mosquito technology with is Oxitec, the company that has tested its self-limiting mosquito technology in controlled release studies in Brazil

Mr. COLE. Because I want to make sure our remaining two Members get an opportunity.

So, with that, Mr. Harris, you are recognized for 3 minutes.

MARIJUANA ADDICTION

Mr. HARRIS. Thank you very much.

Dr. Volkow, let me just continue and just follow up a little bit because the marijuana use and full legalization is a huge issue. It comes before this Congress. It is, you know, we have a rider that affects the District of Columbia on our appropriations bills usually.

And let me just—you know, you were a co-author on a 2014 review article in the New England Journal of Medicine, pretty prestigious medical journal. And let me just review some of the statistics in it and just confirm that these are still true.

With regard to marijuana addiction, although the overall rate is around 9 percent, if you look at young users or if you look at daily

users, it is higher with young, perhaps as high as 17 percent. Daily users, 25 to 50 percent. Is that still true? That is still the state of our knowledge?

Marijuana dependence, though, can be much higher, and depending upon other—because it depends on other factors as well, can even be twice that, 20 percent just in general use.

With regard to the gateway theory, because this is continually controversial, my best understanding is there is some reason to believe from other studies in rat models that potentially there is a gateway. It is a gateway drug, but it is still not clear whether that is true in humans. Is that true, or are we developing an understanding that it, in fact, is a gateway drug to other addictive behavior?

Dr. VOLKOW. Animal studies, there is evidence that, yes, marijuana could change the sensitivity of the reward centers of the brain to other drugs, which would provide a means by which you become more vulnerable for addiction. But you cannot necessarily directly translate into humans, and the issue in humans is still being investigated.

Mr. HARRIS. Okay. So, but it is not settled science that it is not a gateway drug in humans?

Dr. VOLKOW. It is not. And all of the epidemiological studies show that it is a drug that frequently precedes the addiction to other drugs.

Mr. HARRIS. Right, and it is associated with or it is causal. I understand. I did animal research. I understand you can't always extrapolate to humans.

Finally, which was interesting to me that when you look at the effect on school-age children, and if you are not careful in how you control the access to children in school, that it impairs critical cognitive function for days after use, which was interesting. And that was stated in the article. Is that a fact?

Dr. VOLKOW. That has been replicated by independent investigators.

Mr. HARRIS. So that if we don't write the laws carefully and you allow children in school access to it, that critical cognitive functioning can, in fact, be impaired for days. And this is—and again, this is in the setting of where we want to actually have children go to school and learn and be cognitively functional.

From a scientist point of view, would you urge jurisdictions that are looking into fully legalizing marijuana to exert extreme caution in taking that position at this point?

Dr. VOLKOW. I basically ask people to look at what the data is telling us. We have seen consistently that the most devastating effects of drugs in our country are from the legal drugs, not from the illegal. Not because they are more dangerous, but the legal status makes them much more available and more likely to expose many more people and explains why we have so many more adverse effects from legalization.

So I always say do you want to have a third legal drug? Can we as a nation afford it?

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

Mr. COLE. Thank you.

Now for the last question of the day, we go to my good friend, the gentlelady from California.

ZIKA VIRUS'S RELATIONSHIP TO MICROCEPHALY

Ms. ROYBAL-ALLARD. Dr. Fauci, my colleague Congresswoman Herrera Beutler and I have recently started a new congressional caucus on maternity care to promote optimal birth outcomes for women and to highlight issues like the Zika virus that pose a risk to childbearing women. And so we have been following with great interest the World Health Organization's finding and counsel regarding this disease.

The Committee stressed the urgency for research and development of the Zika virus vaccine, which you have talked about earlier. But the WHO urgency committee also recommended both retrospective and prospective studies of the rates of microcephaly and other neurological disorders in areas known to have had Zika virus transmission, but where such clusters have not been observed.

So my question is whether or not it is possible that the Zika virus has been responsible for cases of microcephaly in the United States over the past three to four decades, and has there ever been any tracking of this birth defect to see if there have been clusters or increased incidences of it in the United States?

Dr. FAUCI. That has not been formally examined with regard to retrospective studies, but there has been no Zika virus in the United States previously. We know that is true because when we do serological surveys of what has been in the United States, we have not detected locally acquired Zika virus in the United States.

What we have now in the United States are more than 190 cases that have been imported, mostly people who have been in the Caribbean and South America who were infected there and came back home to the United States. What we haven't had is local outbreaks of Zika virus in the United States similar to what we did see a few years ago with dengue in Florida and Texas and with chikungunya in Florida.

There is a very important surveillance capability, which will tell us the answer to your question—we haven't had Zika in the United States in the past—but will also tell us if and when we do have Zika outbreaks in the United States in the future. And unfortunately, it is probably likely that we will, as the summer comes, see local outbreaks, particularly in the Southeast, the Gulf Coast States, Texas, Florida, et cetera, because the mosquito—*Aedes aegypti*, which is the major transmitter of Zika virus—is in those areas of the country, as it is in Puerto Rico and in South America.

Finally, what we do have in South America are cohort studies to determine definitively what is the fundamental baseline level of microcephaly and what is the relationship of microcephaly to pregnant women infected with Zika. Two relevant studies were recently published. One came out a week ago, showing that if you looked at Zika-infected women who were pregnant and pregnant women who were not infected with Zika in Brazil, 29 percent of the Zika-infected women had ultrasounds indicating abnormalities of the fetus, which is very disturbing. This is the reason why we feel very compelled to develop a vaccine to protect not only the people in

South America and the Caribbean, but if necessary, if it comes to that, in the United States.

Ms. ROYBAL-ALLARD. Let me just give you the personal reason, my personal interest in this particular area. My grandson was born with microcephaly. This had to be probably over about 12 years ago. And as a result of that, both my daughter-in-law and my son took every test imaginable to find out what the cause was, especially since they planned on having other children. And they could find nothing, none of that research.

And so I am just wondering, we are trying to figure out what possibly could have been the cause?

Dr. FAUCI. There are a number of causes of microcephaly. That is an excellent question, Ms. Roybal-Allard, a very important question. People sometimes get the misimpression that microcephaly is only associated with Zika because of the publicity we are seeing now about Zika.

Microcephaly has been observed in infants forever, and it is typically associated with something that happens usually in the first trimester. The cause could be a viral infection such as cytomegalovirus, or CMV. The cause could be any of a number of viral infections. The cause can be fetal alcohol syndrome. The cause could be a variety of things that interfere with the developmental process, usually concentrated in the first 15 to 20 weeks of pregnancy.

Although we do know now from a recent study that even women who get infected with Zika in the second and early third trimester can also have abnormalities in the fetus. These abnormalities may not necessarily be microcephaly, but the abnormalities are nonetheless concerning. Again, this gives us further motivation to develop a vaccine.

Dr. COLLINS. Another cause, just to mention, is genetics. And in the days gone past, it was very hard to actually nail that down. The technology wasn't good enough.

Now that we have the ability to look at the complete genome sequence in a situation like that, and many centers are now doing that, we are uncovering causes of microcephaly that are due to DNA changes that we previously didn't know about.

Ms. ROYBAL-ALLARD. And now they have three healthy, beautiful——

Dr. COLLINS. And that is wonderful.

Ms. ROYBAL-ALLARD [continuing]. Bright, intelligent——

Mr. COLE. Well, thank you very much, Dr. Collins. Let me begin by thanking you and your colleagues for not only your appearance here today, but obviously, your accessibility to all of us when we have questions. And appreciate the wonderful work that you do.

This may be—well, we will have plenty of opportunities to continue to work together, may be your last appearance before this committee. That will be a decision, I would suspect, of a new President of the United States at some point. But we hope it is not your last appearance here, quite frankly, just speaking for myself personally.

And I again want to thank you for the exceptional leadership that you have shown at the NIH for a lifetime, and that would go to all of you, quite frankly, of putting the health and security of

our people, but all people as your principal goal in life. It is a quite remarkable achievement, and you are all very, very distinguished in your own fields.

And to see the manner in which you collaborate together and work across disciplinary lines and institutional lines is really very, very inspiring. And so we, again, just appreciate the values that you show and the basic and decent humanity that each of you exhibit.

And it is no surprise to me that it is the NIH that tends to bring this committee together, where it puts aside partisan differences, ideological differences, and really does try to work in common to advance and support the splendid work that you are doing. And I am sure that will continue.

We have plenty of other things, I guess, we can fight about, but this isn't going to be one of them. This is going to be one of the areas where we work together and, frankly, where we protect the discretionary funding that you got last year due to the bipartisan efforts on this committee. And well, we try to build on that, and frankly, where hopefully, Dr. Collins, we can go to the sunny question I asked you in the first round, and that is perhaps do a little bit better than even the President proposed, who certainly has proposed a generous increase.

But if we can go beyond that and put additional means in your hand, then I know, on a bipartisan basis, we will want to do that.

So thank you, and we are adjourned.

Ms. DELAURO. Thank you very much, Mr. Chairman. You speak for all of us.

Thank you.

Mr. COLE. Thank you.

Cole 1
Institutional Development Award (IDeA)

Chairman Cole: I certainly am a fan of the Institutional Development Award (IDeA) program. The program broadens the geographic distribution of NIH funding for biomedical research and enhances the competitiveness of investigators at institutions located in states like Oklahoma. The FY 2016 Omnibus provided an increase for the program but more importantly requested NIH maintain at least a floor of 1 percent of the NIH total funding in future budgets. I was disappointed to see that your budget did not follow this recommendation. Can you tell me why?

Dr. Collins: Excluding special targeted Presidential initiatives, the overall proposed FY 2017 National Institute of General Medical Sciences budget and the proposed budget for other NIH Institutes and Centers was held flat relative to FY 2016 in the President's FY 2017 Budget Request, and so funding for the IDeA program was held flat relative to FY 2016 as well to remain consistent with the overall FY 2017 proposal.

Cole 2
Basic Research

Chairman Cole: Basic, foundational research is a major driver of progress across the biomedical sciences. It is the seed corn used to support all future translational research. Historically, about 55 percent of NIH funds had been invested in basic research. I understand it takes 12-17 years of investment before new basic research may be translatable.

The FY 2016 budget request assumed about 54 percent of NIH requested funds would be spent on basic research.

Although the FY 2017 request notes the value of basic science as foundation for discovery, I understand the current FY 2016 estimate of support for basic science has dropped to about 52 percent or a decrease of $640 million, after receiving a significant funding increase, and the FY 2017 level is held level to 52 percent.

a) What percentage of NIH's FY 2016 and FY 2017 budget request do you expect NIH and its IC to spend on basic research?
b) Further, what can be done to increase the percentage support to basic research across NIH?

Dr. Collins: We expect the percentage of the budget spent on basic research to be close to your estimates. Basic research is the cornerstone of scientific discovery, and thus is fundamental to NIH's mission to enhance health, lengthen life, and reduce illness and disability. As such, it is a main focus of NIH investment and a crucial part of the first objective outlined in the Agency's NIH-Wide Strategic Plan (FYs 2016-2020): Advance Opportunities in Biomedical Research.[1] By providing information about how living systems work, basic research sets the stage for translational research and clinical studies that can lead to new preventive methods, treatments, or cures for diseases.

It is almost impossible to predict which pieces of new scientific knowledge may come together to create the next breakthrough. For example, the science behind the first anti-retroviral drug for treating AIDS (zidovudine (AZT)) works by inhibiting an enzyme called reverse transcriptase, which HIV uses to replicate. Reverse transcriptase was discovered through basic research on viruses several years before doctors or scientists identified AIDS. Moreover, basic science leads to development of new technologies and methods that hold promise for future scientific advances. This is illustrated by cryo-electron microscopy (cryo-EM), which is facilitating huge leaps in the field of structural biology in ways that researchers could not have anticipated only a few years ago. By determining the shape of structures impossible to visualize before, cryo-EM will help identify mechanisms that could lead to new drugs and other interventions to combat diseases and disabilities.

To affirm NIH's unwavering support of basic research in the Agency's portfolio, the NIH Director and Deputy Directors, along with all Institute, Center, and Office Directors, recently penned a letter published in *Science* titled, "Basic science: Bedrock of progress."[2] This letter

[1] https://www.nih.gov/about-nih/nih-wide-strategic-plan
[2] http://science.sciencemag.org/content/351/6280/1405.1.full

acknowledges the concern that investigators may be submitting fewer basic research applications due to misperceptions about NIH's funding priorities. In order to dispel this myth and to encourage submission of more high-quality basic science research applications, NIH has revised its application instructions so that the Public Health Relevance statement reflects NIH's mission and commitment to a diverse portfolio, including robust support for basic research. The instructions indicate that applicants should describe how their research could contribute to NIH's mission in the short term or the long term, thereby clarifying the agency's commitment to the full spectrum of biomedical research.[3] It is our hope that the dissemination of the *Science* letter and the revised instructions will encourage more applicants with innovative ideas for basic science research to apply for funding.

[3] http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.220-r&r-other-project-information-form.htm#8

Cole 3
Young Investigators

Chairman Cole: This Committee has had concerns for years about the next generation of investigators. NIH has a number of programs, like the Science Education Partnership Awards (SEPA) to foster important connections between biomedical researchers and K-12 teachers and their students. These connections establish an educational pipeline to careers in biomedical sciences, which is one of the most important areas of workforce development for the U.S. economy.

a) Can you highlight for us what NIH is currently doing and planned in the budget request to grow the next generation of young investigators at the K-12 level?
b) Are there ways NIH, its grantees, or supported institutions can further work with local school systems to foster interests in students early on, in middle and grade school, which would increase the likelihood that more kids would work towards a STEM education track?

Dr. Collins: Early science, technology, engineering, and mathematics (STEM) experiences develop students' interest and knowledge, and contribute to later success in science-related careers. Each year, many students, particularly from low-income and other underserved groups, lose interest or fail in elementary school science classes and never catch up. Studies suggest that a disproportionately high numbers of low income and underrepresented minority students are behind in science and other subjects by third grade.

The NIH Research Education Projects (R25) supports the Science Education Partnership Award (SEPA) program. SEPA's goal is to invest in educational activities that enhance the training of a workforce that meets the Nation's biomedical, behavioral, and clinical research needs. In FY 2010, SEPA was expanded to include the pre-kindergarten community, making SEPA's target audience pre-kindergarten to grade 12 (P-12). Currently, SEPA has 71 active projects.

SEPA's areas of early learning focuses on: 1) courses for P-12 teachers' STEM skills development; 2), research experiences for P-12 teachers and students that provide hands-on STEM exposure; 3) mentoring opportunities to P-12 students; and 4) curriculum development opportunities that will increase students interest in STEM and veterinary-based P-12 projects to encourage students to consider careers in veterinary medicine. Further, the next generation of students will have the opportunity to participate in game-based projects where scientists partner with educators and game developers to create digital game-based learning resources for P-12 students. The digital learning element allows teachers and students to solve STEM and health-related challenges such as the incidence of obesity, diabetes, cardiovascular disease, the spread of a new flu strains, or the impact of environmental pollution on community health.

This investment in the next generation is well placed, because NIH depends on a constant supply of dedicated, talented, and highly creative individuals to make the medical discoveries necessary to solve America's health problems. The Nation's economy benefits from a well-educated STEM workforce.

The SEPA program requires dissemination of the SEPA-supported and -generated resources and curricula beyond the SEPA program and into settings such as local school systems. SEPA requires that all dissemination plans: 1) are well-designed and appropriate for the materials that will be created; 2) relevant to the target audiences; and 3) include diverse underrepresented groups in science, including underrepresented racial and ethnic groups, individuals from disadvantaged backgrounds and individuals with disabilities. SEPA dissemination plans must include both sexes. Project dissemination plans may include posters, presentations, workshops and other dissemination practices at local, regional and national conferences. SEPA projects utilize cutting edge social media venues such as Wikis, YouTube, and Facebook. Additionally, current SEPA grantees are encouraged to expand their resources and curricula to embrace the recently added pre-kindergarten target audience.

National Library of Medicine (NLM)

NLM has developed a suite of information resources related to K-12 Science and Health Education, created in conjunction with teachers and scientific experts.[4] These include websites developed specifically for targeted grade levels, such as an the *Environmental Health Student Portal* for middle school students, the *ToxMystery* interactive site on toxic substances in the home for elementary school students and the *GeneEd* genetics education site for high school students.[5,6,7]

In addition to specialized resources NLM also supports school-based programs designed to enhance awareness and preparation for biomedical careers as well as promote greater health literacy. For example, the Mentoring In Medicine science and health career exploration program reaches seven public and charter high schools in New York City and three middle schools in the Washington, D.C. area with an after school program to enrich the high school biology curriculum. Over the past five years, the program has exposed more than 800 minority students to health care career instruction. Efforts to create a toolkit to provide general access to this curriculum are underway.

NIH believes that these programs provide resources that can help foster interest and training in STEM at crucial early stages in a child's development. Furthermore, resources developed in these programs can be widely used as tools for improving STEM engagement in the larger P-12 education community. NIH will continue to support such programs, disseminate their products, and emphasize the importance of having the scientific community engage with the next generation of future scientists.

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[4] https://sis.nlm.nih.gov/outreach/k12.html
[5] https://toxmystery.nlm.nih.gov/
[6] https://geneed.nlm.nih.gov/
[7] http://kidsenvirohealth.nlm.nih.gov/

Cole 4
Stewardship to Inspire Public Trust

Chairman Cole: To the NIH Director: Thanks for responding to the Congressional desire that NIH develop a NIH-Wide strategic plan for priority setting. I appreciate how the budget request highlights a focus on Stewardship to Inspire Public Trust. This is certainly a goal all agencies should be working toward. We look forward to hearing about how recent advances in portfolio analysis methods have aided efforts to prioritize NIH investments by helping to identify emerging scientific opportunities and optimize future scientific investments as part of the stewardship focus.

a) Please share how NIH used its strategic plan for resource allocation in a request that is at best level funded for most institutes and centers?

All NIH IC Directors,

b) Outside of the highlighted initiatives of the Cancer Moonshot, PMI, and BRAIN initiative, please share how each Institute is aligning its internal plans to the NIH-wide plan and how the budget request denotes movement toward a more NIH-wide scientifically strategic approach across NIH?

Dr. Collins: The NIH-Wide Strategic Plan was designed to harmonize decision-making across the Agency, enhance NIH's responsibility to be a good steward of the provided resources, and highlight opportunities to advance biomedical research. Three of the four objectives outlined in the Strategic Plan are focused on setting priorities, enhancing stewardship, and managing for results. To advance these efforts, NIH has taken additional steps to enhance transparency of its decision-making processes by making public a standard metric for funding each year. Each Institute and Center (IC) will post clear information about its funding threshold for grant applications. Overlap analyses have also been conducted on the NIH grant portfolio to compare each IC, and help maximize synergies in the portfolio. Additional analyses have been performed on the diversity of the scientific workforce to inform discussions on how best to tailor programs and increase the success of those researchers from underrepresented backgrounds. Also, a large study analyzing a component of the peer review process will begin later this year to help improve and optimize this critical activity at NIH. Further, NIH recently implemented new policies to enhance rigor, reproducibility, and transparency in research. These recent changes to the application instructions and review criteria apply to applications submitted for the January 25, 2016 due date and beyond.

Additionally, the NIH-Wide Strategic Plan was developed to complement, but not replace, the strategic plans of the NIH ICs and Program Offices. Going forward, the NIH-Wide Strategic Plan format will be used as a standardized template as each IC updates their strategic plan. To highlight NIH's commitment to implementing changes and ensuring consistency across NIH, the IC Directors' performance evaluations have been modified to include elements of the NIH-Wide Strategic Plan, including fostering partnerships, optimizing funding decisions, improving transparency, using evidence-based processes, and engaging in proactive risk management practices.

Cole 5
National Cancer Moonshot Initiative

Chairman Cole: The President has proposed a National Cancer Moonshot to accelerate research efforts and break down barriers to cure cancer. It calls for using $195 million of the increase Congress provided in FY 2016 at NIH and $680 million at NIH in FY 2017.

a) Please describe the specific objectives the American public should expect to see in the next five years if these funds were to be provided?

Dr. Collins: Currently, each year more than 1.6 million people are diagnosed with cancer, and almost 600,000 will die from the disease. The resources supporting the FY 2017 Cancer Moonshot Initiative will allow the National Cancer Institute (NCI) to improve these statistics. The FY 2017 initiative will dramatically accelerate the pace of discovery in ways that can produce tangible benefits for patients with all types of cancer, those at risk of cancer, and the growing population of cancer survivors.

The FY 2017 initiative currently has seven elements, and summaries of five of them appear below. The sixth element will enable and encourage data sharing to speed cancer discovery. This element will support shared bioinformatics resources to greatly increase our understanding of cancer and strengthen our ability to select the most appropriate treatment for patients. The seventh element will allow NCI to fund exceptional opportunities by awarding research funding – prioritized through a competitive process – to pursue innovative new ideas that target intractable problems in cancer science.

Although it is impossible to predict with certainty the specific progress we will achieve during the next five years, the speed at which we are gaining new insights into the causes of many cancers, and how cancers develop, will generate important opportunities to translate these discoveries throughout cancer clinical practice. Given the scientific promise identified in the areas described below, we anticipate that the FY 2017 budget increase will allow NCI to further accelerate the pace of discovery and deliver important results for the patients that we serve.

Detecting Cancer Earlier: Even small tumors shed biomarkers into fluids of the body, such as blood, saliva, and urine. Recent advances in genomic and proteomic technologies have greatly increased the sensitivity of methods that can detect biomarkers in fluids, which raises the possibility of using such methods to screen for and identify cancers earlier. Such minimally invasive methods have recently been used for assessing whether cancer has recurred in individuals who were previously diagnosed and treated. The goal here is to detect at a very early stage a range of cancer types for which we do not yet have effective screening methods and to improve the detection of cancer types for which screening is already established practice.

Research on Mutations: Gaining a greater understanding of the mutations that occur within the cancer cell, the changes that occur within surrounding stromal tissues, and the nature of the immune system's response to cancer will serve as a springboard to advance immunotherapy and targeted drug therapy. Such research can also identify mechanisms used by cancer cells to co-opt the vascular tissue and other parts of the micro-environment near the cancer. Moreover, this approach can identify what type of immune response is already present, but may need a boost to

combat the cancer. Coupling this information with the clinical response to drug therapy and immunotherapy could greatly enhance our understanding of the therapeutically relevant interplay between the tumor and the many cell types that surround it, leading to an increased ability to improve patient responses to treatment.

Speeding Progress on Childhood Cancers: Cancer in children poses unique challenges. Childhood cancers generally possess many fewer mutations than adult cancers and are less likely to have activation of enzymes known as kinases, which are the most frequent targets of cancer drugs for adult tumors. Furthermore, characteristic molecular changes that drive many childhood cancers arise in transcription factors and other cellular targets that are often considered "undruggable." However, new technologies, built upon advances in chemistry that allow the preparation of libraries of small chemical molecules with a much more complex arrangement of molecular shapes, offer the promise of identifying inhibitors for the abnormalities found in pediatric cancers.

Cancer Immunotherapy and Combination Therapies: Immunotherapy is based on the principle that a patient's immune system, when properly primed, can often detect and destroy cancer cells. However, the challenge of immunotherapy is two-fold: first, tumors often effectively blunt anti-tumor immune responses, and second, the immune system must be successfully primed to recognize the tumor. Despite these challenges, during the past few years there have been some remarkable successes in overcoming these problems. NCI is working to extend these early successes in cancer immunotherapy to virtually all tumor types through improved understanding of the mechanisms that enable and limit immunotherapy. This element of the initiative will also support advanced research on combination therapies. Compared with single agent treatment, combinations of drugs that impair the growth and development of tumors along multiple molecular pathways are more likely to prevent the development of resistance and to produce long-lasting remissions. However, to benefit more patients, we urgently need to identify and understand the most effective combinations of targeted agents or targeted agents used in combination with immune-modulating molecules.

Vaccines to Prevent or Treat Cancer: Vaccines against cancer-causing infections can prevent certain cancers. The NCI research that led to pediatric vaccines to prevent cervical cancer and other cancers caused by infection with human papillomaviruses (HPV) represents an important milestone in cancer prevention. The development of vaccines to treat early stage cancers and pre-malignant lesions not related to infections is another exciting opportunity that NCI will target with additional resources under the FY 2017 initiative. Such vaccines can target unique or signature genetic changes found in cancers and premalignant lesions. Candidate lesions to target include those found in patients with early prostate cancer, patients with premalignant lesions such as ductal carcinoma in situ (DCIS) in the breast, and patients at high risk of colorectal cancer.

b) If the additional mandatory funds are not provided and the National Cancer Moonshot moves forward with only the NCI base and the $195 million provided through the FY 2016 appropriations, what is the impact?

Dr. Collins: If NCI does not receive the $680 million for the FY 2017 initiative, we will miss many opportunities to make important progress in preventing, diagnosing, and treating cancer, and delivering research results to patients.

The $680 million increase proposed for FY 2017 will accelerate the pace of discovery in ways that will produce tangible benefits for patients with many types of cancer and for many patients in the United States at risk of cancer. Without the FY 2017 increase, NCI will continue to support compelling research. However, the pace of discovery and the pace of delivering new discoveries to cancer patients or to individuals who may receive a cancer diagnosis will be slower.

c) The taskforce is expected to proposal by the end of December 2016 for what activities the moonshot will include. Please describe the timeline and activities that will need to be done to review, approval, and validate the scientific opportunities related to the moonshot once the task force report is complete? Plus, the length of time for each step?

Dr. Collins: The Blue Ribbon Panel (BRP) for the National Cancer Moonshot Initiative is a Working Group of the National Cancer Advisory Board (NCAB). BRP is comprised of scientific experts, cancer leaders, and patient advocates. It will provide expert advice on the vision, proposed scientific goals, and implementation of the National Cancer Moonshot Initiative. In addition, the BRP will consider how to best advance the themes proposed for the Initiative and may recommend other cancer research activities to enhance this effort. Through its deliberations, the BRP will conduct an intensive examination of the opportunities and impediments in cancer research.

To gather input from the cancer research community across disciplines and sectors, and with approval of the Panel chairs, BRP may call upon other experts, assemble ad hoc work groups, convene workshops, and conduct other activities. NCI will also seek input from the research community, advocacy groups, general public, and others that will be integrated into the Panel's discussions and deliberations. Findings and recommendations of the Panel will be reported to the NCAB. NCAB will be responsible for providing final recommendations to NCI's Director, who in turn is responsible for providing recommendations to the Federal Task Force, chaired by the Vice President.

The 28-member BRP was announced on April 4, 2016 and held its first meeting on April 11th. The BRP met for the second time on April 18 at the American Association for Cancer Research (AACR) annual meeting in New Orleans. During the second meeting, the BRP decided to establish seven working groups focused on major scientific elements to be advanced as part of the Cancer Moonshot Initiative. Over the next several months, BRP will consider how to advance several proposed scientific themes, and will form working groups around the final set of themes. The timeline is tight, with a final report to be delivered to NCAB in August so that NCI can issue funding opportunity announcements by October.

Specific milestones are as follows:

- Working group recommendations submitted to the BRP expected in late May or early June

- BRP discussion during June-July
- Final BRP report sent to NCAB in August
- NCAB recommendations to be delivered to NCI Director by the end of August
- NCI to prepare funding opportunity announcements (FOAs) for approval and publication by October
- January-March 2017 receipt dates for responses to FOAs
- June-July 2017 – NCI review of applications and funding of awards

Cole 6
Ebola, Zika, and Universal Flu

Chairman Cole: Dr. Fauci, in the past year, besides the normal work on infectious diseases, you and your team have worked on responses to Ebola, Zika, and continued efforts for a Universal Flu Vaccine.

a) Please provide an update on where we are with Zika vaccine and Ebola Vaccine?

Dr. Fauci: The National Institute of Allergy and Infectious Diseases (NIAID) has a dual mandate encompassing both research on ongoing public health issues and the capability to respond rapidly to newly emerging and re-emerging infections such as Ebola and, more recently, Zika virus. NIAID is well-positioned to rapidly respond to infectious disease threats as they emerge by leveraging fundamental, basic research efforts; domestic and international research infrastructure that can be quickly mobilized; and productive partnerships with industry.

NIAID was able to respond rapidly to the Ebola crisis in West Africa because of its longstanding investment in biodefense and emerging infections research. This includes a well-established, comprehensive suite of preclinical services; importantly, NIAID's vaccine testing and manufacturing services have helped advance several vaccine candidates. Developing a safe and effective Ebola vaccine that could serve as a critical public health tool to help prevent Ebola virus disease and contain future outbreaks has been a top priority for NIAID. In 2015, the Partnership for Research on Ebola Virus in Liberia (PREVAIL), a partnership between HHS and the Liberian Ministry of Health, launched PREVAIL I, a randomized, placebo-controlled clinical trial of two Ebola vaccine candidates, NIAID/GSK cAd3-EBOZ and NewLink Genetics/Merck rVSV. Results of the PREVAIL I study released in February 2016 showed that both vaccine candidates were safe and elicited an antibody response against the Ebola virus after one month. The PREVAIL partnership also is working to develop a Phase II safety and immunogenicity study in all three of the affected West African nations. This Phase II trial would study the Janssen/Bavarian Nordic Ad26.ZEBOV vaccine followed by a boost with the MVA-BN Filo vaccine alongside the NewLink Genetics/Merck rVSV. NIAID supported the early development of these vaccines. This trial is expected to begin in 2016.

NIAID also has collaborated with the biopharmaceutical industry, academia, and other Federal agencies to develop additional Ebola vaccine candidates. For example, Phase I clinical trials are planned or underway to evaluate the safety and immunogenicity of NIAID-supported vaccines including the Profectus rVSVN4CT1 vaccine; HPIV3-EbovZ GP, an intranasal Ebola vaccine; and an NIAID-developed vaccine targeting both Ebola and rabies viruses.

While the Federal Government and international response to Ebola virus in West Africa has resulted in the containment of the diseases with very few new Ebola cases emerging in the affected region, this also limits the capacity to conduct large, randomized trials to evaluate Ebola vaccine candidates and other medical countermeasures. However, through PREVAIL I, NIAID has made significant progress toward identifying effective vaccines and continues to work with domestic and global partners to advance promising Ebola vaccines and other medical countermeasures. It is anticipated that the data from the ongoing efforts will be of value in eventual licensure decisions by the FDA.

NIAID's longstanding commitment to flavivirus research, including extensive efforts to combat diseases caused by such viruses as dengue, West Nile virus (WNV), Japanese encephalitis, tick-borne encephalitis, and yellow fever, provides a strong foundation for research efforts on Zika virus. NIAID is currently investigating multiple Zika virus vaccine candidates, including vaccines based on technologies that have shown promise in targeting other flaviviruses. For example, NIAID Vaccine Research Center scientists are working on a DNA-based Zika virus vaccine candidate similar to the approach employed against WNV. The WNV vaccine candidate was safe and induced a robust immune response in humans in Phase I testing. NIAID scientists also are designing a live-attenuated Zika vaccine that employs an approach similar to that used for the NIAID-developed dengue virus vaccine candidate currently in Phase III clinical trials in Brazil. NIAID, in partnership with the Walter Reed Army Institute of Research (WRAIR) and the Biomedical Advanced Research and Development Authority (BARDA), is pursuing the development of a whole particle inactivated Zika virus vaccine. In addition, NIAID grantees are in the early stages of developing a Zika virus vaccine based on a recombinant vesicular stomatitis virus (VSV) – the same animal virus used to successfully develop the NewLink Genetics/Merck rVSV investigational Ebola vaccine tested in West Africa.

NIAID plans to begin early-stage clinical testing of one or more NIAID-supported Zika vaccine candidates in fall 2016. To enhance ongoing efforts to prepare for and respond to the Zika virus domestically and internationally, the Administration has requested $1.9 billion in emergency funding. The supplemental funding will be critical to NIAID preparation and execution of Phase II/IIb trials for promising vaccine candidates. In addition to supporting Zika vaccine development from the discovery phase through preclinical and clinical testing, the emergency funding request would support basic research to understand the pathogenesis of the virus, including how it causes microcephaly; establishment of animal models to test candidate countermeasures; development of rapid, sensitive, and specific diagnostic tests; and discovery and preclinical development of new therapeutics. This research is necessary to better understand this emerging infection and uncover the best ways to diagnose, treat, and prevent Zika virus disease. NIAID remains committed to pursuing the development of safe and effective Zika virus vaccines as well as accelerating efforts to develop improved diagnostics and candidate therapeutics for Zika virus.

b) What is the status of the research for the Universal Flu vaccine, how long before it will be available to the public (if everything goes as planned), and how often a person will need one of these shots?

Dr. Fauci: NIAID's longstanding influenza research program supports basic, translational, and clinical research to develop improved influenza diagnostics, therapeutics, and vaccines. As part of this effort, NIAID is investing in research to develop "universal" influenza vaccine candidates capable of providing broad and long-lasting protection against a wide range of distinct influenza strains over multiple years. A universal influenza vaccine could be an important tool for improving U.S. and global public health by reducing or eliminating the need for yearly seasonal influenza vaccination.

NIAID is pursuing multiple strategies to develop a universal influenza vaccine. One strategy is to identify parts of the influenza virus that are similar across multiple strains and to maximize the immune system's response to them. Current seasonal influenza vaccines work by stimulating the production of antibodies that target the head region of the influenza surface protein hemagglutinin (HA). The head region of the HA protein differs among influenza strains, and this is part of the reason why the seasonal influenza vaccine changes from year to year depending on the type of HA on the circulating influenza strains. However, the stem region of the HA protein tends to be similar from strain to strain, making it a more stable target for universal influenza vaccine development.

NIAID researchers recently developed two universal influenza vaccine candidates that have demonstrated proof-of-concept that a universal influenza vaccine can offer broad protection against multiple influenza strains. NIAID Vaccine Research Center scientists developed a nanoparticle vaccine displaying the HA stem. Using the HA stem from the H1N1 influenza strain, this vaccine candidate generated an immune response to a variety of influenza strains when tested in two different animal models. NIAID investigators using another approach created a vaccine cocktail with multiple virus-like particles (VLP) having different HA subtypes. The vaccine cocktail provided protection against a wide array of influenza viruses in mice, suggesting that VLP vaccine cocktails could be used to develop human universal influenza vaccines. These NIAID-developed vaccine candidates will be investigated for further development and clinical testing. Other approaches supported by NIAID include HA stem-only candidates and hybrid HAs which contain regions that are conserved among different influenza strains.

The commercialization of a safe and effective universal influenza vaccine is dependent on several factors, including outcomes of future clinical testing and engagement of industrial partners. For these reasons, it is difficult to predict when universal influenza vaccines could be made publicly available. In order to determine how often universal influenza vaccinations would be needed, promising candidates will need to be evaluated over several influenza seasons to determine the extent and durability of their protection. Though it is not possible to predict when universal influenza vaccines would be publicly available, NIAID-led efforts continue to make encouraging progress toward this goal.

Cole 7
Precision Medicine

Chairman Cole: We provided $200 million in FY 2016 to support the Precision Medicine Initiative (PMI). The budget requests another $100 million for PMI in mandatory funds.

a) Please describe your how long it will take to for the PMI to become fully up and running?
b) How far away, in terms of years, are we from this becoming routine for the majority of patients and treatments?
c) What is the impact if the additional mandatory funds are not provided

Dr. Collins: The PMI Cohort Program received $130 million of the $200 million in FY2016 to support the PMI research programs at the NIH. The Cohort Program will be implemented in phases. The NIH will begin enrolling participants and collecting data in calendar year 2016. We project that approximately 79,000 volunteers will be enrolled by the end of 2016. Data collections begun in 2016 will include participant provided information; limited, structured electronic health record (EHR) data; physical evaluations; biospecimens; and digital data. The data collected will evolve over time, and the collection for each individual will be progressive. We project that the Cohort will reach 1 million volunteers by the end of 2019, and the full potential of the rich data sets being collected longitudinally will be realized.

A precise delineation of the molecular, environmental, behavioral, and other factors that contribute to health and disease will lead to more accurate diagnoses, more rational disease prevention strategies, better treatment selection, and the development of novel therapies. Coincident with advancing the science of medicine is a changing culture of medical practice and medical research that engages individuals as partners – not just as patients or research subjects.

The combination of a highly engaged population and rich biological, health, and environmental data will usher in a new and more effective era of American healthcare. We have already witnessed early successes of precision medicine. These include, for example, the development of targeted treatments for cancer and cystic fibrosis that are effective in patients who share an underlying causal genotype. Precision medicine is also yielding a wealth of potential information to help ensure that each patient is given the right drug at the right dose the first time. For example, there are clear examples of therapies where individual genetic profiling can be used to avoid drugs likely to cause serious adverse effects and progress is being made in understanding how to optimize therapies based on how different polymorphisms predict therapeutic response. With individual genome sequencing, patients with previously undiagnosed genetic diseases are being successfully diagnosed. In addition, new subtypes of disease are increasingly being defined through molecular profiling of affected tissues, an advance that is expected to lead to more focused design and testing of both therapeutic and preventative strategies – for example, treatments for specific subtypes of a disease, or behavioral interventions tailored to specific subgroups of the population. The PMI Cohort Program will propel the discoveries that will enable a deepening and widening of precision medicine preventive care and treatments over time.

If the $100 million in additional funds are not provided for the PMI Cohort Program (i.e., if the program has a flat budget), the Cohort will need to slow enrollment, reducing our ability to collect data (including physical evaluations and biospecimens). Thus, the impact on the program and its ability to reach its full potential would be substantial.

Cole 8
Native American Health

Chairman Cole: Please provide an update on what the NIH is doing specifically to address Native American health.

Dr. Collins: NIH has taken several major steps in building the necessary infrastructure to obtain relevant input from and for enhancing the coordination and support of activities that address American Indian/Alaska Native (AI/AN) health. In 2015, NIH established its Tribal Consultation Advisory Committee (TCAC). The TCAC serves as an advisory committee to NIH and the NIH Director. The inaugural meeting, held on September 29-30, 2015, included an orientation to NIH, presentations on selected NIH programs, the NIH health disparities strategic plan, and NIH policies, as well as discussions about ethical research, partnerships with Tribal Epidemiology Centers, and an open dialogue with the NIH Principal Deputy Director. Representatives from many NIH ICs attended the TCAC meeting and had the opportunity to meet and talk to TCAC members. A lunch session with NIH AI/AN Scholars also provided an opportunity for a rich discussion about scientific training for American Indians and Alaska Natives and workforce diversity. The second meeting of the TCAC was held on February 25-26, 2016. Topics discussed included NIH policies, presentations on a selection of NIH programs, including an update from a workshop on Tribal Ecological Knowledge; grant review issues; Institutional Review Board training; how tribes can build research capacity with NIH resources; and updates from the NIH Director and Principal Deputy Director.

NIH held a Tribal Consultation session at the National Indian Health Board meeting in Washington, D.C., on September 21, 2015. The consultation included an overview of NIH and presentations by NIH staff on specific programs that work with and support AI/AN communities. NIH received questions and comments regarding research supported by NIH in AI/AN communities and the training opportunities NIH provides to AI/AN individuals.

In the fall of 2015, the Tribal Health Research Office (THRO) was created in the NIH Office of the Director. The new office is located in the Division of Program Coordination, Planning, and Strategic Initiatives which is the home for other offices that address trans-NIH research and related issues. Functions of the THRO include coordinating tribal health research-related activities across NIH; serving as a liaison to and NIH representative on tribal health related committees and working groups; coordinating and supporting the NIH Tribal Consultation Advisory Committee; collaborating with NIH Institutes and Centers (ICs) on the development of reports on tribal health topics; managing information dissemination related to tribal health research coordination; convening trans-NIH committees, workshops, meetings and other activities related to tribal health research and scientific priorities; coordinating with NIH ICs to leverage resources or develop initiatives to support tribal health research; and convening at least yearly Tribal Consultation sessions. A director for the office will be recruited and hired in 2016. Creation of the THRO is an essential building block in strengthening NIH's relations with tribal governments. Establishment of the THRO and hiring a Director of that office responds to a request from the TCAC for NIH to designate a single point of contact when AI/AN populations need assistance from the NIH. The TCAC provides a standing mechanism for the NIH to obtain feedback and for the agency to share information relevant to AI/AN populations.

NIH supports a wide range of research activities that address American Indian and Alaska Native health. For example, the Strong Heart Study (SHS) is the largest epidemiologic study on cardiovascular disease ever undertaken in Northern Plains American Indians.[8] Investigators found that cardiovascular disease rates in the AI population were almost twice as high as the rest of the U.S. population and that diabetes is a key factor for developing heart disease among American Indians. Another project, the Healing of the Canoe, enabled investigators working with two Pacific Northwest tribes to develop a culturally-grounded social skills intervention to promote well-being and prevent substance abuse among Native youth.[9] Investigators found that delivering the intervention as a community workshop or high school-based curriculum increased cultural identity, cultural practices, hope, and self-efficacy, as well as decreased substance use. Another project supports the career and research development of AI/AN scholars dedicated to pursuing substance abuse and addiction research within AI/AN communities. These mentoring programs are designed to improve AI/AN health and eliminate substance abuse-related health disparities by developing transdisciplinary research training and mentorship and cultivating novel partnerships with AI/AN communities and tribal colleges. In December 2015, NIH hosted a workshop on the value of Tribal Ecological Knowledge (TEK), organized by representatives of seven tribal communities, NIH, the Indian Health Service, the Smithsonian, and the Centers for Disease Control and Prevention.[10] Topics at the workshop included trust and ethics in academic-tribal research and methods for incorporating community-acquired data and local TEK into research studies.

NIH is also actively seeking to create new grant' opportunities to support AI/AN health. Significant recent funding opportunities include the Interventions for Health Promotion and Disease Prevention in Native American Populations, which seeks applications to develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in American Indian populations; and the Collaborative Hubs to Reduce the Burden of Suicide among American Indian and Alaska Native Youth, which seeks applications to conduct research focused on reducing the burden of suicide and promoting resilience among American Indian and Alaska Native youth.[11,12] This program aims to establish three collaborative research hubs in FY 2017 to increase the reach and research base for effective, culturally relevant, preventive interventions that will increase resilience and reduce suicide in tribal or urban Indian communities.

NIH sponsors websites focused on AI/AN health topics. For example, the American Indian Health website is an information portal to issues affecting the health and well-being of American Indians. It brings together health and medical resources pertinent to the American Indian population including policies, consumer health information, and research.[13] The Arctic Health website serves as a central source for information on diverse aspects of the Arctic environment and health of northern peoples. The site provides access to evaluated health information from hundreds of local, state, national, and international agencies, as well as from professional societies and universities.[14]

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[8] http://strongheart.ouhsc.edu/
[9] http://healingofthecanoe.org
[10] http://www.niehs.nih.gov/about/events/pastmtg/2015/tek_workshop/index.cfm
[11] http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-350.html
[12] http://grants.nih.gov/grants/guide/pa-files/PAR-14-260.html
[13] https://americanindianhealth.nlm.nih.gov/
[14] http://arctichealth.nlm.nih.gov/

NIH also supports a variety of outreach and training projects in AI/AN communities to enhance health literacy, ensure access to health information, create health information workstations in Native communities, enable capacity-building for health resources in tribal college libraries, and promote community-based projects around health awareness. The overall goal of such programs is to enhance the health information available to tribal members and families, to contribute to healthy lifestyles and dietary practices, and thereby to help strengthen the health promotion and disease prevention programs of the tribal communities. The NIH Research Portfolio Online Reporting Tools (RePORT) provides detailed, public access to information about NIH's AI/AN projects.[15]

[15] https://report.nih.gov/categorical_spending.aspx

Cole 9
Precision Medicine Initiative

Chairman Cole: We are pleased the NIH is considering novel approaches to recruiting and retaining people in the Precision Medicine Initiative (PMI), including the use of social media to attract volunteers. However, some scientists have expressed concern that using social media in this capacity will affect how representative PMI volunteers will be of the general population.

a) How will you understand the inherent biases this approach presents, particularly given the fact many people do not use social media at all?
b) Is the NIH working with NCHS or other federal partners that fund or conduct large, representative surveys to understand the biases in the PMI million person cohort?
c) How is NIH sponsoring research on the general question of how to use social media for research purposes?
d) What is the annual level spent across NIH since FY 2006, each year, for personalized or precision medicine? Plus, the FY 2016 and FY 2017 estimate level for this category of research.
e) Specifically related to the $130 million provided in FY 2016 for PMI to the Common Fund:
    i. What will the funds support;
    ii. What is the estimated length of this entire project;
    iii. What is the five year estimated projection costs, with annual breakouts;
f) As NIH has been shaping the PMI effort for the U.S., have you considered what projects other countries are working on to further personalized medicine and whether they are complimentary or competitive? There are for example press reports of a $10B program being developed in China.
g) At the White House PMI Summit event in February all of the patients presenting precision medicine success stories attributed those successes to genome sequencing. To date there has been no announced plans for collecting sequencing data from PMI participants. Why is this given the criticality of that class of data?

Dr. Collins: The PMI Cohort Program will use a variety of methods to attract volunteers. Social media is but one of the outreach methods that will be used to attract participants, and the enrollments of the Cohort will be carefully monitored to ensure that our outreach approach is reaching a broad range of U.S. participants. NIH supports research on how to use social media for research purposes through funding opportunity announcements, like two recent companion RFAs on Using Social Media to Understand and Address Substance Use and Addiction (RFA-CA-14-008 and RFA-CA-14-009), which support 11 awards across three NIH Institutes for $11 million (over three years) to explore the use of social media to advance the scientific understanding, prevention, and treatment of substance use and addiction. NIH also sponsored the NIH Digital Health Summit 2015: Optimizing Digital to Reach Patients, Scientists, Clinicians, and the Public which was designed to encourage discussion and to strengthen scientific communications communities around the digital and social media strategies used in health and science agencies.

The PMI Cohort will not attempt to be a representative sample of the United States. Rather, the PMI Cohort will build a very large and very diverse cohort of participants from across the United

States. This will allow the PMI Cohort to establish generalizability using a different approach: by having a diverse sample, it will have many subsamples that are composed of members of specific subgroups. By having a large sample, those subsamples will be large enough to develop estimates of effect and association for many of those subgroups. That will allow researchers to judge how similar those estimates of effect and association are across a variety of subgroups within the PMI Cohort, and so, to establish the generalizability of their findings. The development of this approach included extensive consultation and input from expert advisors through the ACD PMI Working Group process.

NIH funded a portfolio of personalized or precision medicine (PM) research activities, from more than $375 million in FY 2007 to over $700 million in FY 2015. The PMI Cohort builds upon this on-going research portfolio and will provide a large-scale platform for the development of new medical treatment and prevention strategies that take individual variability into account. The NIH expects that its trans-NIH PM research portfolio for FY 2016 and FY 2017 will continue to grow given the increasing importance of the field of precision and personalized medicine across the agency, as well as with the addition $123 million in FY 2016 and $220 million in FY 2017 from the PMI Cohort Program-funded grants and contracts dedicated to build this research resource and its associated research.

To begin implementation of the PMI Cohort Program, NIH issued six funding opportunities for the building blocks of the program: a direct volunteer pilot, an engagement pilot, a coordinating center, partnerships with healthcare provider organizations, a participant technologies center, and a biobank. In addition to supporting these major funding opportunities to build this key research resource, NIH will support targeted implementation projects to support specific Cohort functionalities. Finally, NIH is standing up a major Office and hiring leaders with significant expertise. The project is estimated to last 10 years or more. While NIH anticipates that $130 million will allow us to begin building the cohort, the initial estimates of the cost for the full implementation, data collection, and maintenance indicate these activities could cost $230 million in FY 2017, $330 million in FY 2018, and $430 million in FY 2019 after which we anticipate cohort funding will plateau. Future funding levels will be subject to the competing priorities of the annual budget process.

NIH continues to interact with industry, nonprofits, and academia with other efforts and cohorts, including Google's Baseline Study, patient groups, NIH's own funded cohorts, Department of Veterans Affairs efforts like the Million Veteran Program, as well as the growing number of international research precision medicine-oriented cohorts. NIH's ongoing interaction with these important potential partners will allow opportunities for appropriate, mutually beneficial coordination to emerge as the PMI Cohort Program develops.

NIH has consistently identified the collection of biospecimens for laboratory and genomic analyses as a critical component of the research cohort. The award to establish a biobank to receive such specimens will be issued this summer. Once the biobank is established, then the PMI Cohort Program may begin specimen collections, processing, and storage to be conducted over the next 4 years, during which time the timing and platform for genomic analyses will be identified and implemented.

Cole 10
National Children's Study Alternative

Chairman Cole: The revised NCS-A includes a component called ECHO.

a) Please describe how is proposing to use existing cohorts – perhaps augmented with some new data collections – as a key part of understanding child health.
b) Please describe how the cohorts will be large, representative samples of children, which ensure that different groups are included, such as children in low- income families or minority groups.
c) What measures does NIH plan to include measures that are specifically designed to compare the study cohorts to known national samples? For example, are you working with National Center for Health Statistics (NCHS) to ensure that the ECHO cohorts include measures that would allow you to compare subjects to studies such as the National Health and Nutrition Examination Survey (NHANES)?

Dr. Collins:

a) The Environmental influences on Child Health Outcomes (ECHO) program will leverage existing resources to investigate the longitudinal impact of early childhood environmental exposures (e.g., physical, chemical, biological, social, behavioral, natural and built environments) on pediatric development and health outcomes with high public health impact. There will be two phases to the ECHO program – the first will focus on harmonizing existing data and performing retrospective analyses, while the second will focus on collecting new (prospective) data using standardized methods that will allow researchers to combine data from across all the cohorts. By integrating the information gathered from these existing cohorts of study participants, ECHO will create a new, larger cohort that will greatly increase scientists' ability to answer critical public health questions. The ECHO program will also allow researchers to test new tools for environmental and pediatric monitoring, maximize the use of existing resources such as biological tissues collected during pregnancy and delivery, leverage available data sets by funding additional analyses, and develop statistical models to predict disease development.

b) NIH recognizes the importance of robust recruitment plans that can address racial and ethnic minority health issues reflective of the needs of the U.S. population. One specific component of ECHO – the IDeA States Pediatric Clinical Trials Network (ISPCTN) – will leverage the infrastructure at existing IDeA State centers by embedding clinical trials experts at IDeA State locations, facilitating their partnership with other academic institutions.[16] This national pediatric research network may also help address access gaps for rural and medically underserved children. When making awards across the ECHO program as a whole, NIH will strive for a balance between a robust characterization of environmental factors, including consideration of geographic diversity, and health-related endpoints. Additionally, the ECHO program aims to utilize both large studies to build a repository on the trajectory of healthy development over childhood (health controls), and small, selective studies to address interesting targeted questions that are specific to a disease or have a high-risk population. The goal is to support a combined cohort size of approximately 50,000 children.

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[16] https://www.nigms.nih.gov/Research/CRCB/IDeA

c) A major feature of the ECHO program is the sharing and harmonization of data across all of the cohorts. Standardized core data elements will be addressed across all studies: demographics; typical early health and development; genetic influences on early childhood health and development; environmental factors; and Patient/Person (parent and child) Reported Outcomes (PROs). During the planning phase, the ECHO Steering Committee, which will be composed of the principal investigators of the ECHO projects, cores and centers, the ECHO ISPCTN, and the NIH ECHO Program Director and staff, and the External Scientific Board, composed of external experts, will develop and provide valuable input on standardizing the collection of the core elements. They will be strongly encouraged to consider how these data could be compared to known national samples. Additionally, the Children's Health Exposure Analysis Resource (CHEAR) is a network of laboratory hubs that provides researchers access to comprehensive laboratory and data analysis services to measure environmental exposures.[17] CHEAR is expected to become operational in the summer of 2016, and will have the capability of measuring the majority of targeted analytes CDC measures for NHANES, as well as others. The ECHO program is leveraging this existing resource to analyze personal environmental exposures from existing and prospective ECHO sample collections. Therefore, researchers should be able to compare much of the data generated from ECHO with that of other large studies.

[17] http://www.niehs.gov/research/supported/exposure/chear

Cole 11
National Nutrition Policy Research

Chairman Cole: Since the mid-1950s, the National Institutes of Health have invested billions of dollars in investigating the questions of whether dietary fats, of some type or amount, cause nutrition-related diseases, such as heart disease, cancer, obesity and diabetes. This effort has results in multiple rigorous clinical trials, on tens of thousands of subjects, as well as many observational studies. However, the majority of these studies appear not to have been considered by successive expert committees in the formulation of national nutrition policy, the U.S. Dietary Guidelines for Americans. Please provide an estimate of the total NIH has spent on studies related to nutrition and dietary patterns that have not been included in the Nutrition Evidence Library.

Dr. Collins: NIH is committed to supporting the highest quality nutrition science to inform the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) in its development of the Dietary Guidelines for Americans every five years, including support for some of the studies summarized in the USDA's Nutrition Evidence Library.

As indicated in the methodology section of the Scientific Report of the 2015 Dietary Guidelines Advisory Committee, which was used to inform the 2015 Dietary Guidelines for Americans, the Nutrition Evidence Library was only one of several sources of evidence used by the Dietary Guidelines Advisory Committee. The majority of the science-based questions considered by the Committee were addressed using sources other than the Nutrition Evidence Library, including existing systematic reviews, meta-analyses, reports, and analyses of data and food pattern modeling.[18] The Committee also considered information submitted during a public comment period and in a public meeting in 2015. Notably, the introduction to the 2015 Dietary Guidelines for Americans states that these recommendations are aimed at helping individuals improve and maintain overall health, including reducing risk of chronic disease with a focus on disease prevention.[19] As such, the report notes that its focus does not include treatments for any given disease.

Nutrition research supported by NIH is a trans-agency effort, involving many NIH Institutes, Centers, and Offices, and is coordinated by the National Institute of Diabetes and Digestive and Kidney Diseases Office of Nutrition Research through efforts such as the Nutrition Coordinating Committee. NIH staff involved in overseeing nutrition research efforts also contributed their expertise to assist with the development and review of the 2015-2020 Dietary Guidelines for Americans.

Since 2008, available data for NIH nutrition research have been captured each year by the agency's Research, Condition, and Disease Categorization database. In recent fiscal years (FYs 2012 through 2015), NIH-funded nutrition research has averaged approximately $1.6 billion annually.[20] This funding supports a range of studies, including the types of clinical studies that

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[18] See section entitled "Approaches to Reviewing the Evidence" at: http://health.gov/dietaryguidelines/2015-scientific-report/05-methodology.asp
[19] http://health.gov/dietaryguidelines/2015/guidelines/introduction/dietary-guidelines-for-americans/
[20] https://report.nih.gov/categorical_spending.aspx

inform the USDA's Nutrition Evidence Library reviews, in addition to basic/preclinical and clinical research focused on treatments and nutrition-related issues in various diseases. The latter types of NIH studies may not have been included in the Nutrition Evidence Library or in other forms of evidence considered by the Committee, given the focus of the Dietary Guidelines for Americans on promoting human health and preventing disease, rather than treatment.

Cole 12
Laboratory Challenges

Chairman Cole: NIH notified the committee last year of significant laboratory issues that appeared to stem from lack of management oversight related to training, procedures, internal evaluations, and construction/facility planning. The issues ranged from the internal compounding pharmacy to other pharmacy operations all within the NIH Clinical Center. Please provide an update on the status of the corrective action plan for each finding. Specifically, what changes the Clinical Center Director has made to improve management oversight of clinical operations to ensure training, procedures, and oversight has improved for all laboratory and clinical operations. Please describe any root-cause analysis the Clinical Center Director has planned or has used to ensure the same lack of attention to detail does not occur in other clinical center functions. Please provide a summary of the annual cost of the impact of the laboratory issues in FY 2016, FY 2017, and beyond due to construction, training, enhanced oversight, and other related activities.

Dr. Collins: Learning of the serious deficiencies in the Pharmaceutical Development Section (PDS) and Intravenous Admixture Unit (IVAU) last May was deeply disturbing, and the NIH Director immediately established an internal Task Force to manage the response and to investigate the root cause. Through these investigations, it became clear that NIH needed a broader review of clinical research operations by outside experts in hospital management and administration, patient safety, and clinical laboratory quality and safety regulations. In December, NIH's Director established a working group of the Advisory Committee to the Director (ACD) to evaluate and make recommendations on the organization, financing, and management of clinical operations at NIH. On April 21, 2016, NIH's Director accepted a set of strong recommendations based on the working group's findings that aim to improve the Clinical Center by fortifying a culture and practice of safety and quality; strengthening leadership for clinical care quality, oversight and compliance; and addressing sterile processing to ensure quality controls are at the highest standards. NIH is taking the following immediate actions in response to the ACD recommendations:

- Establishing a hospital board and appointing Laura Forese, M.D., as chairperson. Dr. Forese, who was a member of the working group, and is executive vice president and chief operating officer at NewYork-Presbyterian. The board's charge will include inpatient and outpatient clinical operations, and it will advise on management, leadership requirements, and policies that promote quality and safety.
- Establishing a Clinical Practice Committee of senior clinical and laboratory experts, with a charge to carry out continuous surveillance of all clinical activities at NIH and suggest strategies for improvement.
- Announcing the selection of Kathryn Zoon, Ph.D., as interim director of the newly established NIH Office of Research Support and Compliance to improve the agency's ability to maintain the highest levels of compliance with research regulations and standards. This office will be instrumental in coordinating compliance and regulatory activities across the NIH Institutes and Centers (ICs) and ensuring that high standards are met universally.

- Making changes to performance plans for clinical staff by adding patient safety elements that are consistent across all NIH ICs. This will enhance accountability and ensure that staff are meeting uniform hospital standards for patient care.
- Retaining consultants from Working Buildings and Clinical IQ who specialize in quality assurance for manufacturing and compounding to conduct assessments of all facilities that produce sterile or infused products for administration to research participations at NIH. This work is already well underway.
- In addition to these immediate actions, NIH will implement other recommendations provided by the ACD over the course of this year. These changes and improvements will help ensure that the Clinical Center will reinforce its commitment to patient safety and compassionate care, while continuing its record of outstanding scientific advances.

Clinical Center staff have been diligently working on an ongoing basis to remediate the serious deficiencies identified in the IVAU and PDS last May. NIH will obtain sterile products previously made at the PDS from commercial sources and carefully vetted outsourcing facilities. To date, almost all high priority requests for former PDS products have been fulfilled through alternative sources. Non-sterile operations have continued on a limited basis, based on the degree of risk to staff working with bioactive materials.

Having a fully functioning, fully compliant IVAU is essential for ongoing Clinical Center operations, and reaching full compliance is a very high priority. A significant amount of progress has been made in the past six months toward addressing deficiencies.

In addition, Working Buildings and Clinical IQ have begun a systematic review of facilities that have been or will be involved in processing sterile products for administration to research participants and patients. The first phase of that review is complete and a number of the facilities were noted to be exemplary. Three facilities were found to have serious problems, and sterile processing and product administration was immediately suspended; the directors of these facilities are working with the consultants and the Interim Director of Office of Research Support and Compliance to remediate the problems or find alternatives so that enrollment of new participants can resume quickly.

NIH is committed to ensuring that all clinical operations exceed regulatory requirements and are regularly maintained at the highest standards. This will require ongoing monitoring and metrics. As noted above, some facilities will require remediation, and it may be possible to consolidate some of the current facilities; any new facilities must meet regulatory standards from their inception – this will all be facilitated by the new Office of Research Support and Compliance. Additionally, NIH will implement enhanced prioritization strategies to ensure that facilities are not operating beyond their capacity. The timelines and full costs of implementing the ACD report recommendations and ensuring that all of the NIH clinical operations are maintained at the highest standards are still being determined.

Cole 13
Funding Restrictions

Chairman Cole: For each funding restriction included in the FY 2016 Omnibus, please provide an explanation on how they are implemented, validated, enforced, and monitored to prevent violations by intramural and extramural actors.

Dr. Collins: NIH has a long-standing and well-established system for working with funding recipients to ensure compliance with a host of laws, regulations, and policies, as summarized in the NIH Grants Policy Statement.[21] NIH informs the research community about any changes (or reiterates standing policy) in a number of ways, including notices published in the NIH Guide to Grants and Contracts (the official publication for NIH grant policies, guidelines, and funding opportunities), policy included in the NIH Grants Policy Statement, a term and condition of all NIH grant awards, and outreach initiatives that target grantees. In response to provisions in the FY 2016 Consolidated Appropriations Act (Public Law 11-113), NIH released NOT-OD-16-044.[22] This Guide Notice informed the community of the following FY 2016 Legislative Mandates:

(1) Salary Limitation (Section 202)
(2) Gun Control (Section 210)
(3) Anti-Lobbying (Section 503)
(4) Acknowledgment of Federal Funding (Section 505)
(5) Restriction on Abortions (Section 506)
(6) Exceptions to Restriction on Abortions (Section 507)
(7) Ban on Funding Human Embryo Research (Section 508)
(8) Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
(9) Dissemination of False or Misleading Information (Section (515(b))
(10) Restriction on Distribution of Sterile Needles (Section 520)
(11) Restriction of Pornography on Computer Networks (Section 521)

Additional details regarding these provisions were included in the Guide Notice. These funding restrictions or legislative mandates are specifically applicable to extramural researchers and not NIH's intramural scientists. These legislative requirements are incorporated into the terms and conditions of all NIH grant awards.

When submitting a funding application for research, the applicant organization certifies that it will comply with all applicable assurances and certifications referenced in the application. Once a grant award is made, the recipient is responsible for ensuring that it complies with applicable Federal laws and regulations, its application, and the terms and conditions of grant awards. NIH also requires recipients to re-certify when additional funding is awarded that they are in compliance with all applicable requirements.

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[21] http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
[22] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-044.html

Recipient noncompliance with terms and conditions of NIH grant awards may cause NIH to take one or more actions including the imposition of special award conditions, corrective actions, or enforcement actions, which include disallowing costs, withholding future awards, wholly or partly suspending the grant, termination of the grant, or Federal-wide debarment or suspension.

Recipients are subject to audits to examine adherence to compliance requirements and internal controls, among other things. Organizations that spend $750,000 or more in Federal awards during their fiscal year are generally required to undergo an annual audit in compliance with the Single Audit Act and 2 CFR Part 200, subpart F, implemented by HHS at 45 CFR Part 75 subpart F. Also, NIH retains the authority and discretion to conduct, or arrange for the conduct of, other audits and/or evaluations of NIH awards.

Investigators within NIH's intramural research program (the NIH's internal research program) are held to the same standard as other NIH-funded investigators in terms of adhering to applicable legal requirements and NIH policies. In addition to these restrictions, NIH scientists paid with intramural funds may not receive salary support or any other funds from NIH extramural grants, either as principal investigators, other key staff, or as consultants. The NIH Deputy Director for Intramural Research, in concert with the Scientific Directors of each NIH Institute or Center (IC), provides guidance and oversight of intramural principal investigators to ensure that all laws and requirements are observed. The Scientific Director of each NIH IC also certifies compliance of all investigators on an annual basis.

Cole 14
NIH Initiatives

Chairman Cole: Please update the table that lists all the NIH annual initiatives begun or underway over the past 10 years that are expected to continue through FY 2017 that was provided in last year's questions for the record. It should include new initiatives identified for FY 2017.

Further, please describe the process and criteria NIH uses to select each new initiative as compared to on-going research and how each initiative is linked to the NIH-wide strategic plan.

Dr. Collins: Below is a table that shows annual funding levels for NIH initiatives (new initiative in bold). In some cases growth in the out years is expected, but all future funding levels will be subject to the competing priorities of the annual budget process. Recommendations for the BRAIN Initiative from the Working Group Report to the Advisory Committee to the Director (ACD), NIH can be found at http://www.braininitiative.nih.gov/2025/BRAIN2025.pdf; an excerpt from page 122 regarding long-term funding is shown after the table below. There are ACD Working Group reports on the Diversity Initiative at http://acd.od.nih.gov/Diversity in the Biomedical Research Workforce Report.pdf, and on the Big Data Initiative (including BD2K) at http://acd.od.nih.gov/Data and Informatics Working Group Report.pdf, although those reports did not specify a long-term funding stream.

The process and criteria NIH uses to select each new initiative varies. Some have been generated within NIH or the Administration, while others have started in the research community. Initiatives reflect the goals of the NIH-Wide Strategic Plan (https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf) and many are featured in the Plan as examples of significant NIH priorities (*e.g.*, BRAIN Initiative at p. 14, Big Data at p. 16, Environmental influences on Child Health Outcomes (ECHO) at p. 24, Precision Medicine Initiative at p. 25, Diversity at p. 34).

(Dollars in Millions)

Fiscal Year	2008	2009	2010	2011	2012	2013	2014	2015	2016 Est.	2017 PB
Alzheimer's Disease[1]	$412	$457	$450	$444	$503	$504	$562	$631	$991	$991
National Cancer Moonshot									**$195**	**$680**
Enhancing Diversity						$6	$39	$54	$57	$58
BUILD[2]							*$27*	*$45*	*$48*	*$48*
BRAIN							$46	$85	$150	$195
BD2K (Big Data)						$1	$33	$79	$102	$108
Precision Medicine Initiative									$200	$300
CTSA	$472	$484	$490	$483	$461	$432	$474	$472	$500	$500
Antibiotic Resistance[3]	$228	$251	$356	$366	$377	$325	$277	$310	$413	$413
HIV Vaccine	$556	$561	$535	$550	$557	$518	$533	$535	$553	$554
AMP							$20	$23	$23	$23
HRHR (Common Fund)	$96	$164	$175	$192	$209	$210	$204	$177	$161	$153
CAN					$10	$9	$10	$10	$26	$26
ECHO (NCS follow-on)								$165	$165	$165

[1]Levels from the Research, Condition, and Disease Categories (RCDC) table; 2015 and later includes Alzheimer's Disease Related Dementias.

[2]BUILD is a subset of Enhancing Diversity

[3]Levels from the Research, Condition, and Disease Categories (RCDC) table.
Table does not include ARRA funding in FY 2009-2010.

BRAIN Report from the Working Group of the Advisory Committee to the Director:
The first year of the BRAIN Initiative, FY 2014, was seeded by a new $40 million commitment from NIH; in the second year, FY 2015, NIH will contribute $100 million to new and continuing grants. The working group believes that the program presented in the preceding sections could ramp up to $400 million per year over the next five years (FYs 2016-2020), and continue at roughly $500 million per year for the last five years (FYs 2021-2025). In total this might represent around 5 percent of the budget for brain-related research at NIH. A possible trajectory of costs per fiscal year is diagrammed below.

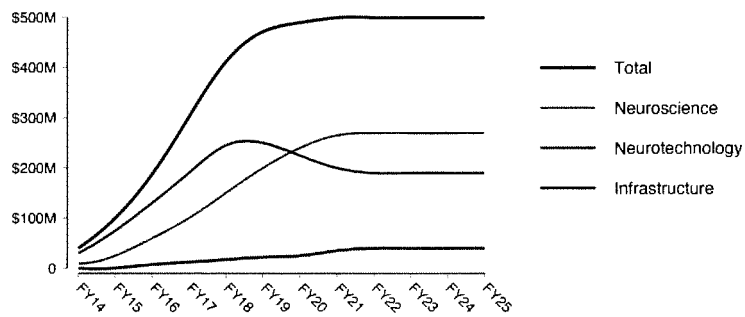

Figure caption. Proposed 12-year budget for the BRAIN Initiative. Collaborative technology development is emphasized through FY2019, while discovery-driven science receives priority beginning in FY2020. 'Infrastructure' is for facilities and capabilities that will benefit researchers across the entire nation, with emphasis on data sharing resources, training in the use of new technologies and quantitative methods, and possible regional instrumentation centers during the last half of the BRAIN Initiative.

Cole 15
Scientific Research Coordination between CDC and NIH

Chairman Cole: Please describe the systematic process that NIH leadership and Centers for Disease Control (CDC) leadership use to review and evaluate research gaps identified by CDC programs for consideration to be incorporated within the NIH funded research portfolios.

Dr. Collins. As described in the *NIH-Wide Strategic Plan, Fiscal Years 2016–2020*, NIH carefully considers a number of factors to create research portfolios that take advantage of scientific opportunities and address public health needs.[23] Research portfolios are carefully balanced and continually evaluated to ensure that NIH investments are flexible enough to pivot to new advances or emerging threats.

To ensure that the most pressing public health needs are incorporated into the priority-setting process, NIH leadership works with CDC leadership to evaluate research gaps that NIH may be able to help close. In FY 2015, NIH reported working with CDC on 398 collaborative activities.[24] Much of this coordination occurs through involvement of both agencies on federal interagency coordinating committees and working groups that bring together relevant agencies to harmonize their strategic planning and programmatic activities. Among just a few of the groups where NIH and CDC work together to ascertain research gaps where their work could be complementary are the HHS Biosafety and Biosecurity Coordinating Council, the Interagency Autism Coordinating Committee, and several working groups to coordinate activities under Healthy People 2020, the Interagency Pain Research Coordinating Committee, and the Public Health Emergency Medical Countermeasures Enterprise.[25,26,27]

One specific example of coordination is the work that NIH and CDC did together on the government-wide strategic planning initiative to develop the *National Strategy for Combating Antibiotic-resistant Bacteria (CARB)*. This plan, now in its implementation phase, includes specified and coordinated activities for different agencies, including NIH and CDC.[28] Similarly, the Interagency Pain Research Coordinating Committee (IPRCC) will soon release a National Pain Strategy, outlining the federal government's first coordinated plan for reducing the burden of chronic pain that affects millions of Americans.[29] Since the National Pain Strategy focused primarily on treatment, the IPRCC has also initiated development of a separate federal pain research strategy.

In addition to co-participation on committees and working groups, in FY 2015, NIH and CDC collaborated on more than 50 research projects. These projects addressed a range of public health issues, including HIV/AIDS, potentially harmful environmental exposures, and disease prevention. One study that involves several of the NIH Institutes and Centers (ICs) is the Environmental Determinants of Diabetes in the Young (TEDDY) study. The purpose of this

[23] http://www.nih.gov/about-nih/nih-wide-strategic-plan
[24] https://report.nih.gov/crs/
[25] https://iacc.hhs.gov/
[26] http://iprcc.nih.gov/
[27] http://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx
[28] https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf
[29] http://iprcc.nih.gov/National_Pain_Strategy/NPS_Main.htm

consortium is to organize international efforts to identify infectious agents, dietary factors, or other environmental factors that trigger type 1 diabetes in genetically susceptible individuals.

NIH and CDC leadership also work together closely when urgent public health threats arise. Recently, NIH and CDC worked together to respond to the Zika virus outbreak, with CDC determining a definitive link between Zika virus and microcephaly at birth and NIH working to develop better diagnostics as well as treatments, including a vaccine to prevent Zika virus infection.

While NIH maintains its own targeted, IC-mission-specific epidemiology portfolio, much of the public health information that NIH uses in its priority-setting process comes from partnerships with its sister agencies across HHS. NIH often co-funds specific surveillance and epidemiological efforts to generate needed data for research and program planning. NIH works closely with CDC, collaborating on a variety of projects including co-funding and sponsoring several questions on CDC's National Health Interview Survey (NHIS) and sponsoring mission-relevant components of the National Health and Nutrition Examination Survey (NHANES). These partnerships, among others, allow NIH to gather mission-relevant data that can inform priority-setting.

Moving forward, NIH and CDC leadership will continue to work together to coordinate responses to public health crises and to address myriad public health needs.

Cole 16
Valley Fever Randomized Controlled Trial (RCT)

Chairman Cole: We appreciate the continued movement on the Valley Fever RCT. Please provide an update and timeline of the RCT with specific actions to be taken in the next six months on participant enrollment, and how CDC and NIH are coordinating on the research.

Dr. Collins. The National Institute of Allergy and Infectious Diseases (NIAID), in coordination with the Centers for Disease Control and Prevention (CDC), has been working to develop and initiate a randomized controlled trial (RCT) to evaluate early treatment of the initial infection of coccidioidomycosis, or Valley Fever, in the context of community-acquired pneumonia (CAP). Valley Fever is a fungal infection caused by airborne spores of several soil-dwelling *Coccidioides* species. While most Valley Fever patients experience mild flu-like symptoms and recover, some experience severe and life-threatening infection. RCT will study patients with CAP, which may be caused by bacteria or by fungi like *Coccidioides,* to evaluate whether adding treatment with the antifungal drug fluconazole to the standard-of-care treatment for CAP with the antibacterial drug azithromycin improves patient outcomes compared to those given standard-of-care treatment alone. The primary goal of this trial is to assess the safety and effectiveness of early treatment of Valley Fever with fluconazole in patients with CAP in Valley Fever-endemic regions. In addition, RCT will likely help increase awareness of the disease in the endemic area, prompting those experiencing symptoms to seek medical care earlier in the course of the disease, and potentially enhancing early recognition of the disease by healthcare providers.

In June 2015, NIAID awarded an initial $5 million to the Duke Human Vaccine Institute through the NIAID-funded Vaccine and Treatment Evaluation Unit to conduct the RCT study. NIAID has worked closely with subject matter experts from Valley Fever-endemic regions to finalize the clinical trial protocol. RCT has been initiated and enrollment began in Arizona in March 2016. Over the next six months and beyond, it is anticipated that additional sites in Arizona and California, identified by CDC as areas where cases of Valley Fever commonly occur, will be activated and will enroll patients with CAP as they seek care at these sites. CDC, State and local health officials, and community healthcare providers will play an important role in helping to increase public awareness of the trial and encourage enrollment of eligible individuals at participating sites.

In addition to RCT activities ongoing in 2016, NIAID also is funding research to evaluate the antifungal drug Nikkomycin Z (NikZ) in a planned Phase II clinical trial in patients diagnosed with pneumonia caused by *Coccidioides*. This trial will complement the RCT examining treatment with fluconazole in patients at the earliest stages of coccidioidal pneumonia, prior to diagnosis. NIAID intramural researchers also are studying patients with disseminated coccidioidomycosis at the NIH Clinical Center. As of April 2016, 27 patients have been enrolled in this intramural study.

NIAID will continue to support Valley Fever research to increase basic understanding of the infection and develop new therapies and vaccines to prevent and treat the disease. The ongoing RCT will help provide valuable information on effective treatment strategies. Continued engagement with Federal partners and the scientific, public health, and affected communities will be essential to these efforts.

Cole 17
NIH Intramural Advance Coordination with Extramural

Chairman Cole: Please describe the specific activities over the past year NIH used to systematically consult with the extramural community on polices that impact the extramural community and to ensure parity of policies with the intramural policies for researchers.

Dr. Collins. NIH policies are coordinated and reviewed through the Office of Management Assessment, the Office of Science Policy, as well as by the Office of Extramural Research and Office of Intramural Research. This assures that policies apply in the same fashion to NIH intramural research as they apply to programs funded by extramural mechanisms. Further, intramural and extramural research programs are overseen by the National Advisory Councils and Boards who have oversight responsibility at the NIH Institute and Center level.

Cole 18
Administrative Burden Reduction Workshop

Chairman Cole: Please a summary of the activities, recommendations, number of meetings, and participates to the NIH Administrative Burden Reduction Workgroup. It should note the planned meeting and timeline to implement recommendations over the next three years. Finally, it should note how NIH and the stakeholders have agreed to measure burden reduction and a summary of the tracking systems implemented toward these measures.

Dr. Collins: NIH is committed to implementing policies and processes that reduce administrative burden for its grantees. To this end, NIH serves in a leadership capacity on Federal-wide organizations and working groups, including the Federal Demonstration Partnership (FDP) and the Research Business Models (RBM) Working Group. These groups aim to identify opportunities to reduce administrative burden and develop the appropriate trans-agency policies and processes to achieve this objective.

To fulfill the request made in the Explanatory Statement accompanying H.R. 3547, Consolidated Appropriations Act, 2014, NIH is supporting the *ad hoc* committee of the National Academy of Sciences (NAS) National Research Council that has recently convened to examine and report on *Federal Research Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century.*[30] The study was commissioned by Congress and is being jointly supported by the Department of Education and NIH. A complete list of the meeting dates and agendas can be found at the project website, along with a list of committee members.[31] The NAS committee has reviewed and identified regulations with significant impact and reporting requirements, and has recommended improved approaches that reduce administrative burden.[32] The committee provided specific recommendations on how burden that results from regulations and reporting requirements can be reduced by Federal agencies that support research at academic institutions. In addition to participating in the NAS committee, NIH and other Federal agencies will continue to work with the Federal Demonstration Partnership and to head the Research Business Models Working Group on ways to reduce administrative burden.

The NAS committee had its first meeting in February 2015 and had three additional meetings and one regional workshop to hear from various stakeholders. Although the study was originally planned for 18 months, Senator Lamar Alexander, Chair of the Senate Committee on Health, Education, Labor, and Pensions, asked the committee to deliver an expedited report by the end of summer 2015, as Congress would be considering several legislative actions involving higher education, research policy, and medical innovation. On September 22, 2015, NAS released a preliminary report titled, "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1 (2015)."[33] The committee will continue its assessment, seek additional data regarding the effects of regulations on the conduct of research, hold additional meetings, and issue the second part of the committee's report in 2016 which will

[30] https://www.gpo.gov/fdsys/pkg/CREC-2014-01-15/pdf/CREC-2014-01-15-house-bk2.pdf
[31] http://www8.nationalacademies.org/cp/projectview.aspx?key=49675
[32] http://sites.nationalacademies.org/PGA/stl/researchregs/index.htm
[33] http:// http://www.nap.edu/catalog/21803/optimizing-the-nations-investment-in-academic-research-a-new-regulatory

address outstanding items and other regulations. NAS indicates that the report is currently on track to be released in the summer of 2016. NIH will consider the recommendations of this final report when it is received, and integrate them with the ongoing activities described below.

The initial report reviews the federal regulatory framework for research institutions as it currently exists, considers specific regulations that have placed burdens on the research enterprise, and reassesses the process by which these regulations are created, reviewed, and retired. The report identifies specific actions that Congress, the White House, federal agencies, and research institutions should take to reduce regulatory burden.

Summary of Report Recommendations:

- Recommended actions for Congress include:
  - Task a single agency with developing a central database of investigator information;
  - Work with OMB to develop a uniform format for grant proposals across all research funding agencies;
  - Develop a federal-wide financial conflict of interest policy to be used by all research funding agencies.
- OMB was asked to develop a uniform format for research progress reporting and review agency research grant proposal documents to develop a uniform format.
- Recommended actions for federal agencies include:
  - limit research proposals to the minimal information necessary for peer evaluation, allowing other information to be submitted "just-in-time" or when the application is being considered for funding;
  - develop a central repository to house assurances; and
  - reduce and streamline reporting, assurances, and verifications, particularly for vertebrate animals.
- The committee recommends the creation of a Research Policy Board, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies.
- Inspectors General responsibilities should be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse, and to advising on economy, efficiency, and effectiveness. The relationship between Inspectors General and research institutions should be based on a shared commitment to advancing the nation's interest through a dynamic and productive research enterprise.

NIH is considering methods to measure burden reduction in response to the NAS report. Some of the systems that may be utilized for tracking include SciENcv and ASSIST (Application Submission System & Interface for Submission Tracking). SciENcv, which was built by NIH's National Center for Biotechnology Information (NCBI), enables researchers to easily assemble biographical information and simplify the work flow associated with federal funding. In its current version, SciENcv helps researchers assemble an NIH biographical sketch by leveraging existing information from NIH eRA Commons and PubMed. If adopted across the Federal Government SciENcv could become the central database of investigator information.

ASSIST is a web-based system for the assembly of grant applications. ASSIST facilitates the online preparation and submission of grant applications to NIH and other Public Health Service

agencies. ASSIST reduces burden by prepopulating information into application forms, facilitating on-line collaboration for preparation of the application, automating the assembly of budget tables, and allowing previewing and error checking of the application prior to submission. During the October 2015 round of grant applications, over 25 percent of the applicants voluntarily switched from using downloadable forms to ASSIST even though ASSIST had just been made available. They successfully submitted their applications on the first try over 90 percent of the time compared with only 60 percent of the time for those still using the standard downloadable forms. This improvement represents a significant reduction in researcher time and frustration spent on administrative tasks.

Cole 19
Replication of Scientific Research

Chairman Cole: Please describe the actions being taken and planned for FY 2017 to improve the replication of scientific research supported by NIH. Further, describe how progress is being monitored and measured.

Dr. Collins: NIH is committed to continuing and expanding its efforts to address rigor, reproducibility, and transparency in biomedical research. NIH recently implemented new policies to enhance reproducibility of research findings, which apply to applications submitted for the January 25, 2016 due date and beyond. These recent changes to the application instructions and review criteria for research grants and mentored career development awards focus on the scientific premise of the proposed research, rigorous experimental design, consideration of relevant biological variables, such as sex, and authentication of key biological and/or chemical resources. The first applications submitted using these revised instructions will progress to initial peer review in the summer 2016 review meetings. Staff and reviewer guidance has been prepared in anticipation of these review meetings. Applications, reviewer summary statements, progress reports, and publications will be assessed for adherence to the policy. Updates to institutional training grants, institutional career development awards, and individual fellowships are projected to be released and implemented in FY 2017.[34]

Training is a crucial component of the NIH activities. In FY 2015, NIH issued six training module awards (totaling $463,000) to various academic institutions and societies that focused on experimental design and data analysis, as well as on enhancing scientific rigor and data reproducibility. The National Institute of General Medical Sciences (NIGMS) also issued 15 pre-doctoral administrative supplement awards (totaling $1.2M) to support curricular activities focused on conducting reproducible and rigorous research. Recently, NIGMS, along with several other Institutes and Centers, reissued a funding opportunity announcement (FOA) to support the development and implementation of curricular activities aimed at: 1) providing graduate students with a strong foundation in research design and methods in areas related to conducting reproducible and rigorous research; 2) broadening training to better prepare students for research careers in a variety of venues, such as industry, government, or entrepreneurial enterprises; and 3) promoting the reworking and revitalization of biomedical pre-doctoral research education and training.[35,36,37] Additionally, multiple Institutes, Centers, and Offices within the Office of the Director recently released an FOA to address the problem of misidentified cell lines.[38] This FOA will support Small Business Innovation Research (SBIR) projects to improve existing technologies, and/or develop novel, reliable, and cost effective tools that will make it easier for researchers to confirm the identity and/or sex of the cells that they use in their work.

Finally, NIH is continuing engagement with a variety of stakeholder groups. For example, NIH leadership and staff have participated in meetings with the Center for Open Science, F1000,

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[34] http://grants.nih.gov/reproducibility
[35] http://grants.nih.gov/grants/guide/pa-files/PA-16-133.html
[36] http://grants.nih.gov/grants/guide/pa-files/PA-16-142.html
[37] http://grants.nih.gov/grants/guide/pa-files/PA-16-060.html
[38] http://grants.nih.gov/grants/guide/pa-files/PA-16-186.html

numerous journal editors and professional societies, and the trade organization PhRMA to gain feedback from the extramural community and identify opportunities for partnerships.

Cole 20
Office of Directors Cost Breakout

Chairman Cole: Please update with FY 2015 actuals, FY 2016 and FY 2017 estimates the table for each NIH IC Director's Office and the NIH Director's office for the total funding breakout on the cost of travel, personnel, performance bonus for each such office.

Dr. Collins.

IC Director's Office Cost Summary
FY 2015
(Dollars in Thousands)

FY 2015	Personnel Compensation & Benefits	Cash Awards & Performance Bonus (Non-add)	Travel & Transportation of Persons	All Other	Total
NCI	$1,856	$25	$64	$2,174	$4,094
NHLBI	$2,118	$308	$29	$21	$2,168
NIDCR	$965	$5	$23	$271	$1,259
NIDDK	$1,573	$56	$78	$745	$2,396
NINDS	$722	$27	$48	$61	$832
NIAID	$2,677	$60	$50	$126	$2,853
NIGMS	$911	$31	$13	$135	$1,058
NICHD	$1,754	$41	$35	$234	$2,024
NEI	$1,191	$25	$115	$516	$1,822
NIEHS	$917	$16	$59	$75	$1,050
NIA	$1,403	$35	$15	$12	$1,431
NIAMS	$1,151	$51	$28	$150	$1,329
NIDCD	$859	$28	$3	$30	$892
NIMH	$1,046	$31	$35	$50	$1,131
NIDA	$1,207	$30	$122	$275	$1,605
NIAAA	$2,598	$42	$199	$149	$2,946
NINR	$792	$6	$13	$67	$872
NHGRI	$908	$24	$68	$274	$1,251
NIBIB	$463	$19	$79	$458	$1,000
NIMHD	$1,052	$52	$18	$433	$1,503
NCCIH	$1,009	$32	$16	$166	$1,190
NCATS	$1,597	$38	$73	$251	$1,921
FIC	$1,402	$15	$106	$201	$1,709
NLM	$1,307	$32	$95	$557	$1,959
CSR	$959	$17	$30	$131	$1,120
CIT	$249	$11	---	$741	$990
CC	$1,743	$36	$95	$1,766	$3,604
OD	$1,805	$55	$67	$295	$2,166
NIH Total	**$36,234**	**$1,148**	**$1,576**	**$10,366**	**$48,176**

IC Director's Office Cost Summary
FY 2016

(Dollars in Thousands)

FY 2016	Personnel Compensation & Benefits	Cash Awards & Performance Bonus (Non-add)	Travel & Transportation of Persons	All Other	Total
NCI	$1,424	$25	$65	$2,200	$3,689
NHLBI	$3,082	$339	$60	$28	$3,170
NIDCR	$960	$16	$24	$278	$1,263
NIDDK	$1,931	$58	$80	$599	$2,610
NINDS	$788	$28	$49	$62	$899
NIAID	$2,815	$65	$75	$130	$3,020
NIGMS	$938	$27	$16	$136	$1,090
NICHD	$1,726	$27	$50	$200	$1,976
NEI	$1,290	$29	$114	$590	$1,994
NIEHS	$934	$17	$60	$77	$1,071
NIA	$1,417	$35	$31	$12	$1,461
NIAMS	$1,179	$55	$30	$90	$1,299
NIDCD	$961	$28	$4	$30	$995
NIMH	$1,062	$31	$35	$51	$1,148
NIDA	$1,464	$38	$125	$275	$1,864
NIAAA	$2,624	$44	$200	$152	$2,976
NINR	$802	$6	$13	$80	$895
NHGRI	$1,070	$24	$70	$332	$1,471
NIBIB	$870	$35	$90	$465	$1,425
NIMHD	$1,353	$10	$18	$442	$1,813
NCCIH	$1,095	$36	$16	$170	$1,280
NCATS	$2,007	$38	$78	$290	$2,375
FIC	$1,519	$15	$107	$62	$1,688
NLM	$1,407	$33	$120	$565	$2,092
CSR	$1,006	$18	$33	$133	$1,173
CIT	$251	$11	$17	$724	$992
CC	$1,761	$36	$97	$1,800	$3,657
OD	$1,883	$43	$87	$268	$2,238
NIH Total	**$39,618**	**$1,167**	**$1,764**	**$10,240**	**$51,622**

IC Director's Office Cost Summary
FY 2017

(Dollars in Thousands)

FY 2017	Personnel Compensation & Benefits	Cash Awards & Performance Bonus (Non-add)	Travel & Transportation of Persons	All Other	Total
NCI	$1,781	$27	$66	$2,222	$4,068
NHLBI	$3,196	$339	$50	$28	$3,273
NIDCR	$1,251	$17	$25	$316	$1,592
NIDDK	$1,777	$58	$82	$606	$2,465
NINDS	$812	$29	$49	$63	$925
NIAID	$2,849	$66	$75	$133	$3,057
NIGMS	$938	$27	$16	$136	$1,090
NICHD	$1,694	$41	$50	$200	$1,944
NEI	$1,282	$29	$114	$590	$1,986
NIEHS	$950	$17	$61	$78	$1,090
NIA	$1,431	$36	$31	$12	$1,475
NIAMS	$1,207	$55	$30	$45	$1,282
NIDCD	$971	$28	$31	$30	$1,031
NIMH	$1,072	$31	$36	$52	$1,160
NIDA	$1,478	$39	$125	$275	$1,878
NIAAA	$2,651	$46	$204	$155	$3,009
NINR	$815	$6	$13	$74	$901
NHGRI	$1,112	$25	$71	$345	$1,528
NIBIB	$1,106	$44	$100	$470	$1,676
NIMHD	$1,389	$10	$19	$451	$1,858
NCCIH	$1,116	$36	$16	$173	$1,306
NCATS	$2,087	$40	$81	$302	$2,470
FIC	$1,530	$15	$109	$62	$1,701
NLM	$1,668	$39	$140	$575	$2,383
CSR	$1,057	$18	$37	$135	$1,228
CIT	$254	$11	$17	$727	$998
CC	$1,762	$36	$97	$1,800	$3,658
OD	$2,047	$43	$87	$104	$2,238
NIH Total	**$41,283**	**$1,208**	**$1,830**	**$10,158**	**$53,271**

IC Director's Office Cost Summary

(Dollars in Thousands)

IC	FY 2015 Actual	FY 2016 Estimate	FY 2017 Estimate
NCI	$4,094	$3,689	$4,068
NHLBI	$2,168	$3,170	$3,273
NIDCR	$1,259	$1,263	$1,592
NIDDK	$2,396	$2,610	$2,465
NINDS	$832	$899	$925
NIAID	$2,853	$3,020	$3,057
NIGMS	$1,058	$1,090	$1,090
NICHD	$2,024	$1,976	$1,944
NEI	$1,822	$1,994	$1,986
NIEHS	$1,050	$1,071	$1,090
NIA	$1,431	$1,461	$1,475
NIAMS	$1,329	$1,299	$1,282
NIDCD	$892	$995	$1,031
NIMH	$1,131	$1,148	$1,160
NIDA	$1,605	$1,864	$1,878
NIAAA	$2,946	$2,976	$3,009
NINR	$872	$895	$901
NHGRI	$1,251	$1,471	$1,528
NIBIB	$1,000	$1,425	$1,676
NIMHD	$1,503	$1,813	$1,858
NCCIH	$1,190	$1,280	$1,306
NCATS	$1,921	$2,375	$2,470
FIC	$1,709	$1,688	$1,701
NLM	$1,959	$2,092	$2,383
CSR	$1,120	$1,173	$1,228
CIT	$990	$992	$998
CC	$3,604	$3,657	$3,658
OD	$2,166	$2,238	$2,238
NIH Total	**$48,176**	**$51,622**	**$53,271**

Cole 21
Privacy Protection

Chairman Cole: Please describe how NIH has implemented the requirement related to privacy protection in every grant that involves human subject research to issue issuances of certifications of confidentiality to ensure data collected or consolidated via NIH programs and data bases prevents privacy intrusions of individuals involved in biomedical research.

Dr. Collins: We completely agree that certificates of confidentiality strengthen investigators' ability to protect the privacy of their research participants, and NIH is actively working to implement the requirement. We will report back as soon as we have worked out the procedural changes that need to be made to our grants management system to allow the issuance of certificates to investigators conducting research involving large volumes of data from human research participants. In addition to fulfilling the requirement, we want to be sure we are doing as much as we can to make sure certificates are widely available and easy to obtain.

Cole 22
Kids First Pediatric Research

Chairman Cole. Please describe NIH's plan for the 10-year created through the Kids First legislation. Further, how has NIH implemented the FY 2015 Omnibus report language to change study sections to ensure permanent or ad hoc members who are expects in the filed participate in reviewing pediatric research applications. Please specifically identify the NIH policy and guidance documents that have been changed towards this end.

Dr. Collins. In 2014, the Gabriella Miller Kids First Research Act was passed into law, authorizing $12.6 million per year for 10 years to support pediatric research through the Common Fund, and in FY 2015, funds were appropriated to the Common Fund for this purpose. The NIH undertook a planning process that engaged both internal and external experts to identify strategic areas where this investment could accelerate progress in pediatric research. The Gabriella Miller Kids First Pediatric Research program (Kids First) is developing a data resource for the pediatric research community consisting of well-curated clinical and genetic sequence data from pediatric patients with childhood cancers or structural birth defects. This data resource will allow scientists to identify genetic pathways that underlie these conditions and to explore whether shared genetic pathways exist between childhood caneer and structural birth defects. With the funds appropriated in FY 2015, NIH provided funds for DNA sequencing of selected patient cohorts.[39] These cohorts address a wide range of pediatric conditions, including Ewing sarcoma, treatment-resistant pediatric osteosarcomas, cleft lip and cleft palate, congenital heart defects, and more. Kids First is now soliciting applications to sequence additional cohorts, in order to expand the range of pediatric conditions addressed and enhance the data resource. Plans for future years include continued support for genetic sequencing and development of a user-friendly interface for the data resource that will allow pediatric researchers to mine the data. Projects that demonstrate the utility of the data for understanding gene networks and/or for the identification of compounds that modify gene activity will also be supported in coming years pending availability of funds.

Last year: Our computer system of reviewers who listed their department as "Pediatrics," excluding such hybrid department listings as Pediatrics, Neurology, and Neuroscience and Pediatrics and Microbiology, indicated that for applications that were reviewed at the May 2015 council meetings, the NIH Center for Scientific Review (CSR) used 248 pediatric reviewers. Some manual spot checking suggested that the actual number of pediatric reviewers may have been 50 percent higher, about 360 pediatric reviewers.

Current situation: NIH has populated its study sections with pediatric expertise appropriate for the applications under review. Given the number and distribution of pediatric reviewers, CSR is confident that it is well poised for reviewing future pediatric research applications.

Our computer system of reviewers who list their department as "Pediatrics," excluding such hybrid department listings as Pediatrics, Neurology, and Neuroscience and Pediatrics and Microbiology currently indicates that for the May 2016 council the NIH CSR used 281 pediatric

[39] https://commonfund.nih.gov/kidsfirst/fundedresearch

reviewers. As shown in the attachment, these reviewers were spread across 77 regular/chartered study sections and 97 Special Emphasis Panels (SEPs).[40]

These numbers are known to be underestimates in view of the exclusion of hybrid departments and of the number of reviewers with primary expertise in child health and development whose affiliation is with departments other than Pediatrics (e.g., Psychiatry, Cardiology, Oncology, Immunology, Speech and Hearing). Manual inspection of 10 review panels for which the Pediatric Department approach indicated 43 experts revealed in fact 144 pediatric experts, a multiplier of 3.3x! Thus, the number of pediatric reviewers used on our panels is likely close to 3.3 x 281 = 927.

An important note is that when a panel receives one or more applications with a focus on pediatric research, the Scientific Review Officer ensures adequate pediatric expertise with a combination of regular and ad hoc members. The more pediatric applications, the more pediatric reviewers for that round.

Sixteen regular study sections had 3 or more pediatric department reviewers:
DBD/ Developmental Brain Disorders
IRAP/ Infectious, Reproductive, Asthma and Pulmonary Conditions
LIRR/ Lung Injury, Repair, and Remodeling
CDD/ Cardiovascular Differentiation and Development
CIMG/ Clinical, Integrative and Molecular Gastroenterology
PRDP/ Psychosocial Risk and Disease Prevention
SBDD/ Skeletal Biology Development and Disease
CRFS/ Clinical Research and Field Studies of Infectious Diseases
CADO/ Cellular Aspects of Diabetes and Obesity
CLHP/ Community-Level Health Promotion
LCMI/ Lung Cellular, Molecular, and Immunobiology
PN/ Pregnancy and Neonatology
IHD/ Immunity and Host Defense
TCB/ Tumor Cell Biology
DDR/ Drug Discovery and Mechanisms of Antimicrobial Resistance
GHD/ Genetics of Health and Disease

Seven SEPs had 3 or more pediatric department reviewers:
ZRG1 SBIB-V (82) in Surgical Sciences, Biomedical Imaging and Bioengineering cluster
ZRG1 IRAP-C (07) in Population Sciences and Epidemiology cluster
ZRG1 BCMB-A (51) in Biological Chemistry and Macromolecular Biophysics cluster
ZRG1 EMNR-V (02) in Endocrinology, Metabolism, Nutrition and Reproductive Sciences cluster
ZRG1 SBIB-V (55) in Surgical Sciences, Biomedical Imaging and Bioengineering cluster
ZRG1 EMNR-B (02) in Endocrinology, Metabolism, Nutrition and Reproductive Sciences cluster
ZRG1 CADO-A (02) in Endocrinology, Metabolism, Nutrition and Reproductive Sciences cluster

[40] See Attachment A: Pediatric Reviewers

Poised for the future

The names of the review groups show that the reviewers represent a breadth of scientific areas in which development at clinical, translational, and basic research levels is the focus. It is noteworthy that all five of CSR's review divisions are represented, particularly Physiological and Pathological Sciences, Translational and Clinical Sciences, AIDS, Behavioral and Population Sciences, and Neuroscience, Development, and Aging, but also Basic and Integrative Biological Sciences.

Cole 23
Transforming Basic Science to Preventative Medicine Through Technology

Chairman Cole: The 2015 Appropriations Act requested NIH hold a joint meeting on this subject, please describe how the outcome of this meeting has resulted in tangible aetions and how progress is being measured.

Dr. Collins: We held a series of workshops in 2015 that addressed the role of genomics and health information technology in speeding the transformation of basic science, clinical medicine, and prevention toward precision medicine. A wide array of disciplines and sectors were involved in the workshops, including experts in privacy, patient advocacy, healthcare, epidemiology, genomics, mobile health (mHealth), computer science, and information technology. Links to those workshops and the final report outlining the outcomes and actions to be taken are available at: https://www.nih.gov/precision-medicine-initiative-cohort-program.

Cole 24
National Research Service Award

Chairman Cole: Please describe how NIH evaluates the effectiveness of the NIH training? How they are evaluated? The results of the last evaluation? And the next scheduled comprehensive evaluation? How does NIH use these as a mechanism to provide interest in basic science?

Dr. Collins: The NIH Office of Extramural Research (OER) partners with NIH Institutes and Centers (ICs) to coordinate and monitor awards for research training and career development across the NIH. Per a 2012 Report from the Advisory Committee to the NIH Director[41], the Division of Biomedical Research Workforce (DBRW) was created within OER to provide ongoing analysis of the biomedical research workforce and evaluation of NIH policies, research training, and career development programs. The goal is to enable NIH to sustain the biomedical research workforce at all levels so that the most productive, innovative, and diverse biomedical research endeavors continue to be supported. As part of this effort, NIH training programs are regularly assessed and reviewed through recurring program evaluations. Evaluations such as that related to the outcomes of the National Research Service Award (NRSA), for instance, have routinely found that students participating in NRSA-supported programs complete their degrees in shorter time, are more likely to pursue research careers, and achieve greater subsequent success in research than do students who do not participate in NRSA programs. As an example, a 2015 analysis of former NRSA postdoctoral fellows found that twice as many NRSA-supported fellows received major NIH research grant funding within ten years of their fellowship training as compared to their non-NRSA counterparts.[42] A list of NIH training program evaluations can be found online.[43]

In addition to NIH-wide assessments of programs coordinated through OER, individual NIH ICs undertake periodic, targeted evaluations to improve implementation and assess outcomes of their own training programs. One such NIH IC is the National Institute of General Medical Sciences (NIGMS).

NIGMS takes a leadership role within NIH in the development of the next generation of scientific talent. A major goal in the 2015 NIGMS strategic plan is to "support the development of a highly trained, creative and diverse biomedical research workforce" (Goal 2). NIGMS uses a variety of mechanisms to fund students and trainees at various career stages and educational settings to prepare them for a range of research and research-related careers, and to enhance workforce diversity. Per the Institute's research mission, the emphasis of NIGMS supported training programs is on basic biomedical science. NIGMS supports nearly half of all NRSA T32 predoctoral trainees in eleven basic biomedical science disciplines to promote interest and rigorous training in these fields. The strategic plan also sets forth the specific objective to "assess institute research training and education programs and policies to ensure they achieve positive outcomes related to the NIGMS mission" (objective 2-1). Through its Office of Program Planning, Analysis and Evaluation, NIGMS has begun evaluation of all training and diversity initiatives, including the Maximizing Access to Research Careers, Postbaccalaureate

[41] http://acd.od.nih.gov/biomedical_research_wgreport.pdf
[42] http://www.hhs.gov/about/budget/fy2017/performance/performance-plan-goal-2-objective-a/index.html
[43] https://researchtraining.nih.gov/resources/data-outcomes-and-evaluations

Research Education Program, Medical Scientist Training Program, Institutional Research and Academic Career Development Awards, and Diversity Supplement Program. The results of these evaluations are presented to the National Advisory General Medical Sciences Council and made publicly available on the NIGMS website.[44].

A key NIH-wide training initiative is the Common Fund Diversity Program Consortium (DPC) aimed at enhancing workforce diversity.[45] A central element of DPC is the Coordination and Evaluation Center which will evaluate the efficacy of the training and mentoring approaches developed by the Building Infrastructure Leading to Diversity (BUILD) and National Research Mentoring Network (NRMN) awardees. Results from these evaluations will be disseminated through publications by DPC grantees, websites, and staff presentations as well as via NIH websites and staff presentations.

[44] https://www.nigms.nih.gov/News/reports/Pages/default.aspx
[45] https://commonfund.nih.gov/diversity/overview

Cole 25
Capstone Awards

Chairman Cole. In FY 2016, Congress expressed it desire for NIH to use is 301 authority to promote partnership between senior and junior investigators through a Capstone Award that would allow more senior investigators a way to more into a new phase within the community. Please provide the timeline and criteria expected to be used for this new award program?

Dr. Collins. In 2014, NIH convened an internal working group to consider new ideas for decreasing the time required for early career investigators to reach research independence. Among the many proposals discussed by the working group was the concept of a new "Emeritus" award (later renamed the "Capstone" award) that would allow established investigators to complete important research goals and bring their research programs to an orderly conclusion. The expectation would be that an investigator supported by a Capstone award could not have principal investigator status on future NIH grants. The idea was that by facilitating the transition of some investigators out of the NIH-funding pool, this may provide opportunities for early career scientists.

To gauge community interest in such an award program and the community's perspectives on whether such an award program would further the interest of junior investigators, NIH issued a Request for Information (RFI) in February, 2015 (NOT-OD-15-064[46]). RFI described a few potential ideas for how an Emeritus Award could be used, such as enabling senior investigators to complete their projects and help them close out their laboratories; supporting a senior investigator during the transition to a new role, such as full time teaching or executive research administration; or facilitating a senior investigator in forming a partnership with a junior faculty member to hand off his or her line of research inquiry.

Feedback from RFI was mixed; roughly half of the respondents indicated support for the concept, while the other half expressed skepticism that such an award would be helpful to junior investigators. This skepticism was also voiced over social media.[47,48] One frequent comment was that NIH did not need a new type of grant to facilitate mentorship between junior and senior investigators, as mentorship is already fostered through existing mechanisms, such as the Ruth L. Kirschstein National Research Service Awards and research career development awards. Moreover, if a senior investigator wishes to transfer his or her research project to a junior investigator, the grantee institution can request a change in the status of the key personnel named on the grant through existing mechanisms. Other RFI respondents advocated for higher priority for additional funding opportunities that directly target early career investigators.

Over the course of numerous internal NIH discussions, while considering the research community's concerns, it became clear that the Capstone award concept was unlikely to achieve its intended goals. The decision was not made due to perceived limitations in Section 301 research authority, but due to programmatic concerns. Rather than pursue the Capstone award, NIH staff decided to explore other strategies for sustaining the biomedical workforce. Several

[46] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-064.html
[47] http://news.sciencemag.org/funding/2015/02/nih-proposal-create-grant-aging-scientists-hits-nerve
[48] http://www.nature.com/news/nih-plan-to-give-ageing-scientists-cash-draws-scepticism-1.16895

NIH Institutes are currently piloting new mechanisms for providing stable, long-term funding for both early career and established investigators.[49,50,51,52,53,54,55] For example, the Emerging Investigator Award, offered by the National Heart, Lung, and Blood Institute (NHLBI), will support the research program of early career investigators for up to seven years in order to promote scientific productivity and innovation. A parallel funding opportunity, called the NHLBI Outstanding Investigator Award, will provide up to seven years of support to experienced investigators who have outstanding research records and have demonstrated their ability to make major contributions to heart, lung, blood, and sleep research.

As requested in the Consolidated Appropriations Act of 2016, NIH will work with the National Academies to conduct a comprehensive study on policies affecting the next generation of researchers in the United States. Over the years, NIH has been persistent and creative in its efforts to support early career investigators through policy changes and new programs. However, the biomedical workforce is shaped by a complex interplay of regulatory, institutional, and individual-level factors that may evolve over time. For example, the careers of early stage investigators are likely influenced by the effects of sequestration, tenure policies at research institutions, publication practices and timelines, and work-life/family balance issues. NIH is especially interested in understanding the factors that affect the success of early-career investigators who have achieved some degree of independence (e.g., have obtained a research grant) but remain vulnerable, particularly at the time of their first grant renewal.

In this environment of increased competition, we must make every effort to enhance the career trajectories of the next generation of researchers. It is our hope that by consulting a broad range of stakeholders with varied perspectives, the National Academies study will produce unique insights into sustaining the biomedical research enterprise for NIH and other stakeholders to consider. While NIH does not yet have the timeline for the National Academies study, we understand that consensus studies typically take 18 months to 2 years, depending on size and scope.

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[49] https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-025.html
[50] https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-024.html
[51] https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-17-002.html
[52] https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-003.html
[53] https://grants.nih.gov/grants/guide/rfa-files/RFA-DE-17-002.html
[54] https://grants.nih.gov/grants/guide/pa-files/PAR-15-342.html
[55] https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-16-001.html

Cole 26
Frederick National Laboratory for Cancer Research

Chairman Cole: The operation of the National Laboratory is provided through a contract with the National Cancer Institute. This contract provides scientific, technical and administrator support, as well as advanced biomedical computing and information technology and clinical trial management. The current contract will expire in 2018.

a) Can you assure the committee that when the current contract expires, a new competition will be held and that full and fair consideration will be given to all applicants?
b) What is the process that will be used and timeline anticipated to publically release the announcement for full and fair consideration in this new competition?

Dr. Collins: The Frederick National Laboratory for Cancer Research (FNLCR) is a Government-Owned, Contractor Operated (GOCO) Federally Funded Research and Development Center (FFRDC), which provides rapid response capabilities and one-of-a-kind resources for the biomedical research community within the National Cancer Institute (NCI), the National Institutes of Health (NIH), and other Federal agencies. Located in Frederick, Maryland, the NCI FFRDC offers a unique array of research support and advanced technologies.

The purpose of FNLCR is to provide a unique biomedical resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), and other diseases.

NCI is committed to a full and fair acquisitions process. Competition is the cornerstone of the Federal acquisition process and a critical tool for achieving the best possible return on the investment of federal funds. NCI believes competition will be an effective motivator to finding the best operator of FFRDC. The re-competition process for the next FFRDC contract is well underway. In October 2015, NCI hosted a public pre-proposal conference for interested parties. During the two-day conference, NCI provided information about FNLCR's mission, purpose, and operations, as well as a summary overview of the planned procurement process including a general timeline. NCI also provided guided tours of the FFRDC operations in Frederick, Maryland.

NCI is promoting the use of fair and open competition for the FFRDC contract in accordance with the Federal Acquisition Regulation (FAR) and the Health and Human Services Acquisition Regulation (HHSAR). NCI has also established a website, the FNLCR Acquisition Portal, containing links to all public announcements and related acquisition information in an effort to increase awareness and provide the latest comprehensive information to interested parties about the FFRDC re-competition.[56] NCI will post all formal announcements related to this competition on the acquisitions portal as well as on the FedBizOpps website.[57]

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[56] http://ncioa.cancer.gov/oa-internet/fnlcr/index.html
[57] http://www.fedbizoppsgov.com/

The timeline for the acquisition process extends through June 2017, with key milestones as follows. The draft Request for Proposals (RFP) was issued on April 15, 2016.[58] The final RFP is anticipated to be released during the fourth quarter of FY 2016. The receipt of proposals is expected to occur in December of 2016. NCI plans to award a contract in June 2017.

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58 https://www.fbo.gov/index?s=opportunity&mode=form&id=0d20dceca41e18060258f9c20220dc52&tab=core&_cview=0

Cole 27
Enhanced NIH Reporting on Research Spending by Disease

Chairman Cole: In the past two year's NIH has been directed to provide additional specific information on the RCDC web site. Please provide an update on the specific timeline and actions directed in the past two years.

Dr. Collins. As requested in the FY 2016 Omnibus report language, NIH is currently drafting a Congressional Appropriations Committee Report that details the timeline and actions NIH is undertaking in response to this request. In addition, NIH will be posting selected data resulting from the consultations detailed in the report. A short summary follows.

NIH believes strongly in the importance of incorporating public health measurements into its priority-setting processes, among other factors, and is committed to maintaining transparency so that Congress and the public can better understand the process by which we set the Agency's research priorities. NIH has taken several steps to identify and obtain the most relevant and appropriate federally-sourced data on disease burden for a majority of disorders and conditions for which Research, Condition, and Disease Categorization (RCDC) spending data is available. NIH sought extensive advice for rigorously using and interpreting this data through consultations with experts both within NIH and throughout the Department of Health and Human Services (HHS), including epidemiology experts at NIH, the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC), and HHS's Assistant Secretary for Planning and Evaluation (ASPE). All of the experts consulted emphasized the complexity of capturing disease statistics for the broad range of diseases and conditions covered by the NIH portfolio, and stressed the caveats of attempting to compare between diseases that impose very different burdens.

NIH's consultations suggest that there is no single, centralized source of prevalence data with broad coverage of appropriate measures for the disease- and condition-related NIH RCDC categories. However, there are some data sources that might be best used to fulfill this request to the greatest extent possible in combination with each other, and with multiple caveats regarding comparability across categories. In the upcoming report, NIH will describe these sources and evaluate them for how well they address Congress' request. In addition, NIH will post data provided by NCHS on mortality and prevalence, which cover a total of 113 RCDC categories, and which NIH believes most closely approximate Congress' request.

Consultations with its internal experts and its sister agencies reaffirmed the difficulties in matching RCDC spending data to disease statistics. NIH believes that the best way to understand disease burdens is by understanding patterns in the larger context of multiple methods and measurements. With that conclusion, NIH will propose in its full report a way forward to provide regularly updated data in a way that ensures transparency and that can act as a starting point for discussions about NIH's priority setting process.

Womack 1
Bisphenol A Research

Congressman Womack: We understand that a major justification for many, if not most of the Bisphenol A (BPA) research is the apparent widespread consumer exposure to this chemical. Further, we understand that regulators worldwide identify food contact materials as a major source of exposure to BPA. Clearly, National Institute of Environmental Health Sciences (NIEHS) research in this area should have had a significant public health role in informing the regulation of this chemical. Indeed, NIEHS itself has touted the importance of the BPA research it has funded to the regulation of BPA. Can you please tell us how NIEHS ensures that BPA research it funds or conducts: 1) follows protocols and methods that meet regulatory standards for food contact; 2) results in publications and press releases that are accurate and do not falsely raise public alarm; and, 3) ensures primary/raw data is openly shared across regulatory agencies in a manner that supports regulatory review.

Dr. Collins:

1) NIEHS funds a portfolio of laboratory and human studies of research on the health effects of BPA, which includes a collaborative research program on BPA, termed the Consortium Linking Academic and Regulatory Insights on Toxicity of BPA (CLARITY-BPA). The CLARITY study is a cooperative agreement, conducted under the auspices of the NIEHS National Toxicology Program (NTP), between NIEHS-funded university-based researchers (grantees), staff at the NIEHS Division of the National Toxicology Program (DNTP) and Division of Extramural Research and Training (DERT), and staff at the Food and Drug Administration's (FDA's) National Center for Toxicological Research (NCTR). This core study being performed under this collaboration is a chronic rodent toxicity and cancer study performed under Good Laboratory Practices (GLP) at an FDA facility in Jefferson, Arkansas. This study is compliant with regulatory guidelines for testing food contact substances.

The CLARITY-BPA program is overseen by a Steering Committee, which sets consortium policies. The Steering Committee includes investigators representing each NIEHS-funded grant, the NCTR staff responsible for the core GLP rodent study, a representative from DERT, a NTP representative responsible for coordinating the project, and DNTP and NCTR project officers responsible for administering the interagency agreement that supports the study. In addition, an External Scientific Panel of three independent scientists provides overall programmatic guidance and offers advice in the management and technical performance of the research.

The study protocols and methods being used by the CLARITY grantees to further evaluate tissues and animals from the GLP-compliant NTP/FDA study do not follow GLP procedures or necessarily meet regulatory standards. Academic researchers do not usually have the facilities or other capabilities to perform studies in their own laboratories according to GLP guidelines. However, NIH-funded CLARITY grantees must meet National Institutes of Health (NIH) standards for reproducibility and rigor, and in some cases those researchers working on BPA go beyond NIH guidelines by measuring internal concentrations of BPA, paying extra attention to issues of dose response, and using dosing protocols and multiple overlapping study endpoints.

2) The publications from all BPA grantees' research, like all NIH-funded research, are the

responsibility of the grantee and the grantee institution. Publications are reviewed for scientific content and accuracy by external reviewers, who are chosen by the particular journal to which the grantees submitted their work for publication. Occasionally, the grantees or their institution will issue a press release on their findings. NIEHS encourages investigators of NIEHS-funded grants to communicate and coordinate any plans for press release of their findings with NIEHS. Since CLARITY is a research consortium, its Steering Committee developed a Publications Agreement that documents procedures for reviewing abstracts and manuscripts arising from the CLARITY-BPA program. Publications are reviewed by NIEHS and FDA staff for policy issues before being submitted to a journal for publication. All members of the CLARITY consortium signed agreements to abide by these policies.

3) All data from the CLARITY studies are submitted to the Chemical Effects in Biological Systems database (CEBS).[59] CEBS is a relational database at NIEHS that houses publicly available data for studies conducted by NTP. All data from the CLARITY study will be made public via this database. Data from academic grantees are submitted in blinded manner to CEBS prior to decoding and releasing back to the academic investigator. After an agreed upon period of time, which allows the consortium to publish the final results and individual researchers to publish findings from their laboratories, all data in CEBS on the CLARITY-BPA study will be made publicly available.

[59] http://www.niehs.nih.gov/research/resources/databases/cebs/

Harris 1
Cyro-electron Microscope

Congressman Harris: It's encouraging to see a Common Fund Phase 2 program to address the accessibility the costly cryo-electron microscope through shared resource centers. These centers offer potential for economies of scale and ultimately saving taxpayers money while expanding access for scientists to these critical tools. Are you considering other strategies for these types of costly tools and centers to ensure they are accessible to NIH-funded scientists and that their use is maximized?

Dr. Collins: The NIH Common Fund supports programs that are strategic, short-term (5-10 year) investments aimed at solving problems to accelerate research throughout the entire biomedical research enterprise. To achieve this goal, some Common Fund programs establish resources or facilities that can be used by a broad range of scientists to support their own research. The role of the Common Fund for these facilities is to lower the barrier to the acquisition of expensive technology; it is not to provide long term support. One such program currently in the planning stage is Transformative High Resolution Cryo-Electron Microscopy (Cryo-EM), which aims to capitalize on new technologies for determining the structure of critically important proteins by providing access to cryo-EM equipment and supporting training and technology development. If a program to build capacity for cryo-EM analyses is ultimately supported, it will follow precedent established for the Common Fund by programs such as the Molecular Libraries program and the Metabolomics program. These types of program build from the recognition that new technologies can be transformative but are often expensive to acquire. The Common Fund provides support for equipment, training activities, and opportunities for new users to collaborate with experts. The Cryo-EM program is currently under consideration for a potential launch in FY 2018 or beyond, and the nature and scope of the program may change depending on scientific opportunities and/or available funding. Additionally, the National Institute of General Medical Sciences (NIGMS) has issued funding announcements for FY 2016 and FY 2017 to provide a measure of short-term relief to scientific user demand by establishing regional Cryo-EM consortia that will increase access to existing facilities.

Many NIH infrastructure programs provide long-standing support for shared resources that benefit the biomedical research community. These include the National Cancer Institute's Cancer Center Cores and the National Center for Accelerating Translational Science' Clinical and Translational Science Awards.[60,61] Additionally, the Office of Research Infrastructure Programs (ORIP), through its Shared Instrumentation Grant (SIG) Program, has provided groups of biomedical investigators access to state-of-the art instrumentation, which are too costly for a single investigator to acquire or operate. The SIG program is critical in enabling the pioneering of research in all biomedical fields, from basic science to translational implementations. NIH's SIG program provides funds for expensive shared instruments which otherwise would not be available to many researchers.

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[60] http://www.cancer.gov/research/nci-role/cancer-centers
[61] https://ncats.nih.gov/ctsa

Harris 2
Capstone Awards

Congressman Harris: In the FY16 Report, the Committee noted an expectation of NIH to pursue the establishment of Capstone Awards. NIH issued an RFI on the creation of Capstone Awards. Why did NIH stop short of creating the Capstone Awards? Does NIH foresee limitations in Section 301 research authority regarding the creation of these Capstone Awards?

Dr. Collins: In 2014, NIH convened an internal working group to consider new ideas for decreasing the time required for early career investigators to reach research independence. Among the many proposals discussed by the working group was the concept of a new "Emeritus" award (later renamed the "Capstone" award) that would allow established investigators to complete important research goals and bring their research programs to an orderly conclusion. The expectation would be that an investigator supported by a Capstone award could not have principal investigator status on future NIH grants. The idea was that by facilitating the transition of some investigators out of the NIH-funding pool, this may provide opportunities for early career scientists.

To gauge community interest in such an award program and the community's perspectives on whether such an award program would further the interest of junior investigators, NIH issued a request for information (RFI) in February, 2015 (NOT-OD-15-064).[62] The RFI described a few potential ideas for how an Emeritus Award could be used, such as enabling senior investigators to complete their projects and help them close out their laboratories; supporting a senior investigator during the transition to a new role, such as full time teaching or executive research administration; or facilitating a senior investigator in forming a partnership with a junior faculty member to hand off his or her line of research inquiry.

Feedback from the RFI was mixed; roughly half of the respondents indicated support for the concept, while the other half expressed skepticism that such an award would be helpful to junior investigators. This skepticism was also voiced over social media.[63,64] One frequent comment was that NIH did not need a new type of grant to facilitate mentorship between junior and senior investigators, as mentorship is already fostered through existing mechanisms, such as the Ruth L. Kirschstein National Research Service Awards and research career development awards. Moreover, if a senior investigator wishes to transfer his or her research project to a junior investigator, the grantee institution can request a change in the status of the key personnel named on the grant through existing mechanisms. Other RFI respondents advocated for higher priority for additional funding opportunities that directly target early career investigators.

Over the course of numerous internal NIH discussions, while considering the research community's concerns, it became clear that the Capstone award concept was unlikely to achieve its intended goals. The decision was not made due to perceived limitations in Section 301 research authority, but due to programmatic concerns. Rather than pursue the Capstone award, NIH staff decided to explore other strategies for sustaining the biomedical workforce. Several

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[62] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-064.html
[63] http://news.sciencemag.org/funding/2015/02/nih-proposal-create-grant-aging-scientists-hits-nerve
[64] http://www.nature.com/news/nih-plan-to-give-ageing-scientists-cash-draws-scepticism-1.16895

NIH Institutes are currently piloting new mechanisms for providing stable, long-term funding for both early career and established investigators.[65,66,67,68,69,70,71] For example, the Emerging Investigator Award, offered by the National Heart, Lung, and Blood Institute (NHLBI), will support the research program of early career investigators for up to seven years in order to promote scientific productivity and innovation. A parallel funding opportunity, called the NHLBI Outstanding Investigator Award, will provide up to seven years of support to experienced investigators who have outstanding research records and have demonstrated their ability to make major contributions to heart, lung, blood, and sleep research.

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[65] https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-025.html
[66] https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-024.html
[67] https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-17-002.html
[68] https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-003.html
[69] https://grants.nih.gov/grants/guide/rfa-files/RFA-DE-17-002.html
[70] https://grants.nih.gov/grants/guide/pa-files/PAR-15-342.html
[71] https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-16-001.html

Harris 3
Bayh Dole

Congressman Harris: Bayh-Dole was never intended to serve as a mechanism for regulating the pricing of any particular products, including prescription medicines. On petitions for exercising march-in rights related to biopharmaceuticals, NIH has consistently concluded that the products had reached practical application and met health or safety needs. NIH has publicly stated "that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients." Given NIH's long-standing position in this area, can you please provide a sense of the agency's current thinking on this?

Dr. Collins: NIH shares the public's concern about any individuals who need medical treatments may be prevented access to treatment on the basis of the cost. Some have suggested that NIH utilize the Bayh-Dole march-in authority as a means of addressing the difficult situation with drug pricing. The Bayh-Dole Act, however, does not appear to have been designed to address situations where the price is the obstacle for access to products utilizing government-funded inventions. The Act seems to address the circumstances where the products are not available because they are not being commercialized and have not entered the market. Another case for using march-in may occur when serious public health needs are not being reasonably met by the owner of the patent or the company selling the product. In such cases, NIH has the authority to utilize the march-in authority. NIH reviews each request for the use of march-in on case by case basis. In previous cases where requests were based on drug pricing issues, NIH did not find that the march-in statutory criteria were met.

Harris 4
Biomedical Research

Congressman Harris: As NIH has noted, "Requiring direct financial recoupment of the federal investment in biomedical research can potentially impede the development of promising technologies by causing industry to be unwilling to license federally funded technologies." If the risk of the government marching in and acquiring a particular technology increases, the private sector may be hesitant or unwilling to license the technology, potentially impeding progress against some of our most costly and challenging diseases to the detriment of public health and safety. If NIH marches in, venture and other private capital investment will dramatically decrease in response to the increased risk and uncertainty associated with supporting small biotech start-ups. Can you provide NIH's thinking of how exercising march-in will not be to the detriment of biomedical innovation?

Dr. Collins: NIH considers the use of the march-in statutory criteria on a case-by-case basis. While NIH takes these matters and its responsibility seriously, Dr. Collins has expressed concerns about negative consequences that might result from inappropriate use of this authority. If NIH begins to use march-in in a very broad way to address drug pricing, there could be substantial negative effects on the Agency mission in terms of a loss of interest by industry to further develop discoveries that NIH has supported.

Harris 5
Human Fetal Tissue Funding

Congressman Harris: NIH has published a chart estimating funding levels for various research categories. In this chart you estimate spending $84 million in FY 2017 for research involving Human Fetal Tissue. Does this category include research involving cell lines created using the organs or tissue of unborn children who have been aborted? If not, please provide the total amount of NIH funding for research involving cell lines created from the organs or tissue or unborn children for FY 2012, FY 2013 and FY 2015.

Dr. Collins: The Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC) provides official NIH figures on research spending by category. FY 2015 is the most recent year for which final, validated NIH figures are available.[72] The entire research budget of the project is counted in the category, irrespective of how much of the budget is used to support fetal tissue research. This means that even if only a small component of a project was devoted to fetal tissue research, the entire budget of the project would be counted in this category.

For the Human Fetal Tissue category, research is captured if it entails basic, pre-clinical, and/or clinical research involving the study, analysis, or use of human fetal tissue. This category excludes secondary products, such as long established cell lines, as these are derivative products and are no longer considered primary tissue. Research projects involving only derivative (secondary) products of human fetal tissue are not captured in a single unique RCDC category.

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72 https://report.nih.gov/categorical_spending_project_listing.aspx?FY=2015&ARRA=N&DCat=Human%20Fetal%20Tissue

Harris 6
Congressman Harris. Human Fetal Tissue (monitoring)

Congressman Harris: What, if anything, have you done to monitor NIH-funded research involving human fetal tissue and cell lines derived from the organs or tissues of children who have been aborted? Has NIH ever conducted an audit or review of all NIH-funded research involving organs, tissues or cell lines created from unborn children? If yes, please provide copies of the audit or review.

Dr. Collins: The majority of the NIH's funding (over 80 percent) is used to support research grants and contracts at research organizations across the country (extramural research). Therefore, NIH employs a long-standing and well-established system for working with funding recipients to ensure compliance with a host of laws, regulations, and policies, as summarized in the NIH Grants Policy Statement.[73] When submitting a funding application for research involving fetal tissue, the designated representative of the external organization receiving the funding certifies that researchers using these samples are in compliance with applicable legal requirements. In addition, by accepting an award, funding recipients agree that they will follow all applicable legal requirements and the NIH's Grants Policy Statement, and must be able to demonstrate their compliance. NIH also requires funding recipients to re-certify when additional funding is awarded that they are in compliance, and they are responsible for establishing internal procedural controls to ensure compliance.

Grantee organizations, including those that conduct research with human fetal tissue, are subject to audits to monitor compliance responsibilities. For example, organizations that spend $750,000 or more in Federal funds during their fiscal year (or $500,000 or more prior to December 26, 2014) are generally required to undergo an annual audit in compliance with the Single Audit Act and 2 CFR Part 200, subpart F, implemented by HHS at 45 CFR Part 75 subpart F. Also, NIH retains the authority and discretion to conduct, or arrange for the conduct of, other audits and/or evaluations of NIH awards. However, there have been no NIH-conducted audits specifically directed at compliance with applicable laws or requirements on human fetal tissue research that NIH is aware of, as NIH has no record of complaints about violations of the laws or requirements pertaining to human fetal tissue. There has been no indication, nor is there any current indication that NIH is aware of, that organizations might be violating laws or requirements pertaining to human fetal tissue. Tissues are obtained by individual NIH-funded investigators as determined by needs of their specific research. Federal human fetal tissue procurement policies and guidance were found to be consistent with Federal law per a Government Accountability Office review in 2000.[74]

Investigators within NIH's intramural research program (NIH's internal research program) are held to the same standard as other NIH-funded investigators in terms of adhering to applicable legal requirements and NIH policies. There are several policies that pertain to research with human fetal tissue, which are posted to the NIH sourcebook.[75] The NIH Deputy Director of

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[73] http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
[74] http://www.gao.gov/new.items/d0165r.pdf
[75] https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research/oversight-fetal-tissue-research

Intramural Research, in concert with the Scientific Directors of each NIH Institute or Center (IC), provides guidance and oversight of intramural principal investigators engaged in research using human fetal tissue to ensure that all laws and requirements are observed. The Scientific Director of each NIH IC also certifies compliance of all investigators on an annual basis. The NIH Office of Human Subjects Research Protections (OHSRP) provides additional guidance to intramural principal investigators who are using or considering using fetal tissue in their research.

Harris 7
Human Fetal Tissue (consent)

Congressman Harris: What, if any, requirements does NIH place on researchers to guarantee that sufficient informed consent is obtained prior to collection of fetal organs or tissue to be used in NIH-funded research?

Dr. Collins: For research with human fetal tissue for transplantation purposes, Sec. 498A of the PHS Act (42 USC §289g-1) specifically outlines the requirements for the donor providing consent, and the responsibilities of the attending physician and individual conducting research. For research with human fetal tissue for non-transplantation purposes, there are no specific provisions within the PHS Act addressing consent requirements. However, 45 CFR 46, Subpart B, states that if there is information associated with human fetal material that is recorded for research purposes in a manner that living individuals can be identified, then those individuals are research subjects, and the provisions of 45 CFR 46, Subpart A (the "Common Rule"), including informed consent, apply. In general, grant recipients must provide a certification to the NIH that the non-exempt research with human subjects has been approved by an appropriate Institutional Review Board (IRB), consistent with 45 CFR 46 and the Office for Human Research Protections (OHRP) guidance. Prior to award, the NIH must receive the certification of the final IRB approval of the project's proposed use of human subjects.

While there are no provisions within the PHS Act that specifically require informed consent for the use of human fetal tissue in research apart from 42 USC 289g-1, NIH released an Agency policy on February 11, 2016, on consent for the use of human fetal tissue in research (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-033.html). The policy articulates NIH's longstanding commitment to ensuring that research involving human fetal tissue is conducted responsibly and meets the highest ethical standards. As such, NIH expects informed consent to have been obtained for the use of human fetal tissue in research that it supports. This expectation is in line with current practice, as most states require informed consent for the use of fetal tissue in research. All NIH conducted or funded research, regardless of program or funding mechanism, is subject to the policy.

Roby 1
Opioid Drug Abuse

Congresswoman Roby: Too often, I learn about a new family in my community who has been devastated by the opioid drug epidemic. This public health crisis knows no limits—families from every economic and social background have been confronted with the crisis. Prescription drug abuse and misuse has translated into a heroin epidemic, as well. Many people addicted to prescription drugs turn to heroin, which is generally cheaper, when they can no longer get ahold of pills. Just yesterday, I met one-on-one with the head of DEA, Chuck Rosenberg, and we discussed this in great detail. This crisis demands a dynamic and rapid response from our federal agencies and stakeholders.

Dr. Collins:

a) Please provide the committee a brief description of how the National Institute on Drug Abuse (NIDA) is collaborating with counterparts at CDC, FDA, and DEA to create a national plan for ending this epidemic?

Dr. Collins: The sharp increase of opioid-related morbidity and mortality is an issue that is of the highest importance across the Federal Government. In March of 2015, the HHS Secretary's Opioid Initiative was announced to coordinate efforts across all HHS agencies, including NIH, to implement a detailed, targeted plan to reduce opioid abuse and overdose through evidence-based strategies to:

1. Improve opioid prescribing practices
2. Increase the use of naloxone to reverse opioid overdose
3. Expand the use of medication assisted treatment for opioid use disorder

In addition, in October of 2015, President Obama announced his Opioid Initiative that expanded coordination across HHS, DOD, DOJ, and a wide range of private sector partners. In addition to addressing the three areas listed above, the President's Initiative includes strategies for nationwide public service announcement and public education campaigns.

NIDA contributes to these initiatives and coordinates activities with other agencies through:

- The Behavioral Health Coordinating Council Prescription Drug Abuse Subcommittee. This group (including NIDA, FDA, CDC, SAMHSA, HRSA, AHRQ, CMS, IHS, IOS, OASH, and ASPE) meets monthly to coordinate efforts around prescription opioids and heroin in the areas of education and prevention, treatment, surveillance, prescription drug monitoring programs (PDMP) and electronic health records, naloxone, and neonatal abstinence syndrome.
- The National Heroin Task Force, chaired by ONDCP and DOJ, includes more than 25 Federal agencies. The Task Force was charged with developing a comprehensive response to the nation's opioid crisis, and released a report in December 2015. The recommendations are premised on the following principles:
    - public safety and public health authorities must integrate and harmonize their response to the misuse of prescription opioid medications and use of heroin

  - policies regarding heroin use and misuse of prescription opioid medications must be grounded in a scientific understanding that substance use disorder is a chronic brain disease that can be prevented and treated
  - treatment and recovery services and support must be accessible and affordable
- The Office of the Assistant Secretary for Planning and Evaluation (ASPE) coordinates of the Secretary's Opioid Initiative and collects detailed qualitative and quantitative information about the implementation of the Initiative from all HHS agencies. Agency efforts are published on a rolling basis to the ASPE website[76].
- HHS Agency Priority Goal. NIDA and FDA are co-leads of the HHS FY16-17 agency priority goal to reduce opioid-related morbidity and mortality. This APG comprises discrete, quantitative goals to reach by September 30, 2017:
  - Decrease by 10 percent the total morphine milligram equivalents (MME) dispensed.
  - Increase by 15 percent the number of prescriptions dispensed for naloxone
  - Increase by 10 percent the number of unique patients receiving prescriptions for buprenorphine and naltrexone in a retail setting.

  Updates on agencies efforts are published quarterly at performance.gov[77].

NIDA's collaborations with other agencies are ongoing and have led to some recent notable results. For example:

- The recent FDA approval of NARCAN Nasal Spray for opioid overdose reversal in November 2015 was supported by a collaborative effort among NIDA, private partners, and FDA.
- Development of a buprenorphine implant (Probuphine), a novel formulation that provides stable round the clock dosing for six months. This new formulation improves the efficacy and acceptance of buprenorphine maintenance treatment by: 1) removing the need to take a daily pill, promoting continuous patient adherence; 2) preventing diversion of the drug; and 3) eliminating the risk of accidental ingestion by children. FDA accepted a resubmission of the Probuphine New Drug Application (NDA) that includes results from a Phase III double-blind clinical study in September of 2015. Agency action is expected by May 27, 2016.
- In response to the severity of opioid morbidity and mortality in Appalachia, NIDA has partnered with the Appalachian Regional Commission to provide a funding opportunity for research projects to address injection opioid use and its consequences in the Appalachian Region to determine how best to leverage available resources and programs to address the epidemic, and to improve service delivery. Results from this effort should inform better strategies to develop improved prevention and treatment interventions that can be implemented on a larger scale throughout the region. In an additional HHS collaborative effort, NIDA and FDA have partnered on a prize competition for the development of a mobile app to assist in delivering naloxone to reverse opioid overdose.
- FDA approval of extended release naltrexone, Vivitrol, for the treatment of opioid use disorders was also supported through a NIDA partnership with the pharmaceutical company Alkermes. NIDA continues to support research on effective implementation of

[76] https://strategicplanning.aspe.hhs.gov/user/login?destination=my-to-do-list
[77] https://www.performance.gov/content/reduce-opioid-related-morbidity-and-mortality?view=public#overview

this medication including a recent study demonstrating the effectiveness of Vivitrol for the prevention of opioid relapse among criminal justice offenders.[78]

b) Please explain how you already, or plan to, share that information with the states to guarantee that a collaborative effort actually is implemented at the state and local levels to combat this ongoing epidemic?

Dr Collins: NIDA disseminates scientific findings generated from our research portfolio through a variety of strategies including:

The National Drug Early Warning System (NDEWS) – NIDA has partnered with the Center for Substance Abuse Research (CESAR) to create a coordinating center for the National Drug Early Warning System (NDEWS). NDEWS was launched in August 2014 and serves as the first national public health surveillance system with the ability to identify emerging drugs threats (i.e., new synthetic drugs). NDEWS generates critically needed information about local drug use trends and their public health consequences so that rapid, informed, and effective public health responses can be developed at the national, state, and local levels. The NDEWS network includes scientists, public health experts, law enforcement representatives, and others who are part of a virtual community sharing information and assisting with local research. It utilizes both traditional and innovative sources, including social media, web scans, and information from poison control centers, and harmonizes community indicators for tracking drug trends nationally and in 12 Sentinel Sites. NDEWS has also established a Rapid Response Team (RRT) to conduct local studies of emerging drugs. NDEWS Alerts and annual reports are used to disseminate findings to a large virtual community and on the NDEWS web site.

Blending Initiative – NIDA and SAMHSA developed the Blending Initiative in 2001 to reduce the gap between publication of research results and impacts on treatment delivery. This initiative supports the development of user-friendly treatment tools and educational products to facilitate the adoption of research-based interventions into front-line clinical settings. Through this initiative, NIDA and SAMHSA's Addiction Technology Transfer Centers (ATTCs) disseminate treatment and training products based on NIDA-supported research. The ATTC network consists of 10 regional centers, four national focus area centers, and a network coordinating office that serves all 50 U.S. States, D.C., and the U.S. territories. The Blending Initiative established a Medication Assisted Treatment (MAT) work group in 2015 to focus specifically on revising health care training tools that incorporate the latest information about opioid pharmacotherapy and other treatment modalities for opioid use disorder (OUD). This work group is revising an online training module focused on effective MAT strategies that is expected to be released in 2016. Once completed, this training module will be disseminated across the ATTC network to capitalize on the local center expertise for effective implementation at the local level.

NIDAMED – NIDAMED provides evidence-based resources to help medical students, residents, practicing physicians, and other healthcare clinicians identify patient drug use early to prevent it

[78] Lee JD et al. Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders. N Engl J Med 2016; 374:1232-1242.

from escalating to addiction as well as to identify and refer patients in need of specialized addiction treatment. Several training tools have been generated:

- From 2007-2014, NIDA partnered with the American Medical Association to establish the NIDA Centers of Excellence for Physician Information (CoE) to create 12 curriculum resources about substance use, addiction, and health consequences – six focusing specifically on prescription pain medication abuse. These resources and are currently available on the NIDAMED website and through the individual CoEs.
- The NIDAMED initiative, with funding from ONDCP and in partnership with Medscape, created two continuing education modules on safe prescribing of opioids for pain and managing patients who abuse prescription opioids. From 2012-2016, 115,323 clinicians completed the modules and clinicians continue to access the unaccredited versions on the NIDAMED website.
- NIDA also established a Coalition of Healthcare Organizations to work collaboratively to develop a CME/CE on clinical strategies to prevent and address adolescent substance use and prescription medication misuse. This continuing education module will be launched in summer 2016 and is targeted to clinicians across the professional spectrum.

Stakeholder Outreach – NIDA and HHS also provide substantial educational materials through our respective websites. The NIDA webpage serves as a conduit of all agency activities, including the latest research findings, surveillance data on drug use trends, and educational materials for a variety of audiences including the public and medical and health care professionals. NIDA also has dedicated web resources tailored specifically for teens, parents, and easy-to-read information. The HHS opioids webpage provides detailed information about the current status of the epidemic (surveillance data), opioid drug facts for both consumers and health care providers, prevention and treatment strategies, overdose reversal information, and resources tailored specifically for health professionals and law enforcement. New information is actively shared and promoted using a variety of social media platforms.

NIDA Research Efforts – NIDA also supports research projects that develop and test education, training, and communication strategies to combat the opioid epidemic including:

- South Carolina Opioid Safety Initiative – a pilot study to create the South Carolina Opioid Safety Initiative – Military (SCOSI-M) - an academic detailing (medical education) intervention for physicians who treat military personnel, veterans, and their families with prescription opioids. The overall aim of SCOSI-M is to increase the use of safe prescribing and prescription monitoring practices among primary care physicians to prevent the onset or progression of prescription drug problems among Iraq and Afghanistan veterans, military members, and their families.
- Expansion of Buprenorphine Prescribers – a workforce development project that utilizes the Physician Recruitment Bundle (PRB) to increase buprenorphine prescribing capacity to treat OUD. PRB is utilizing an evidence-based organizational change model to increase buprenorphine prescribing capacity. This program will be tested in four states (FL, MS, OH, & WI).
- mHealth for MMT – developing and testing a semi-automated interactive mobile technology in seven methadone maintenance treatment (MMT) centers in Massachusetts using customizable informational, motivational and monitoring text messages to improve client motivation and build their skills to achieve better outcomes.

- BupPractic.com – developing and testing tools including a Patient Support Center to facilitate open and accurate communication between patients and providers, to help improve patient adherence, and to help providers deliver more patient-centered care for opioid use disorders.
- Implementation science for medication assisted treatment (MAT) – developing and testing strategies to facilitate the effective and sustainable implementation of MAT in settings with high rates of opioid use disorders including criminal justice settings, emergency departments, and HIV treatment settings.

DeLauro 1
Alternatives to Opioids

Congresswoman DeLauro: In 2011, the Institute of Medicine released a report demonstrating that 100 million Americans suffer from chronic pain, at a cost of up to $635 billion annually. To achieve a lasting solution to the opioid abuse, overdose and addiction crisis, there is an urgent need to identify safe, effective therapies that can replace the use of addictive medications in the treatment of chronic pain. According to the FDA, the field of chronic pain treatment is "strikingly deficient" in high-quality evidence to assess risks and benefits, leaving clinicians and patients without evidence to inform clinical decision-making on the safe and effective medical management of chronic pain.

Can you provide us with an update on your efforts to intensify and accelerate a pain research effort that will illuminate the underlying mechanisms of pain and discover safe, effective, non-addictive chronic pain therapies, that is commensurate with the human and economic burden that chronic pain imposes?

Dr. Collins: Although opioid medications have a legitimate and important role in the treatment of severe acute pain and some severe chronic pain conditions, it is clear that they often are overprescribed, or are prescribed without adequate safeguards and monitoring, and that their misuse can have devastating effects. This presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. There is a pressing need for more research to develop safer and more effective strategies for treating chronic pain. NIH's commitment to this research is reflected in our broad research portfolio that ranges from basic research on the biological mechanisms of chronic pain to clinical trials of potential treatments.

The NIH Pain Consortium coordinates research efforts across 25 NIH ICs that include:

Development of Non-opioid and Non-addictive Opioid Analgesics
Early stage drug target discovery focused on molecular pathways of pain. Numerous receptors and channels are being explored as potential non-addictive pain targets.

- Cannabinoid *compounds* have been demonstrated to modulate central and peripheral neuropathic pain. Cannabinoids and opioids have different mechanisms for reducing pain and their effects may be additive, suggesting that combination therapies may be developed that have reduced risks.
- Inflammatory mediators may influence the transition to chronic pain. A novel anti-inflammatory lipid mediator is being developed for chemotherapy induced pain. *Fatty acid binding proteins* and *G protein-coupled receptor 55* are being tested on pain behaviors in preclinical models.
- Ion channel blockers have potential to inhibit pain signaling. For example:
    - *NaV1.7 sodium channel modulation* are being tested to treat chronic pain.
    - Blocking the *Transient receptor potential cation channel A1 (TRPA1)*, a signal integrator for sensory nerve cells, may provide peripherally acting analgesia.
    - *TRPV1 (vanilloid receptor 1)* plays a role in nerve hypersensitivity; blockade may prevent transition to chronic pain.
    - *Calcium channels* are involved in key pain signaling steps.

- Drug screening and testing: A tissue-based tool for screening potential migraine drugs is under development. A library of small molecules is being leveraged to screen for candidates to move forward to optimization and pain behavior testing.
- Medicinal chemistry, safety and toxicity testing: The NIH Blueprint Neurotherapeutics Network supports development of promising drugs towards FDA approval.

Comparative Effectiveness Research

- Pragmatic trials in large health care systems:
  - A trial in Kaiser is comparing integrated pain management with standard care.
  - COllaborative Care to Preserve PErformance (COPE) trial of combined treatment for pain, disability, and disease pharmacotherapy.
  - Telehealth programs for Cognitive-Behavioral Self-management Skills Training.
- Controlled clinical trials of analgesics and unimodal interventions:
  - Surgical approaches and non-invasive interventions such as spinal manipulation.
  - Evaluating efficacy of commonly used drugs for pediatric migraine.
  - Modifications and innovative approaches for delivery of peripheral nerve stimulation to treat neuropathic pain.

Non-pharmacological Mechanisms and Treatments

- Complementary and integrative health approaches such as acupuncture, spinal manipulation, and massage, as well as mind-body approaches such as mindfulness meditation, imaging based biofeedback, stress reduction, and yoga are being assessed to determine mechanisms, long and short term efficacy, utilization, decision points of care, and cost effectiveness.
- Studies related to surgical interventions for pain include outcomes studies of joint replacement, implants of engineered tissue and back surgery, and relevant postoperative care approaches.
- Neural stimulation technologies for chronic pain: transcranial magnetic stimulation, transcranial direct current stimulation, electrical deep brain stimulation, and stimulation devices for peripheral nerves/tissues show promise for the treatment of chronic pain.
- Approaches to selectively silence or inhibit activity of pain fibers including optical stimulation using infrared laser light to inhibit activity in pain neurons.

Behavioral and Psychosocial Mechanisms and Treatment Approaches

- Psychosocial risk factors that predispose individuals to chronic pain, including:
  - Epigenetic regulation of pain following stress.
  - Pain phenotype of catastrophizing, fear of pain, and depression.
  - Risk factors for specific pain conditions.
- Biopsychosocial interventions through behavioral models and delivery of care.
  - Cognitive behavioral therapy (CBT) and its delivery through web-based technology and parent training for CBT for pediatric pain.
  - Behavioral strategies to improve treatment adherence.
  - Comorbidities to pain and disability, such as sleep disorders, depression, and anxiety inform behavioral approaches.

Basic Mechanisms of Pain to Identify New Treatment Targets

- The complex pathophysiology of chronic pain
  - Mast cells may be a therapeutic target for chronic pelvic pain.
  - Antagonists to MGluR5 are potential targets in neuropathic pain.
  - Sodium homeostasis in migraine pathophysiology is being studied.
- Identification of biomarkers for pain conditions through imaging studies of pain-altered brain function as well as molecular markers. A matrix metalloproteinase inhibitor will be evaluated as a potential biomarker for pain response and tolerance.
- The mechanisms underlying the transition from acute to chronic pain
  - Neural hypersensitivity is associated with the transition from acute to maladaptive chronic pain. Epigenetic regulation of such neural plasticity is being studied as is the role of Calcitonin gene-related peptide (CGRP) in neuro-glial interactions.

Pain & Substance Abuse/Addiction

- *Abuse-resistant opioid analgesics.*
  - A partnership with Signature Therapeutics to develop an abuse-deterrent formulation of OxyContin that uses prodrug technology—attaching an extension to the opioid molecule that renders it inactive unless it is taken orally.
  - Compounds that exhibit novel properties due to their combined activity at different opioid receptors (mu, delta, and kappa) may induce analgesia without tolerance or dependence.
  - Adjunct medications that can reduce the dose of opioids needed, resulting in lower potential for dependence and addiction.
- *Pain patient vulnerability to substance abuse:* Understanding the contributions of genetic and environmental influences and comorbidities to the nonmedical use of opioid medications will advance the development of personalized pain treatments.

Novel Devices and Therapy Delivery

- Innovative methods for drug delivery are being developed to increase specificity and efficacy, and to reduce analgesic side effects.
  - Carbon nanotubes, dissolvable micro-needles
  - Biodegradable hydrogel polymer for sustained drug release
  - Enhanced delivery through fluorination or intra-vesicular liposomes to increase bioavailability of peptide-based therapies
- Tissue engineering and regeneration to relieve pain through wound healing and joint cartilage and intervertebral disc replacements.
- Genetic manipulation and nanotechnology to modify pain by inhibiting abnormal neural activity through targeted photo-stimulation, gene expression, and toxins.
  - Viral delivery of genes to modify neural activity and inflammation for amelioration of bone cancer pain in veterinary clinics.
  - Macrophage-targeting nanoparticles to reduce inflammation.
  - Stem cell grafts targeting spinal and peripheral nerve damage.
- Portable technology such as wearable ultrasound devices and implantable micro-stimulators to relieve pain and monitoring devices to prevent falls and mange patient data are being developed.

Pain Registry
NIH is supporting the first open-access, no-cost, clinically based, retrospective and prospective chronic pain data registry to help identify pain-management interventions that are most effective for specific patient types with chronic pain.

Translational Opportunities
NIH also supports the dissemination and implementation of research findings, so that they reach patients who can benefit from them. Educating clinicians and clinicians-in-training regarding the most effective treatment modalities for pain is a crucial element of this objective. The NIH Pain Consortium coordinates collaborative pain research initiatives and activities at NIH and funds 11 Centers of Excellence for Pain Education (CoEPEs) that act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, and pharmacy schools.

DeLauro 2
HIV/AIDS Research

Congresswoman DeLauro: In the President's FY 2016 Budget, NIH requested an overall increase of $1 billion – including an increase of $100 million for HIV/AIDS research. The budget request noted that more than 35 million people worldwide are believed to be infected with HIV. The final FY 2016 Omnibus provided an increase of $2 billion for NIH – $1 billion more than requested – and yet, NIH is no longer planning to increase funding for HIV/AIDS research in 2016. Moreover, the FY 2017 Budget request would leave funding for HIV/AIDS research at the same level as 2015. I am disappointed that NIH has reversed course on HIV/AIDS funding. The Omnibus provided sufficient funds to support your initial request for HIV/AIDS research and I think you should have followed through on that proposal.

a) Dr. Fauci, can you provide an update on HIV/AIDS research? Are we making progress on a universal vaccine?

Dr. Fauci: NIH sponsors and conducts a robust and comprehensive research program of basic, translational, and clinical research on HIV/AIDS with the goal of ending HIV transmission and achieving an "AIDS free generation." Substantial progress has been made in combating HIV/AIDS through the implementation of prevention and treatment strategies developed by NIH-supported research. For example, antiretroviral drugs have significantly improved prognosis for people living with HIV by helping to control HIV infections. Recent results from an NIAID study demonstrated that starting antiretroviral treatment soon after HIV diagnosis reduces the risk of developing AIDS or other serious illnesses. NIAID research also has shown that pre-exposure prophylaxis with antiretroviral therapy is capable of preventing HIV infection in high-risk individuals. Despite this important progress, the development of a safe and effective HIV vaccine is critical to achieve a durable end to the HIV/AIDS pandemic and thus remains an overarching NIH HIV/AIDS research priority.

NIAID supports a comprehensive HIV vaccine research program through extramural and intramural research, including at the NIAID Vaccine Research Center (VRC). Investigators are working at all stages of the vaccine development pipeline to design, develop, and test vaccine candidates to prevent HIV infection. To date, NIAID has supported 148 vaccine trials to evaluate 109 vaccine products and 27 adjuvants.

NIAID's HIV vaccine development effort is built upon a foundation of basic research that provides insights into the mechanisms by which HIV establishes infection and causes disease. Understanding of viral and host factors involved in host immune responses to HIV will help investigators develop novel vaccine strategies. For example, VRC scientists discovered VRC01, a broadly neutralizing antibody that is capable of inhibiting multiple HIV strains. Phase I studies are currently ongoing to evaluate the safety and immunogenicity of VRC01. In addition, Phase IIb studies initiated in March 2016 are evaluating the ability of infusions of VRC01 to prevent infection. Knowledge of VRC01 and other broadly neutralizing antibodies' preventive properties can aid in the design of vaccines that prevent HIV infection by inducing production of these antibodies in vaccinated individuals.

In collaboration with the Pox-Protein Public-Private Partnership, NIAID supports research that builds on results from the U.S. Military HIV Research Program RV144 clinical trial. RV144 was the first study to show a candidate HIV vaccine strategy could protect individuals from infection. Based on the modest protection demonstrated by the RV144 vaccine regimen, NIAID launched the HVTN 100 Phase I/II clinical trial in South Africa to study an investigational HIV vaccine regimen that was designed to improve upon the efficacy of the RV144 regimen. If the HVTN 100 vaccine regimen is found to be safe and adequately immunogenic, NIAID and collaborators will launch a follow-up randomized controlled trial, HVTN 702, in late 2016 to test the regimen's protective efficacy.

In addition to high-priority HIV vaccine research, NIH continues to support research on HIV prevention strategies, optimization of treatment modalities, and novel therapeutic approaches toward a cure for HIV infection. Combating HIV/AIDS requires a combination of strategies and partnerships with scientific and community stakeholders. Development of an HIV vaccine would greatly advance these efforts to end the HIV/AIDS pandemic.

b) What about the long-term cost of treating HIV/AIDS? In addition to saving millions of lives, wouldn't it save the health care system – and taxpayers – an extraordinary amount of money in future health care costs if we develop a vaccine? Can you talk about the impact of a vaccine on human lives, as well as the long-term budget implications?

Dr. Fauci: Long-term treatment of HIV/AIDS represents a significant financial burden to the health care system (and often to the patient). A recent study found that the costs associated with HIV/AIDS treatment are divided among these categories: antiretroviral therapies (60 percent), other medications (15 percent), and non-drug costs (25 percent). Researchers estimated that preventing a single HIV infection could save $326,500 over the lifetime of that individual. Furthermore, cost savings could be as high as $338,400 if all HIV-infected individuals were detected early, treated early, achieved viral suppression, and remained in care.[79] These results highlight the importance of HIV prevention, early detection, and consistent antiretroviral treatment.

Approximately 1.2 million people in the United States and 36.9 million people worldwide are currently living with HIV. HIV-positive individuals who are not receiving antiretroviral treatment have significant health risks, including opportunistic infections and a dramatically shortened lifespan. However, even those living with HIV who have access to therapy often suffer from side effects associated with antiretroviral drugs. The ability to prevent additional HIV infections with an HIV vaccine would alleviate these burdens for future generations. In addition to easing strains on the health care system, development of a vaccine to prevent HIV infection would likely have a significant impact on public health and improve the quality of life for millions of people around the world.

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[79] The lifetime medical cost savings from preventing HIV in the United States. Schackman BR1, Fleishman JA, Su AE, Berkowitz BK, Moore RD, Walensky RP, Becker JE, Voss C, Paltiel AD, Weinstein MC, Freedberg KA, Gebo KA, Losina E. Med Care. 2015 Apr;53(4):293-301. doi: 10.1097/MLR.0000000000000308.

DeLauro 3
Cancer Research Initiative: Data Sharing

Congresswoman DeLauro: I'd like to hear more about your efforts to improve data sharing in the Cancer Research Initiative. According to NIH's announcement, "The cancer initiative will encourage data sharing and support the development of new tools to leverage knowledge about genomic abnormalities, as well as the response to treatment and long-term outcomes."

a) Given the huge investment of U.S. taxpayer dollars – more than $32 billion this year – how do we ensure that taxpayer-funded data are being shared most effectively by researchers, to expedite the discovery of new cures and treatments?
b) What kind of leverage is NIH using to encourage, persuade, or even compel researchers to share data, so we don't miss potential breakthroughs due to overly strict protections of data? In other words, what are the mechanisms at your disposal to expand access to taxpayer-supported information that can be useful to other researchers?

Dr. Collins: NIH has a long history (e.g., via the Consolidated Appropriations Act, 2008, P.L. 110-161, division G, section 218) and continued commitment to ensure that, to the fullest extent possible, the results of federally-funded scientific research are made available to and are useful for the general public, industry, and the scientific community. NIH has maintained the principle that "data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health." Validation and progress in science are predicated on access to research results, and, to that end, NIH has developed a number of policies to support this effort and has many activities underway to further promote sharing of data, such as the 2003 *NIH Data Sharing Policy* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html) and the 2014 *NIH Genomic Data Sharing Policy* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html).

In February 2015, NIH issued the *NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research* (http://grants.nih.gov/grants/NIH-Public-Access-Plan.pdf) in response to a White House Office of Science and Technology Policy memorandum that called for "increasing access to the results of federally funded scientific research." The goals of this directive are in keeping with NIH's ongoing and future commitments to facilitate data sharing, and the NIH Plan outlines mechanisms for expanding and strengthening access to data and publications from NIH-funded research.

NIH is working with the FDA on the development of the *Final Rule on Clinical Trials Registration and Results Submission* for applicable clinical trials. In parallel, NIH is proceeding with the development of a NIH Policy to expect the registration of all NIH-funded clinical trials and the submission of results from those trials to ClinicalTrials.gov. Additionally, in October 2015, the *NIH Intramural Human Data Sharing Policy* for responsible sharing of and secondary research with human data generated in the intramural research program, became effective.

At the programmatic level, the NIH Institutes and Centers also promote maximal scientific benefit from the data and samples generated with their funds through the establishment and maintenance of data repositories. A list of some of the data repositories that NIH supports may be found at: https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html. For

example, the NIH National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) has established data, biospecimen, and genetic repositories (https://www.niddkrepository.org/pages/about/) to ensure that these resources are available to the broader scientific community, to increase the impact of its current and previously funded studies.

NIH is also involved in many other high-level initiatives, such as the Precision Medicine Initiative (PMI), that aim to advance research, technology, and policies that empower patients and promote data sharing.

The National Cancer Institute (NCI) is also supporting a number of data sharing efforts, and the Vice President's Cancer Moonshot Initiative will provide an important opportunity to enhance and expand data sharing to support cancer research and address the needs of cancer patients.

A key example is NCI's Genomic Data Commons (GDC, http://www.cancer.gov/about-nci/organization/ccg/programs/gdc), which will provide a publicly accessible, robust, scalable infrastructure for the secure sharing of patient-level genomic data along with associated patient outcomes, diagnostic information, and therapeutic course. GDC will enable researchers and cancer health care providers to leverage information from tens of thousands of cancer cases with carefully annotated genomic abnormalities. Genomic abnormality information will also be contributed to other publicly-accessible NIH databases, such as ClinVar (http://www.ncbi.nlm.nih.gov/clinvar/) and ClinGen (https://www.clinicalgenome.org/). During FY 2016 and FY 2017, NCI will expand the GDC and similar NCI efforts with the support of cloud computing designed to provide elastic computing and cloud capabilities to the broader cancer research community. NCI plans to include in vivo and digital histopathology images and other forms of data such as gene expression data, proteomics, and tumor microenvironment within the data that we make available to extramural researchers.

In addition to the 2014 *NIH Genomic Data Sharing Policy* mentioned above, NCI further stipulates that the data supporting the primary aims of genomic experiments must also be made available, and these data be deposited in the Genomic Data Commons (http://www.cancer.gov/grants-training/grants-management/nci-policies/genomic-data).

Also, NCI is evaluating opportunities to expand the Surveillance, Epidemiology, and End Results (SEER, http://seer.cancer.gov/) registry program to establish a broader foundation for a National Learning Health System for Cancer. SEER currently includes data from roughly 30 percent of the U.S. population. The SEER registry could provide a place where every cancer treatment and care organization could upload data from every cancer patient. This would span diagnosis, pathology, biomarkers, genomics, therapeutic course, pharmacy data, and outcomes, as well as mortality data on a broad swath of cancer patients, further supporting precision medicine for oncology and a National Learning Health System for Cancer.

DeLauro 4
Ebola and Zika Updates

Congresswoman DeLauro: Dr. Fauci, in December of 2014, Congress provided $238 million in emergency funding to NIH and $157 million to BARDA for research and development of an Ebola vaccine.

a) Can you give us an update on the status of Ebola vaccine candidates, as well as therapeutics and diagnostics?

Dr. Fauci: The National Institute of Allergy and Infectious Diseases' (NIAID's) longstanding investment in biodefense and emerging infections research, which includes research on Ebola virus, enabled NIAID to respond rapidly to the Ebola outbreak in West Africa. NIAID's ongoing investment in Ebola virus research, including NIAID preclinical services offered to researchers in academia and industry, has helped to facilitate the advancement of promising candidate vaccines and therapeutics into clinical trials. Clinical trials in West Africa began in early 2015 as part of the Partnership for Research on Ebola Virus in Liberia (PREVAIL), the research partnership between HHS and the Liberian Ministry of Health.

Results released in February 2016 from the ongoing PREVAIL trials reveal significant progress toward identifying effective vaccines and therapeutics for Ebola. PREVAIL I, a randomized, placebo-controlled trial of two Ebola vaccine candidates, NIAID/GSK cAd3-EBOZ and NewLink Genetics/Merck rVSV, showed that both vaccine candidates were safe and elicited an antibody response against Ebola after one month. The PREVAIL partnership also is working to develop a Phase II safety and immunogenicity study in all three affected West African nations to study the Janssen/Bavarian Nordic Ad26.ZEBOV vaccine followed by a boost with the MVA-BN Filo vaccine alongside the NewLink Genetics/Merck rVSV. NIAID supported the early development of these vaccines. This trial is expected to begin in 2016.

NIAID also has collaborated with the biopharmaceutical industry, academia, and other Federal agencies to develop additional Ebola vaccine candidates. For example, Phase I clinical trials are planned or underway to evaluate the safety and immunogenicity of NIAID-supported vaccines including the Profectus rVSVN4CT1 vaccine; HPIV3-EbovZ GP, an intranasal Ebola vaccine; and an NIAID-developed vaccine targeting both Ebola and rabies viruses.

The NIAID-supported PREVAIL II study evaluated the candidate Ebola therapeutic ZMapp, a combination of three monoclonal antibodies targeting the Ebola virus, in a randomized controlled trial comparing optimized standard of care versus optimized standard of care plus ZMapp. This trial closed for enrollment in January 2016 due to declining cases of Ebola virus disease. Preliminary results from PREVAIL II released in February 2016 indicated that ZMapp was well tolerated and showed promise as a treatment for Ebola virus disease, however, enrollment was insufficient to establish statistically significant efficacy. In addition, BCX-4430, an investigational broad spectrum antiviral developed by BioCryst Pharmaceuticals with support from NIAID, has demonstrated protection against Ebola and Marburg viruses in animals. A Phase I trial to study intramuscular delivery of BCX-4430 is fully enrolled, and a Phase I trial evaluating intravenous delivery is planned for 2016.

NIAID-supported researchers have been working to fill the need for rapid, point-of-care diagnostics, using genomics and other novel technologies such as lateral flow immunoassay devices. NIAID provided support for several Ebola virus diagnostic tests that have been granted Emergency Use Authorization by the Food and Drug Administration (FDA) for use in the United States and approved by the World Health Organization for emergency deployment in West Africa. These include FilmArray (BioFire Diagnostics), a multiplex polymerase chain reaction system; ReEBOV Antigen Rapid Test Kit (Corgenix), a rapid immunodiagnostic; and the Xpert Ebola Assay (Cepheid), a real-time reverse transcription polymerase chain reaction test to detect Ebola RNA. In addition, ongoing genome sequencing efforts and resources through NIAID's Genomic Center for Infectious Diseases and Virus Pathogen Resource (ViPR) Bioinformatics Resource Center provide additional genomic information about the circulating Ebola virus strain and computational tools for data analysis. Shared in real-time in publicly accessible international data repositories at the NIH's GenBank, this genomic information is helping researchers to understand Ebola virus evolution, transmission, and pathogenesis, as well as inform strategies for developing new therapeutics, vaccines, and diagnostics.

NIAID, in collaboration with CDC and the government of Liberia, continues to support the ongoing PREVAIL III trial, a natural history study following survivors of Ebola and their close contacts. The study is aimed at developing a better understanding of the long-term health consequences of Ebola virus infection to determine if survivors develop immunity that will protect them from future Ebola infection and assess whether individuals can transmit Ebola infection to close contacts and sexual partners. Preliminary findings from NIAID researchers and colleagues have revealed eye, musculoskeletal, and neurological problems among Ebola survivors. These initial results also outlined the risk of sexual transmission, demonstrating that Ebola virus material could persist in semen up to 18 months after Ebola symptoms subsided, and that individuals could have intermittent detection of the virus. PREVAIL III will continue to inform our understanding of Ebola virus disease.

Emergency funding provided by Congress in 2014 has allowed NIAID to conduct studies to advance the development of medical countermeasures for Ebola virus disease. While Ebola virus in West Africa has been largely contained with the support of the Federal Government and international response efforts, the successful suppression of new Ebola cases also limits the ability to conduct large, randomized trials to evaluate Ebola medical countermeasures. However, NIAID has made significant progress toward identifying effective vaccines and therapeutics through the PREVAIL trials, and will continue to pursue promising Ebola vaccines and other medical countermeasures with international and domestic partners. It is anticipated that the data from the ongoing efforts will be of value in eventual licensure decisions by the FDA.

b) The administration has also asked for $130 million in emergency funding for NIH – as well as $100 million for BARDA – to develop a vaccine for Zika and chikungunya, as well as support basic research on Zika. You've said in the past that a Zika vaccine candidate could be ready for a Phase I clinical trial by the end of this year, and potentially a Phase II clinical trial in early 2017.

Can you tell us about the vaccine research you have been able to support while you wait for Congress to fund a Zika package? Are you still hoping to start a Phase I clinical trial this year?

Dr. Fauci: NIAID has long supported an extensive flavivirus research portfolio which includes efforts to combat diseases caused by such viruses as dengue, yellow fever, and West Nile virus (WNV). NIAID's flavivirus research has provided a strong foundation for the development of a Zika virus vaccine in response to the recent Zika epidemic. The Administration has requested emergency funding to build on the Federal Government's ongoing preparedness efforts for Zika virus and to support strategies to combat this virus, including research to understand the transmission and pathogenesis of the virus and to develop medical countermeasures such as improved diagnostic tests and effective treatments and vaccines.

Currently, NIAID is investigating multiple Zika virus vaccine candidates and leveraging vaccine platforms and technologies that have shown promise in targeting other flaviviruses. For example, NIAID Vaccine Research Center scientists are working on a DNA-based Zika virus vaccine candidate similar to a WNV vaccine previously developed by NIAID. Phase I clinical testing of the WNV vaccine candidate showed it was safe and generated a robust immune response, indicating that this platform may be promising for Zika vaccine development.

NIAID scientists also are developing a live-attenuated Zika vaccine candidate that employs an approach similar to the dengue virus vaccine developed by NIAID that is currently in Phase III clinical trials in Brazil. NIAID, in partnership with the Walter Reed Army Institute of Research (WRAIR) and the Biomedical Advanced Research and Development Authority (BARDA), is working to develop a whole particle inactivated Zika virus vaccine. In addition, NIAID is supporting the early stages of development of a Zika virus vaccine based on a recombinant vesicular stomatitis virus (VSV), which uses the same animal virus platform as the NewLink Genetics/Merck rVSV Ebola vaccine candidate tested in West Africa.

NIAID plans to conduct a Phase I trial to evaluate one or more NIAID-supported Zika vaccine candidates in fall of 2016. NIAID will continue its efforts to respond rapidly to Zika virus and accelerate research to develop needed medical countermeasures, including a vaccine to prevent Zika infection, as well as improved Zika diagnostics and safe and effective Zika therapies. The emergency funding requested by the Administration would support and help advance these ongoing research efforts.

c) If Congress doesn't pass an emergency Zika package, will you have to slow down research on other vaccines to support your work on Zika? If so, what kind of research will be put on hold?

Dr. Fauci: The Administration has requested $1.9 billion in emergency funding to enhance ongoing efforts to prepare for and respond to the Zika virus domestically and globally. In immediate response to the Zika epidemic, NIAID expanded its longstanding flavivirus research portfolio by supporting established flavivirus scientists to conduct research on Zika. Additionally, intramural scientists in NIAID's Vaccine Research Center have quickly transitioned to focus on developing a Zika vaccine. NIAID has been able to rapidly respond to

the Zika virus epidemic with existing resources, but additional resources from the Supplemental are needed to make progress on the next stages of clinical trials and related research. Additional Zika research without the new funding requested in the Supplemental can only come at a cost to other research endeavors.

NIAID plans to conduct a Phase I trial to assess the safety of one or more promising Zika vaccine candidates in fall of 2016. Should this Phase I trial demonstrate that a candidate Zika vaccine is safe and produces a robust immune response, NIAID would be unable to prepare for Phase II/IIb studies to assess vaccine efficacy without additional resources. At that time, NIAID would be required to choose between advancing Zika virus vaccine candidates and continuing research on other important research programs, including development of vaccines for diseases such as malaria, tuberculosis, and HIV.

NIAID will continue to actively pursue effective diagnostics, therapeutics, and vaccines to address the public health threat posed by the newly-emerged Zika virus. However, the funding designated to the NIH in the emergency funding request will be necessary to advance candidate Zika countermeasures to the next stages of development.

DeLauro 5
New Research Project Grants (RPGs)

Congresswoman DeLauro: The FY 2017 Budget for NIH would support an overall increase of about 600 research project grants. But given the significant funding boost in FY 2016, the increase in grants would be devoted to noncompeting awards. In fact, the number of new or competing awards would decline by more than 800 grants. In recent years, NIH has made the case that young researchers are leaving the field – or not starting careers – because they can't get their first grant.

a) Aren't we moving in the wrong direction if NIH is proposing to fund 800 fewer new or competing grants in FY 2017?

Dr. Collins: NIH would prefer to maintain or increase the number of new or competing research project grants each year. However, that is not possible at the funding level of the FY 2017 President's Budget in light of the large increase in FY 2016, which will cause a substantial rise in noncompeting awards in FY 2017. Since NIH has already invested in such research projects for one year or more, it strives to avoid cutting back on those commitments to existing grants. While the estimated FY 2017 level of new or competing awards is less than the FY 2016 level, it is still higher than eight of the last ten years. That should help NIH support young researchers as much as possible within available funding. In addition, the total number of research project grants, which includes new and competing, and noncompeting grants, is projected to increase by 600 at the funding level of the FY 2017 President's Budget. This increase indicates that the amount of scientific projects and opportunities funded by NIH is proposed to increase from the prior year.

Congresswoman DeLauro: According to the NIH budget office, the average cost of a new or competing grant is $468,500. That means we would need to add another $378 million above the President's request in order to maintain the level of new or competing awards in FY 2017.

b) Do you agree with those figures?

Dr. Collins: Yes. Under those assumptions, an additional $378 million would be required to equalize the number of competing RPGs in FY 2017 to the estimated 10,753 competing RPGs supported by FY 2016 appropriations given the projected average cost factor indicated in the FY 2017 President's Budget request.

DeLauro 6
Precision Medicine Initiative

Congresswoman DeLauro: We are pleased the NIH is considering novel approaches to recruiting and retaining people in the Precision Medicine Initiative (PMI), including the use of social media to attract volunteers. However, some scientists have expressed concern that using social media in this capacity will affect how representative PMI volunteers will be of the general population.

a) How will you understand the inherent biases this approach presents, particularly given the fact many people do not use social media at all?
b) Is the NIH working with NCHS or other federal partners that fund or conduct large, representative surveys to understand the biases in the PMI million person cohort?
c) Is NIH sponsoring research on the general question of how to use social media for research purposes?

Dr. Collins: The PMI Cohort Program will use a variety of methods to attract volunteers. Social media is but one of the outreach methods that will be used to attract participants, and the enrollments of the Cohort will be carefully monitored to ensure that our outreach approach is reaching a broad range of U.S. participants. NIH supports research on how to use social media for research purposes through funding opportunity announcements, like two recent companion RFAs on Using Social Media to Understand and Address Substance Use and Addiction (RFA-CA-14-008 and RFA-CA-14-009), which support 11 awards across three NIH Institutes for $11 million (over three years) to explore the use of social media to advance the scientific understanding, prevention, and treatment of substance use and addiction. NIH also sponsored the NIH Digital Health Summit 2015: Optimizing Digital to Reach Patients, Scientists, Clinicians, and the Public which was designed to encourage discussion and to strengthen scientific communications communities around the digital and social media strategies used in health and science agencies.

The PMI Cohort will not attempt to be a representative sample of the United States. Rather, the PMI Cohort will build a very large and very diverse cohort of participants from across the United States. This will allow the PMI Cohort to establish generalizability using a different approach: by having a diverse sample, it will have many subsamples that are composed of members of specific subgroups. By having a large sample, those subsamples will be large enough to develop estimates of effect and association for many of those subgroups. That will allow researchers to judge how similar those estimates of effect and association are across a variety of subgroups within the PMI Cohort, and so, to establish the generalizability of their findings. The development of this approach included extensive consultation and input from expert advisors through the ACD PMI Working Group process.

DeLauro 7
Environmental Influences on Child Health Outcomes (ECHO)

Congresswomen DeLauro: ECHO is proposing to use existing cohorts – perhaps augmented with some new data collections – as a key part of understanding child health. Cohorts can be large, representative samples of children, which ensure that different groups are included, such as children in low-income families or minority groups. This strategy allows researchers to get a better understanding of the normal trajectory of child development.

a) Have you selected any cohorts yet? Will the array of cohorts include broad population samples?

Dr. Collins: NIH states that it will ensure key measures are harmonized across these different cohorts.

b) Will you also include measures that are specifically designed to compare the study cohorts to known national samples? For example, are you working with National Center for Health Statistics to ensure that the ECHO cohorts include measures that would allow you to compare subjects to studies such as the National Health and Nutrition Examination Survey (NHANES)?

Dr. Collins: The Environmental influences on Child Health Outcomes (ECHO) program will leverage existing resources to investigate the longitudinal impact of early childhood environmental exposures (e.g., physical, chemical, biological, social, behavioral, natural and built environments) on pediatric development and health outcomes with high public health impact. One specific component of ECHO – the IDeA States Pediatric Clinical Trials Network (ISPCTN) – will leverage the infrastructure at existing IDeA state centers by embedding clinical trials experts at IDeA State locations, facilitating their partnership with other academic institutions.[80] This national pediatric research network may also help address access gaps for rural and medically underserved children.

NIH recognizes the importance of robust recruitment plans that can address racial and ethnic minority health issues reflective of the needs of the U.S. population. When making awards, NIH will strive for a balance between a robust characterization of environmental factors, including consideration of geographic diversity, and health-related endpoints. Additionally, the ECHO program aims to utilize both large studies to build a repository on the trajectory of healthy development over childhood (health controls), and small, selective studies to address interesting targeted questions that are specific to a disease or have a high-risk population.

Last fall, seven Funding Opportunity Announcements (FOAs) were released to solicit applications for the ECHO program. The applications were due on April 15, 2016, and will be reviewed this summer. Awards are anticipated to be made in September 2016; therefore, no specific cohorts have been selected for funding as of yet. Any investigator with an existing relevant cohort, whether it is supported by NIH or not, was encouraged to apply.

NIH states that it will ensure key measures are harmonized across these different cohorts.

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[80] https://www.nigms.nih.gov/Research/CRCB/IDeA

A major feature of the ECHO program is the sharing and harmonization of data across all of the cohorts. Standardized core data elements will be addressed across all studies: demographics; typical early health and development; genetic influences on early childhood health and development; environmental factors; and Patient/Person (parent and child) Reported Outcomes (PROs). During the planning phase, the ECHO Steering Committee, which will be composed of the principal investigators of the ECHO projects, cores and centers, the ECHO ISPCTN, and the NIH ECHO Program Director and staff, and the External Scientific Board, composed of external experts, will develop and provide valuable input on standardizing the collection of the core elements. They will be strongly encouraged to consider how these data could be compared to known national samples. Additionally, the Children's Health Exposure Analysis Resource (CHEAR) is a network of laboratory hubs that provides researchers access to comprehensive laboratory and data analysis services to measure environmental exposures. CHEAR is expected to become operational in the summer of 2016, and will have the capability of measuring the majority of targeted analytes the Centers for Disease Control and Prevention measures for NHANES, as well as others. The ECHO program is leveraging this existing resource to analyze personal environmental exposures from existing and prospective ECHO sample collections. Therefore, researchers should be able to compare much of the data generated from ECHO with that of other large studies.

DeLauro 8
Role of Taxpayers in Drug Development (plus Zika follow-up)

Congresswoman DeLauro: Taxpayers provide more than $30 billion annually to support NIH's research. As you note in your testimony, Dr. Collins, NIH conducts the basic science that "fosters innovation and ultimately leads to effective ways to treat complex medical conditions." And yet, in many cases, taxpayer-funded research leads to drugs that are then sold back to taxpayers at exorbitant costs. For example, U.S. taxpayers funded research at UCLA that eventually led to a patent for Xtandi, a drug to treat prostate cancer. But the drug now costs U.S. patients $129,000 (before rebates). The same drug costs patients in other countries about one-third that amount. I realize that pharmaceutical companies invest their own resources to bring a new drug to market. And I believe they should make a profit for their innovation.

a) But I want to know why U.S. taxpayers are getting gouged for drugs that wouldn't exist without the significant investment of U.S. taxpayers?
b) Dr. Collins, can you better explain why U.S. taxpayers are paying for biomedical research on the front end and also paying exorbitant prices for the resulting treatments on the back end?

Dr. Collins: NIH funds a broad expanse of biomedical research from basic to applied. Many new drugs are discovered based on the published research supported by NIH where basic biologic mechanisms are elucidated, gene sequences identified, and new targets for disease intervention are identified. Many significant improvements in public health flow from this system of research support where some new drugs are discovered with NIH funds and many more by industry. Overall, the benefits to Americans from these biomedical advances have been quite significant in reducing deaths and debilitating diseases. The issue of patients' access to drugs is of serious concern to the NIH and the HHS. NIH does not have many levers to pull in addressing this matter. However, in her March 2nd letter to members of Congress who expressed concerns about the rising costs of drugs, the Secretary explained actions that HHS has taken to address this matter.

Congresswoman DeLauro: In January, I joined 50 of my colleagues in sending a letter to you and Secretary Burwell, requesting that NIH and HHS assert "march-in rights" when taxpayer-funded research leads to a patented product that is not "available to the public on reasonable terms."

c) In your view, what are "reasonable terms?" Do you believe that it is reasonable for a drug company to charge U.S. taxpayers $129,000 for a drug whose research was funded by those same taxpayers?

Dr. Collins: It is outside the scope of NIH's mission to determine whether a drug is reasonably priced.

Congresswoman DeLauro: Dr. Fauci, the administration's request for emergency supplemental appropriations for Zika includes $130 million for NIH research, as well as $100 million for BARDA to support advanced research and development. The request includes funds for NIH to develop a vaccine for Zika and chikungunya "including the clinical testing phases up to the time when external interests would be willing to take over commercial development."

d) If NIH scientists develop a vaccine candidate that is successful in early clinical testing, what policies would be used to ensure that Americans have access to an eventual vaccine on "reasonable terms?"

Dr. Collins: The NIAID mission is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID research has led to new vaccines, therapeutics, diagnostics, and other technologies that have improved health and saved millions of lives in the United States and around the world.

NIAID's longstanding commitment to research on emerging and re-emerging infectious diseases allows NIAID to quickly respond to newly emerging threats wherever they occur. In response to the ongoing Zika virus outbreak, NIAID has expanded its portfolio of basic research on Zika virus and other flaviviruses and has initiated efforts to develop improved diagnostics, and effective therapeutics, and vaccines. NIAID is currently investigating multiple Zika virus vaccine candidates, including vaccines based on technologies that have shown promise in targeting other flaviviruses. The President's emergency funding request for NIH would help support development of vaccines to prevent Zika virus infection, from the discovery phase through preclinical and early clinical testing. The emergency funding request also would support basic research to better understand Zika virus pathogenesis; establishment of animal models; development of diagnostic tests; and discovery and preclinical development of new therapeutics. NIAID expects to initiate early-stage clinical trials of NIAID-supported candidate Zika vaccines in the fall of 2016.

Partnerships between NIAID and industry, academia, and other federal government agencies are essential to develop and advance promising therapeutics, diagnostics, vaccines, and prevention technologies toward eventual commercialization and licensure for the benefit of the public health. Private businesses and nonprofits who develop effective products with the support of federal funding, by law, may retain ownership of the invention as long as they make reasonable attempts to move the product toward licensure and commercialization. In the case of Zika, there is significant interest from industry partners to work with NIAID to develop and commercialize promising Zika vaccine candidates to address the ongoing outbreak in the Americas.

NIAID remains committed to ensuring that the results and accomplishments of all NIAID-funded activities, including the development of an effective vaccine against Zika, are made as widely available to the public as possible. While NIAID does not play a role in pricing, we will continue to make the reduction of health disparities and improvement of health for all people an overarching priority as research advances are translated into medical products.

DeLauro 9
Hearing Loss

Congresswoman DeLauro: What actions is the National Institute on Aging taking to prioritize research to understand the impact of hearing loss on the health and functioning of older adults, particularly with respect to supporting studies to determine if treating hearing loss could reduce the risk of cognitive decline, Alzheimer's disease, and other dementias?

Dr. Collins: Data from the National Institute on Deafness and Other Communication Disorders indicate that nearly 25 percent of Americans aged 65 to 74, and 50 percent of those 75 and older, have disabling hearing loss. However, among adults aged 70 and older with hearing loss who could benefit from hearing aids, fewer than one in three has ever used them. In addition to the interpersonal, social, and safety challenges associated with hearing loss, epidemiologic studies suggest that age-related hearing loss in older adults is independently associated with accelerated cognitive decline and dementia. The causes of this association are unclear, but mechanisms may include the greater "cognitive load" associated with reduced auditory comprehension, as well as reduced social engagement.

The National Institute on Aging (NIA) continues to support a robust portfolio of research on sensory disorders of aging, including age-related hearing loss. This research includes studies delineating and comparing the effects of normal aging versus neurodegenerative processes or diseases of sensory function; designing assistive technologies; and developing preventive and therapeutic interventions for age-related sensory impairments. Current projects include:

- The Epidemiology of Hearing Loss Study, which explores the associations among age-related impairments in hearing and sense of smell and cognitive decline. (5R37AG011099)
- A Program Project to develop treatments for age-related hearing loss and to determine the relationship between brain plasticity and hearing loss in older adults and animal models. (2P01AG009524)
- Studies to elucidate the interacting effects of cognitive aging and age-related hearing loss on everyday speech comprehension. Results may contribute to a framework for early detection of pathological change as it affects language comprehension in the aging brain. (5R01AG019714; 5R01AG038490; 5R01AG009191)
- Planning activities for a clinical trial to investigate whether existing hearing loss treatments can reduce the rate of cognitive decline in older adults. (R34AG046548)

NIA also supports the National Academy of Sciences Board on Behavioral, Cognitive, and Sensory Sciences, which monitors advances and developments in these areas, including hearing loss. This group meets semi-annually.

Roybal-Allard 1
Obesity Nutritional Intervention

Chairwoman Roybal-Allard: Obesity and diet-related illnesses are at epidemic levels. According to the Centers for Disease Control and Prevention (CDC) data, obesity rates in the United States have doubled for adults and tripled for children since 1980. Two thirds of American adults and one third of U.S. children are obese or overweight, and these high rates of obesity are contributing to an alarming increase in diet-related illnesses. In fact, obesity related illnesses such as heart disease, stroke, type 2 diabetes and certain cancers are now some of the leading causes of death. Furthermore, these largely preventable, diet related illnesses are costing our already strained healthcare system hundreds of billions of dollars. CDC estimates that medical costs related to obesity were as high as $147 billion in 2008, and one can assume they have only risen since then.

CDC's Division of Nutrition, Physical Activity, and Obesity (DNPAO) has identified a promising obesity intervention that uses prescriptions as vouchers for fruit and vegetables with low income pediatric and adult patients. The program has shown remarkable success in lowering BMI and increasing fruit and vegetable consumption in a short timeframe. CDC is interested in testing the model to determine its efficacy in lowering BMI and reducing obesity and obesity-related illnesses in a long term, more rigorous clinical study and has suggested a possible joint trial-study of the model with the NIH, somewhat similar to the collaborative work on the National Diabetes Prevention Program.

a) Do you think that an intervention to reduce preventable, obesity-related illnesses would be relevant to multiple Institutes, and if so, which institutes would be the most appropriate to work on this effort?
b) Who should CDC coordinate with at NIH to discuss and begin the planning for such a study?

Dr. Collins: a) Yes, such interventions would be relevant to many NIH components, including NIDDK, NHLBI, NICHD, NCI, NIMHD, the NIH Office of Disease Prevention and Office of Behavioral and Social Science Research, and others. Recognizing the importance of preventing obesity and its related illnesses, NIH supports research on a variety of intervention strategies, including those focused on diet and physical activity in adults and children, along with research to better understand contributors to obesity and basic research that can lead to ideas for potential new and targeted intervention strategies. Researchers with promising ideas can submit applications, which are then evaluated through a two-step peer review process. When an intervention proves to be successful, potential strategies for scaling the intervention can be evaluated in translational research studies. The efforts of many sectors of society are of benefit to identifying strategies to scale up effective interventions for the broader population.

NIH routinely collaborates with our colleagues at the Centers for Disease Control and Prevention (CDC) on efforts related to obesity and its associated illnesses. One example is the National Collaborative on Childhood Obesity Research, a partnership among the NIH, CDC, Department of Agriculture (USDA), and the Robert Wood Johnson Foundation. (Within NIH, this effort is coordinated within the NIH Obesity Research Task Force.) NIH would welcome discussions

with CDC of their findings from intervention studies that show promise, and consideration of potential next steps.

b) For CDC to coordinate with NIH and discuss their findings about this intervention strategy and future studies they envision, CDC could contact the NIH Obesity Research Task Force, which has representatives from many NIH components.[81] CDC also is welcome to discuss their findings in other venues in which they collaborate with NIH.

[81] http://obesityresearch.nih.gov/about/about.aspx#taskforce

Roybal-Allard 2
Pediatric Inclusion in NIH Research

Congresswoman Roybal-Allard: In 1993, Congress required the inclusion of women and minorities in NIH research (Pub. L. 103-43, 42 U.S.C. 289a-2), but no such provision existed for children. After advocacy by the American Academy of Pediatrics and directives from the House and Senate in Fiscal Year 1996 appropriations reports, NIH published a formal policy requiring the inclusion of children in research. Since that time NIH has tracked the inclusion of women and minorities in NIH funded research by gathering data on the sex/gender and race/ethnicity of enrollees in clinical trials, but has not systematically tracked the ages of those enrolled in trials.

Over the last few years Members of Congress have expressed their concerns that this lack of tracking leaves NIH unable to sufficiently answer questions about whether children are appropriately included in trials pertinent to them. As such, Congress has taken several recent actions to direct NIH to improve its tracking of children, including report language accompanying the FY2016 Consolidated Appropriations Act, and inclusion of the *Children Count* Act (H.R. 2436) as Section 1083 of the 21st Century Cures Act (H.R. 6) which was passed by the House of Representatives last July.

The NIH FY17 Budget Justification responded to Congressional directives on pediatric inclusion by stating that:

> *"... NIH is pursuing plans to collect age-related inclusion information for research studies to support enhanced analyses and reporting on inclusion by age, while balancing the interests of the scientific research community to minimize the administrative burden imposed by new reporting requirements... "*

and noting that :

> *"The collection of age-related data poses a number of special challenges that require thoughtful consideration... Input from experts will be needed to identify the best way to report on age-related inclusion information... NIH leadership is discussing hosting a workshop involving experts on pediatric and older populations to provide input on the best approaches to determine the appropriate age groups to be included in research studies involving human subjects."*

a) Please tell this committee which experts will be invited to the workshop, and when that workshop will be held.
b) Will the same experts be able to identify the best ways to report on age-related inclusion information?
c) Please explain how collecting this information will increase the reporting burden, and how NIH will identify the least burdensome approach to reporting that still achieves a full understanding of pediatric inclusion.
d) What is your timeline for resolving these issues and making universal reporting of pediatric inclusion a part of all NIH research?

Dr. Collins: NIH is committed to the inclusion of all relevant age groups in the clinical research studies and clinical trials it supports; inclusion is essential to ensure that NIH is supporting sound science that will ultimately inform clinical practice to the benefit of all who are affected by the

disease or condition under study. Special attention is warranted for both younger and older (over 65 years) participants in the conduct of health research. NIH is pursuing plans to collect age-related inclusion information for research studies to support enhanced analyses and reporting on inclusion by age, while balancing the interests of the scientific research community to minimize the administrative burden imposed by new reporting requirements.

NIH already collects certain information on age through grant applications and registration and reporting in ClinicalTrials.gov. NIH is examining various approaches to adapt its current information collection on age of research participants (particularly children under 18 years and adults 65 and older) to facilitate more in-depth analyses.

NIH leadership also is exploring different ways to engage the scientific and stakeholder communities on the important issue of considering age in our research portfolio. Two key efforts underway are: 1) to consider additional approaches for collecting age information; and 2) as the Committee is aware, a workshop to discuss issues related to measuring and enhancing inclusion of these populations. Previously, NIH outlined some of the existing concerns around how to implement further collection of age-related information. Age is a continuous variable, whereas the other demographic characteristics about which NIH collects information on inclusion are categorical variables: gender, race, and ethnicity. There are no clearly defined, scientifically meaningful categories to describe age across different diseases/conditions, which poses particular challenges. Rather than adding to the complexity of the current data collection for sex/gender, race, and ethnicity, NIH is planning to conduct a pilot on a subset of NIH-supported clinical trials to collect de-identified individual demographic information (age, sex/gender, race, and ethnicity). This approach would likely reduce confusion among investigators and also would collect the information in a manner that is compatible with how investigators already obtain and store information when conducting a clinical study. Another potential advantage will be that NIH will capture this demographic information in a way that allows more flexibility in the analysis of representation in our scientific portfolio. NIH is currently preparing a request for OMB clearance for this pilot and identifying the resources needed to complete it. In addition, NIH is currently requesting support from the appropriate governance committee to develop the new functionality for monitoring age data, and we hope to implement the pilot by mid- to late 2017. The experiences and data collected from this pilot project will inform a workshop convened for the purpose of refining and improving our approaches to evaluating and enhancing inclusion.

Data from the pilot project for collecting data on participant age is needed to inform the workshop participants about what is feasible in terms of collecting and reporting on age of inclusion. Thus planning for the workshop is still in its preliminary stage. We have not yet identified specific experts who will participate. However, NIH anticipates engaging individuals from key stakeholder groups including, but not limited to, NIH staff members with relevant expertise, including staff at ClinicalTrials.gov, relevant Food and Drug Administration staff members, grantees with expertise in conducting clinical trials and other types of clinical studies, particularly those with expertise in pediatric or aging populations, and professional organizations such as the American Academy of Pediatrics, American Geriatrics Society, Gerontological Society of America, Alliance for Aging Research, and the American Federation for Aging Research. NIH goals for this workshop are to consider a range of approaches to obtain

individual-level patient demographic data in a way that is user-friendly, efficient, affordable, and wholly secure. Some of the feedback NIH would like to obtain includes:

- How investigators consider age in designing their studies;
- Ethical considerations of including pediatric and older populations;
- Ways to avoid exclusion criteria that are not scientifically or ethically driven; and
- Feedback on the pilot study to collect individual demographic information.

Staff members from the Office of Extramural Research in the Office of the Director, NIH and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development recently met with the American Academy of Pediatrics to discuss issues around the inclusion of children, including discussion of the concept of collecting individual-level demographic information. NIH will pursue discussions of this concept further to include feedback from other stakeholder groups.

Roybal-Allard 3
NCATS

Chairwoman Roybal-Allard: The National Center for Advancing Translational Sciences is to be commended for its work to increase the testing and screening of chemicals and compounds for human effects. This science is transformative as it will create more predictive results for regulating chemicals and developing new, targeted drugs, while also seeking to eliminate the use of animals.

a) Your own public statements call for the elimination of animals in this type of testing. When do you predict it will be possible to phase out the use of animals in testing for risk assessments or safety and efficacy testing?

Dr. Collins: Advances in science and technology are providing unprecedented opportunities to develop non-animal biomedical research models that can be used to test chemicals and compounds for safety and effectiveness in humans. While these advances are expected to result in fewer numbers of animals used in biomedical research, there are few alternatives at this time, and the adoption of alternatives to animal models will be gradual, thus making a specific timeframe unpredictable at this time. NIH encourages the use of the most appropriate models for scientific research, including animal models, and also supports scientifically valid new test methods that replace, reduce or refine animal use.

For example, NIH continues to work on alternative test methods through programs such as the Tissue Chip for Drug Screening Program. This program, run by NCATS along with partners from the Defense Advanced Research Project Agency and the Food and Drug Administration (FDA), is developing miniaturized platforms engineered to support 3-D living human tissues and cells, called tissue chips or organs-on-chips. Tissue chip devices are designed to mimic the structure and function of human organs, such as the lung, liver and heart. Researchers intend to use these models to predict whether a candidate drug, vaccine or biologic agent is safe or toxic in humans in a faster and more predictable way than current methods. Currently, the chips are being integrated together to enable researchers to test the effects of a drug or compound across the "human on a chip" before any testing in humans. In addition to those that are models of healthy organs, future plans include the development of tissue chips to model diseases, including rare diseases.

NCATS also works with the National Institute of Environmental Health Sciences, the Environmental Protection Agency, and FDA on the Toxicology in the 21st Century (Tox21) program, through which scientists are developing better toxicity assessment methods to quickly and efficiently test whether certain chemical compounds have the potential to disrupt processes in the human body that may lead to negative health effects. Using NCATS' high-throughput robotic screening system, scientists are testing a collection of 10,000 environmental chemicals and approved drugs (called the Tox21 10K library) for their potential to disrupt biological pathways that may result in toxicity. The team prioritizes promising compounds identified from primary screening for further in-depth investigation. One use of the data being produced is the development of computational models that can predict compounds' interference in biochemical pathways using only chemical structure data.

In addition, the NIEHS National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the 15 Federal agencies of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) work together to promote the regulatory acceptance of scientifically valid new test methods that replace, reduce or refine animal use. NIH recognizes the important contributions animals have made to the conduct of biomedical and behavioral research. Though the responsible use of these invaluable resources continues at this time, NIH is dedicated to identifying innovative approaches that reduce their use while maintaining the highest standards for scientific research aimed at improving public health.

Roybal-Allard 4
Social Media and Health Intervention Information

Congresswoman Roybal-Allard: Social media is increasingly being used to deliver health intervention information, particularly information targeted to specific demographic populations such as pregnant women and young adults.

a) To what extent has NIH research focused on the effectiveness and best practices of social media interventions to encourage compliance with recommended health guidelines and the promotion of healthy behaviors?

Dr. Collins: Social media has substantially changed the internet communication landscape, making it increasingly interactive and participatory. Social media is being leveraged more frequently by the biomedical and behavioral research community to assess population trends, deliver interactive health promotion and disease management interventions, and provide virtual community support. Recent successes in the utilization of social media campaigns to augment traditional approaches to inform and shape the U.S. population's health behaviors has prompted NIH to establish concerted efforts to build the research infrastructure necessary to propel the field forward. In addition, the Agency is fostering research programs that aim to promote the development and dissemination of effective methods for leveraging the power of social media to improve human health.

Evidence of these efforts is borne out in the analysis of the NIH research portfolio on social media. Between FY 2010 and FY 2015, NIH invested in 466 discrete projects regarding the effectiveness of social media interventions on health outcomes. Over 200 of these projects were R-series grants, the primary funding mechanism for scientific research projects, on which the NIH spent a total of $111 million. NIH investments in social media interventions research have increased substantially over time. In FY 2010, NIH funded only 13 projects in this area, spending approximately $6.5 million; in FY 2015, there were over 100 such funded projects, totaling over $150 million.

Social media interventions research funded by NIH spans multiple scientific disciplines and health areas, predominately in the following areas: HIV and sexually transmitted infection prevention and management, adolescent health, smoking cessation, alcohol and substance abuse interventions, and mental health and suicide prevention. Many of these grant awards were from researcher-initiated applications, but some bave originated from NIH research programs designed to evaluate social media as a tool for health. One such program is part of the trans-NIH Collaborative Research on Addiction (CRAN) initiative. CRAN has issued two funding announcements to inspire and support research projects investigating the role of social media in risk behaviors associated with the use and abuse of alcohol, tobacco, and other drugs, including intervention research measuring the reach, engagement, and behavioral and health impact of social media-based interventions for screening, prevention, and treatment of substance use and addiction.[82] To date, these solicitations have garnered a response of 136 applications, 24 of which have received awards, and resulted in 116 base projects.

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[82] CA-14-008 and CA-14-009

One study receiving CRAN initiative funding, led by Dr. Megan Moreno of Seattle Children's Hospital, is examining the impact of social media interventions on substance use in adolescents.[83] The transition to college is a critical time, often associated with initiation or escalation of substance use among teens.[84] Youth substance use behaviors are often shaped by peer and media influences, including peer-generated media messages on social media, a property of social media described by the Facebook Influence Model.[85,86] Dr. Moreno's group will be using marketing research techniques and rigorous testing to develop, deploy, and evaluate a Facebook-based intervention for the prevention of substance use initiation and escalation in college students.

CRAN represents one of many concerted efforts by the NIH to leverage the capabilities and ubiquity of social media to promote health and manage disease, and to rigorously evaluate the impact of these interventions. While considerable research progress has been made, social media is a rapidly evolving technology. NIH research efforts need to keep pace with the technology and continue to support research that fosters the development, evaluation, and rapid implementation of effective, evidence-based social media intervention strategies.

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[83] 1-R01-AA023997-01

[84] Schulenberg, J.E, & Maggs, J.L. (2002). A developmental perspective on alcohol use and heavy drinking during adolescence and the transition to young adulthood. *Journal of Studies on Alcohol.* (S14):54-70. doi:10.15288/jsas.2002.s14.54

[85] Litt, D.M., & Stock, M.L. (2011). Adolescent alcohol-related risk cognitions: The roles of social norms and social networking sites. *Psychol Addict Behav,* 25(4):408-713. doi:10.1037/a0024226

[86] Moreno, M.A., Kota, R., Schoohs, S., & Whitehill, J.M. (2013). The Facebook Influence Model: A Concept Mapping Approach. *Cyberpsychol Behav Soc Netw,* 16(7):504-511. doi:10.1089/cyber.2013.0025

Roybal-Allard 5
National Institute of Minority Health and Health Disparities

Congresswoman Roybal-Allard: Since the elevation of the National Center for Minority Health and Health Disparities to an Institute five years ago, my tri-caucus colleagues and I have been disappointed in the resources allocated to NIMHD to fulfill its mission of improving minority health and eliminating health disparities. Your FY17 budget proposes level funding for this Institute, while other Institutes, comparatively speaking, are thriving with larger budget resources and research policy attention.

a) What is NIH's strategic plan over the next 2-3 years to address the imbalance?
b) How is each Institute and Center working collaboratively with NIMHD to identify and address the major health disparity research issues plaguing our socially disadvantaged populations? How much funding has been invested into collaborative research between NIMHD and the other Institutes?
c) How does NIH determine what is the level of funding at each of the other ICs in support of health disparities research, and can you tell us, by Institute, what has been invested for health disparities and social determinants research?
d) Is there any review reassessing what should be defined and included as health disparities research? If so, what role is NIMHD playing in this reassessment?

Dr. Collins: Health disparities affect many Americans across a wide range of health conditions, including higher infant mortality, higher HIV infection rates, and higher prevalence of obesity, diabetes, hypertension, cardiovascular disease, cancer, stroke, liver disease, and many more. Health disparities are multifactorial and addressing health disparities requires input from many disciplines at many levels. The *NIH-Wide Strategic Plan, Fiscal Years 2016-2020*, which was released in December 2015, includes the evidence-based reduction of health disparities as a key cross-cutting activity for health promotion and disease prevention at NIH.[87] The plan states that:

> "efforts will address the importance of understanding social determinants of health, disease, and disability; disproportionate disease risk; and opportunities for progress in prevention. [...] NIH-funded research also will evaluate methods to disseminate evidence-based interventions to promote health and prevent disease—with particular emphasis on comorbid conditions—in a variety of community health and clinical settings, as well as identify barriers to adoption of such interventions. Understanding mechanisms that lead to disparities in health outcomes by race/ethnicity and socioeconomic status will require multi-disciplinary collaboration of population, clinical, and basic scientists."

NIMHD coordinates the *Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget.*[88] This collaboration across all NIH Institutes and Centers (ICs) is a comprehensive document that sets the overarching research for the NIH health disparities agenda. It outlines the ongoing and planned projects of each NIH IC, and the program offices within the NIH Office of the Director to address minority health and health disparities. Planning for the *2017-2021 Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget* begins in June 2016. NIMHD is working to leverage collaborative funding with many other NIH ICs by initiating

[87] https://www.nih.gov/about-nih/nih-wide-strategic-plan
[88] http://nimhd.nih.gov/about/strategicPlan.html

minority health and health disparities research programs that are critical for many different diseases and conditions. In FY 2015, 16 percent of NIMHD's budget was spent on collaborative activities.

At present, the terms "minority health" and "health disparities" are often used synonymously. However, the differences in these terms are critical even though the distinctions have not been clearly defined. Currently, NIMHD is leading a trans-NIH working group to clearly define "minority health", "health disparities", "inclusion", and "workforce diversity" as related, but distinct, categories of research projects. These definitions are the keystones for a fundamentally needed refinement of minority health and health disparities research at NIH. NIMHD is working to facilitate this critical scientific progress. Clearly distinguishing the definition of minority health research from health disparities research can leverage more directed scientific efforts needed to address the growth in diversity of the demographics of the United States. As the diversity of the population increases and the proportion of racial and ethnic minorities approaches 40 percent of the U.S. population, the burden of health disparities conditions also increases. NIMHD also supports proportionally more underrepresented minority researchers than NIH collectively, which increases workforce diversity. NIMHD is uniquely positioned to support science that addresses the improvement of minority health and the reduction of health disparities. However, the allocated funds, even when leveraged, impact only a fraction of the burden of health disparities on the American people.

The NIH Research Portfolio Online Reporting Tools (RePORT) provides transparent access to funding levels for many terms associated with health disparities and determinants of health.[89] Currently, the reportable budget for these activities is inflated and the performance for each category is challenged by being unable to uniformly distinguish between the minority health and health disparities research. Separate definitions of minority health and health disparities will enable improved coding of minority health and health disparities grants, which will enhance annual reporting on scientific findings and budgets for minority health and health disparities separately.

[89] https://report.nih.gov/categorical_spending.aspx

Roybal-Allard 6
Social Determinants of Health and Health Disparities

Congresswoman Royal-Allard: Over the last several years increasing attention has been given to supporting research into the science of population, health delivery, and social determinants research and the translation of these scientific results into everyday health care settings.

a) By Institute, what is the level of funding for each of these areas?
b) How is NIMHD helping to determine the research methodology and protocols for this science and its application or translation into practice settings?
c) What role will NIMHD play in coordinating these efforts with the other Institutes?
d) What steps is NIH taking to address the social determinants factors contributing to health and mental health problems for socially disadvantaged children, which often worsen into debilitating complications in later life? Please provide funding levels by Institute.

Dr. Collins: The social determinants of health are often described as the conditions in which people are born, live, work, and age. These determinants affect a wide range of health, functioning, and quality-of-life outcomes.[90] This framework has provided a way to examine minority health and health disparities issues, but has not provided a complete understanding of the factors that result in health disparities or impact minority health. As the scientific field of health disparities has advanced, this framework has been expanded to include other health determinants, resulting in a more complex understanding of the interactions that influence health outcomes. The health determinants now encompass the social determinants of health as well as the role that individual behavior, social networks, biological pathways, the environment (physical and sociocultural), and systems-level factors play in impacting both minority health and health disparities.

The National Institute on Minority Health and Health Disparities (NIMHD) is taking a leadership role in defining, coding, analyzing, and reporting on minority health and health disparities. This includes collaborations with other NIH Institutes and Centers (ICs), across the Department of Health and Human Services, and in the field of health disparities research. NIMHD also coordinates the *Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget.*[91] This collaboration across all NIH ICs is a comprehensive document, which sets the overarching principles for NIH's health disparities agenda. NIMHD also is leading a trans-NIH effort with a panel of external experts to enhance the methodology and measurements of minority health and health disparities, including more complex systems analyses that reflect more realistic applied models of factors that impact health. Publications and future research projects may facilitate improved models and measures to report on health disparities.

A life course perspective is critical to understanding the impact of health determinants in both minority health and health disparities research. The cumulative effect that can occur over a lifetime makes it especially important to focus on children and adolescents to prevent future health disparities. NIH supports and collaborates on a wide variety of research that addresses these questions. For example, the Adolescent Brain Cognitive Development Study is the largest

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[90] https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
[91] http://nimhd.nih.gov/about/strategicPlan.html

long-term study of brain development and child health in the United States.[92] This project is recruiting approximately 10,000 children and following them into early adulthood and seeks to better understand the many factors that can enhance or disrupt a young person's life trajectory. NIMHD is participating in this study to better understand factors that lead to health disparities during adolescence. Another example is an educational outreach initiative launched by NIMHD and the Omega Psi Phi Fraternity, Inc., entitled *Brother, You're On My Mind.* The focus is to raise awareness about the mental health challenges associated with stress and depression that affect African American men and their families. Since suicide is a leading cause of death among African Americans age 15-24, this program seeks to intervene at critical time points for undergraduate students. In addition, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's Demography of Health Branch focuses the relationships between demographics and health, with a focus on children and families.[93] This branch has special areas of interest in the relationship between population composition (e.g., income inequality, racial/ethnic composition) and health; the effects of racial and ethnic diversity on population health and health disparities; and the mechanisms through which racial and ethnic differences in health outcomes operate (e.g., culture, racism, and social constraints).

The NIH Research Portfolio Online Reporting Tools (RePORT) provides transparent access to funding levels for many terms associated with determinants of health.[94] However, NIH grants are not coded to determine the specific funding level for grants addressing social or other health determinants. Funding levels also are expected to shift with new definitions of minority health and health disparities and more precise coding of grants, reflective of the distinct definitions.

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[92] http://addictionresearch.nih.gov/abcd-study
[93] https://www.nichd.nih.gov/about/org/der/branches/pdb/programs/Pages/demography-health-population.aspx
[94] https://report.nih.gov/categorical_spending.aspx

Roybal-Allard 7
Latino Health Research

Congresswoman Roybal-Allard: NHLBI's pioneering project on the Study of Latino Health (SOL) offers a promising baseline addressing risk factors including acculturation associated with cardiovascular disease. I understand the SOL study covered only certain geographic areas but not the one with the largest and most diverse concentration of Latinos in the country, namely, Los Angeles County.

a) What plans does NHLBI have in addressing this oversight?
b) What plans are there for each of the other Institutes to undertake similar efforts using the NHLBI's seminal study as a model?
c) What role is expected of NIMHD to advance this type of social risk factors research in other Institutes?

Dr. Collins: The National Heart, Lung, and Blood Institute (NHLBI) is committed to research that improves the health and quality of life of Hispanic/Latino Americans and strives to examine the biological and non-biological factors that influence the health of this heterogeneous population. The diverse nature of the NHLBI-supported cohort studies provides a unique platform for this research. The Hispanic Community Health Study/Study of Latinos (HCHS/SOL) serves as a critical foundation to better understand the drivers of health of the Hispanic/Latino population in the United States.

One of the key goals of the HCHS/SOL is to understand the health profile of Hispanics/Latinos of diverse origin who live in the United States. Before the initiation of the HCHS/SOL, data or research on Hispanic health had been mostly derived from studies in which its Hispanic participants were of Mexican or Mexican American origin and/or living in California and the Southwest. Thus, for a long time our knowledge of U.S. Hispanic/Latino health has been based on findings derived from studies performed in specific regions of the country and at the national level, yet mostly representing Hispanics of Mexican or Mexican American descent.

The HCHS/SOL is an NHLBI initiative, co-funded by other NIH Institutes. The program has four Field Centers for recruitment and examination of study participants, and one Coordinating Center that oversees the coordination of research activities, protocols, and data collection and analysis. Field centers are located in San Diego, California; Chicago, Illinois; New York City; and Miami, Florida. There was no predetermined preference for study locations. All applications for Field Centers and the Coordination Center were evaluated on scientific merit by the standard NIH peer-review process. Although the Los Angeles area is an attractive site for recruiting Hispanic/Latino research participants, there were no competitive applications from the Los Angeles area. The NHLBI always welcomes the opportunity to expand our research portfolio and advance our understanding of disorders that disproportionately affect Hispanic/Latinos living in Los Angeles and other areas of the United States.

The Multi-ethnic Study of Atherosclerosis (MESA) is another critical NHLBI initiative that examines the characteristics of subclinical cardiovascular disease in a diverse group of participants. This study includes 22 percent Hispanic participants recruited from three centers in Los Angeles, California; New York City, New York; and Minneapolis, Minnesota. The MESA

study continues to provide insights on the risk of atherosclerosis among Hispanic Americans and variations among race/ethnic groups in genetic, biologic, and environmental influences on health and disease.

The NHLBI will continue to work with other NIH ICs to address Hispanic health research through the newly created NIH Hispanic Health Research Scientific Interest Group. This group is currently evaluating the NIH portfolio to identify studies that involve Hispanic participants. The results of this analysis will help inform the development of further initiatives by other ICs.

The National Institute on Minority Health and Health Disparities (NIMHD) will use SOL findings, as well as other relevant research, to build upon and advance the research of minority health and health disparities. NIMHD will be hosting a Workshop on Etiology and Interventions that could play a key role in advancing scientific knowledge to address risk factors. In the development of the *Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget*, projects such as the SOL lay the foundation for future studies.[95]

[95] http://nimhd.nih.gov/about/strategicPlan.html

Roybal-Allard 8
Hispanic Population

Congressman Roybal-Allard: As I expressed in a 2015 letter to NIH, I continue to have concerns about the adequacy of research methods currently being used to measure health outcomes among US Hispanic populations, particularly regarding the underclass and assimilating immigrant models and inconsistent definitions of the Hispanic category that deliver questionable predictive power in measuring health outcomes among Latinos.

a) What work, if any, is being done at NIH to improve current research methodologies in measuring Latino health outcomes in the diverse contexts that Hispanic/Latino peoples live?
b) Are NIMHD and the other Institutes working collaboratively toward this end?
c) Are outside Hispanic health experts assisting in this effort?

Dr. Collins: Hispanics/Latinos are the fastest growing population group in the United States. This demographic change highlights a number of challenges in analyzing data on Hispanics and Latinos in the United States that the National Institute on Minority Health and Health Disparities (NIMHD) has been working to better understand and address. NIMHD is taking a leadership role in defining, coding, analyzing, and reporting on minority health and health disparities. This includes collaborations with other NIH Institutes and Centers, as well as collaborations across the Department of Health and Human Services, in the fields of minority health research and health disparities research.

Among the challenges in studying Hispanic/Latino health is the way that the terms "minority health" and "health disparities" are used synonymously. NIMHD is leading a trans-NIH working group to separate the definition of "minority health" from that of "health disparities". Clearer definitions of the types of research that should be categorized as "minority health" will allow for greater focus on the kinds of issues that currently challenge the investigation of Hispanic/Latino health. NIMHD also is working to expand models of social determinants of health to incorporate more complex behavioral, biological, interpersonal, environmental, and structural factors that interact to impact health outcomes. Better understanding of these health determinants may benefit the scientific investigation of overall Hispanic/Latino health, as well as the specific ethnic groups.

Differences in health and health outcomes among different national origin groups of Hispanics/Latinos living in the United States have been documented in a number of diseases and conditions, including asthma, cardiovascular disease, and selected cancers. Analysis of NIH's grants by racial and ethnic category allows NIH to identify the health disparities that are most relevant to Hispanics/Latinos as a whole, but additional variables such as birthplace, years of residence in the United States, language preference, and family country of origin will expand the understanding of group differences and similarities among Hispanics/Latinos. It also provides the opportunity to review the NIH portfolio for gaps that should be addressed. Currently, NIMHD is working with NIH's Research, Condition, and Disease Categorization experts to begin to developing a more complete coding system for the Hispanic/Latino grant portfolios

across NIH.[96] This will provide a platform to better understand and target the health of specific subgroups.

NIMHD recognizes the importance of the rich diversity of Hispanic/Latino populations, including culture, traditions, and lifestyles. The 2015 letter, which referenced the research of Drs. Flores and Hayes-Bautista, sent to NIH underscored key points about the methodologies used to investigate Hispanic/Latino health. NIMHD acknowledges the challenges associated with research related to social class, acculturation, and other groups, especially when addressing health disparities. Hispanic/Latino researchers have developed methodologies that take this diversity into account in working with populations across the United States.

NIMHD is working to address these issues at many levels. NIMHD's scientific planning for FY 2017 included a new proposed project on immigrants as a vulnerable population experiencing multiple health disparities. NIMHD also is hosting a workshop on the *Use of Race/Ethnicity in Genomic Research and Medicine* in October 2016. This workshop is inviting external experts to work with NIH to develop strategies that will complement the current standard of self-reported racial and ethnic identity with the science of genomics in research and help understand the meaning of self-reported ethnicity in a social context. The outcomes from this workshop may have a particular impact on issues surrounding Hispanic/Latino health. NIMHD's Director also is collaborating with the National Heart, Lung, and Blood Institute on a workshop on *Precision Medicine and Hispanic Health: Contributions to Reducing Health Disparities* in July 2016. In addition, nearly 13 percent of the principal investigators supported by NIMHD are Hispanic/Latino and this is higher than the NIH average. These researchers bring diversity to the workforce, as well as an expertise in health disparities.

[96] https://report.nih.gov/rcdc/

Roby-Allard 9
Community Based Research

Congresswoman Roybal-Allard: In a spirit of fiscal responsibility, it is critically important to show the impacts of NIH supported research in improving health outcomes throughout our communities. This would appear most relevant with regard to advancing translational, population and social determinants/risks science.

a) What analysis and strategic planning has NIH given to make use of the assets of community hospitals that have a rich history of serving Medicaid and uninsured populations, addressing health disparities and training culturally competent health providers?
b) How is NIH planning to promote research in community settings to harvest/exploit the community hospital assets and databases?
c) How does the Director see population science and precision medicine coordinating for better healthcare access in the community?

Dr. Collins: Advancing translational science to improve the health of the U.S. population and to address and reduce health disparities is a high priority for NIH. As outlined in the NIH Strategic Plan FY 2016-2020, NIH's health promotion and disease prevention efforts over the next five years will place particular emphasis on research aimed at developing evidence-based interventions to reduce health disparities.[97] Such efforts will include studies to understand social determinants of health, disease, and disability; disproportionate disease risk; and opportunities for progress in prevention. NIH is also promoting the effective research use of clinical data, including efforts to create and implement health data standards in electronic health records and health information exchange systems. Electronic health records are increasingly used in NIH research, notably in comparative effectiveness research, health services research, and pragmatic clinical trials.

A number of programs within the NIH Institutes and Centers (ICs) fund research and research training in community hospitals and community settings through multi-disciplinary collaborations of population, clinical, and basic scientists. This research includes efforts to increase our understanding of the mechanisms that lead to disparities in health outcomes by race/ethnicity and socioeconomic status and to evaluate methods to disseminate evidence-based interventions to promote health and prevent disease – with particular emphasis on comorbid conditions – in a variety of community health and clinical settings, as well as identify barriers to adoption of such interventions. ICs support Minority-serving Institutions, which are uniquely positioned to engage underrepresented and underserved racial and ethnic populations in research and in the translation of research advances into culturally competent, measurable, and sustained improvements in health outcomes. In FY 2015, NIH supported more than 3,500 projects at these Institutions.

The National Cancer Institute is supporting a national network of investigators, cancer care providers, academic institutions, and other organizations. The NCI Community Oncology Research Program (NCORP) conducts multi-site cancer clinical trials and studies in diverse populations in community-based healthcare systems across the United States and Puerto Rico;

[97] https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf

and aims to bring cancer clinical trials (cancer control, prevention, screening, treatment, and imaging), as well as cancer care delivery research (CCDR), to individuals in their own communities, thus generating a broadly applicable evidence base that contributes to improved patient outcomes and a reduction in cancer disparities.[98] NCORP sites are responsible for enrolling over 25 percent of all patients in NCI's National Clinical Trials Network studies.

An NIH Common Fund program, the NIH Healthcare System Research Collaboratory program, is funding demonstration projects aimed to provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research.[99] Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to health practice. These health care systems may include or collaborate with community hospitals to leverage important real-world data from these settings. One of the demonstration projects, the UH3 Project: Strategies and Opportunities to Stop Colorectal Cancer in Priority Populations (STOP CRC) project, for example, has partnered with Federally qualified health centers in the Oregon Community Health Information Network to advance the use of electronic health record resources to optimize guideline-based screening in clinics whose patient populations have disproportionately low colorectal cancer screening rates.[100]

Population sciences such as epidemiology, demography, healthcare delivery research, and surveillance research, play a critical role in furthering precision medicine, which has both individual and population specific implications for subgroups within populations. The NIH Precision Medicine Initiative® (PMI) Cohort Program, a longitudinal research cohort of one million or more volunteers, will engage communities to advance the scientific knowledge that can be used to develop prevention and screening strategies tailored to individuals at the most opportune times across the course of their lives.[101] The program will take advantage of emerging biomedical tools and technologies and pioneer efforts to merge, integrate, and analyze data from a wide variety of sources with implications for prevention, including basic biological data, health status information from electronic health records, individual data on environmental exposures, and geospatial data on community environmental exposures. The data will come from a diverse cohort of participants living in a variety of geographies, social environments, and economic circumstances, spanning all age groups and health and disease states, economic levels, races and ethnicities, and communities. PMI will recruit through direct volunteers and through healthcare provider organizations. NIH is also collaborating with the Health Resources and Services Administration (HRSA) to begin partnerships with several Federally Qualified Health Centers which provide high-quality preventive and primary care to individuals in their communities, to develop and refine approaches for bringing underserved communities into the PMI Cohort Program. Information from the cohort will be a broad, powerful resource for researchers working on a variety of important health questions.

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[98] http://ncorp.cancer.gov/
[99] https://commonfund.nih.gov/hcscollaboratory/index
[100] https://www.nihcollaboratory.org/demonstration-projects/Pages/STOP%20CRC.aspx
[101] https://www.nih.gov/news-events/news-releases/nih-framework-points-way-forward-building-national-large-scale-research-cohort-key-component-presidents-precision-medicine-initiative

Lee 1
Office of AIDS Research

Congresswoman Lee: We are currently at a pivotal point in the global fight against HIV/AIDS. UNAIDS has indicated that we have a (now) 4-year window to turn the tide of the epidemic and end AIDS as we know it, or backslide and undermine the progress we've made. The President's request for HIV/AIDS research at the NIH is flat again this year at $3 billion, with a proposed cut in the area of microbicides research. Dr. Fauci previously presented this Committee with exciting potentially breakthrough scientific opportunities in the field of HIV research, including vaccine development. What will be the effect of stagnant (flat-funding) funding on future progress in these areas?

Dr. Collins: NIH supports a comprehensive program of biomedical, behavioral, and social science research on HIV and its associated coinfections, comorbidities, and other complications. NIH-sponsored HIV/AIDS research has led to extraordinary progress over the last 34 years, transforming what was once a terrifying and almost inevitably fatal disease into a treatable disorder. NIH-funded basic and pre-clinical studies and clinical trials have led to groundbreaking advances in understanding the HIV replication cycle, the development of safe and effective antiretroviral drugs and combination drug regimens for treating HIV/AIDS, and strategies to prevent HIV acquisition and transmission. People living with HIV/AIDS can now experience an almost normal life expectancy if antiretroviral therapy is started promptly and continued for life.

While significant progress has been made, the AIDS pandemic continues to spread with approximately 50,000 new HIV infections in the United States and 2 million new cases worldwide annually. We are now at a critical juncture in HIV/AIDS research in which new exciting research opportunities are emerging and pointing toward the possibility of ending the pandemic. Significant advances in basic and clinical research are raising new hopes for the development of successful prevention strategies such as pre-exposure prophylaxis, an effective vaccine, and even a possible cure.

Now more than ever, NIH is focusing resources on research priorities that will help end the AIDS pandemic in the shortest timeframe possible. Toward this effort, NIH has implemented several new processes to ensure that NIH's AIDS dollars are focused more intensively than ever on the highest priority areas of HIV/AIDS research. In August 2015, NIH announced overarching HIV/AIDS research priorities for the next 3-5 years for determining HIV/AIDS funding, beginning in fiscal year 2016.[102] These priorities are:

- research to reduce the incidence of HIV/AIDS, including the development of safe and effective AIDS vaccines;
- development of next-generation HIV therapies with improved safety and ease of use;
- research toward a cure for HIV/AIDS; and
- research to address HIV-associated comorbidities and coinfections.

Cross-cutting these areas are basic research, research to address health disparities, and training.

[102] NIH Director's Statement on NIH Efforts to Focus Research to End the AIDS Pandemic, August 12, 2015.

In August 2015, NIH also issued new guidelines for ensuring that NIH AIDS funds are directed to the highest research priorities.[103]

While the FY 2017 President's Budget for NIH HIV/AIDS research did not include an increase, this budget was developed ensuring that all new, expanded, and re-competing initiatives are aligned with the highest HIV/AIDS research priorities. Additionally, NIH has redistributed funds within the AIDS budget since August 2015 to support research toward a cure and an HIV/AIDS vaccine. Three additional significant steps with the NIH AIDS budget were taken, effective in FY 2016 and continuing in FY 2017, including: 1) recognizing that research priorities should be based on scientific and public health considerations, not driven by arbitrary formulas, NIH is no longer maintaining a 10-percent set aside of the NIH budget for HIV/AIDS research; 2) the NIH AIDS FY16 and 17 budget requests would remain at $3 billion; 3) the NIH AIDS portfolio would be realigned with the new research priorities. NIH is redirecting funds from research projects eligible to recompete and considered not in alignment with the new HIV/AIDS overarching research priorities to projects that are aligned with the highest priorities while maintaining the overall AIDS budget in FY 2017. NIH has and will continue to redistribute funds within the AIDS budget of $3 billion to support these overarching priorities.

NIH remains strongly committed to supporting important and crucial HIV/AIDS research that will have a major impact on ending the AIDS pandemic. NIH's continued leadership and commitment to build on previous significant scientific advances is essential to develop a safe and effective AIDS vaccine, a cure for AIDS, and ultimately achieve an AIDS free generation.

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[103] NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding, NIH Guide for Grants and Contracts, NOT-OD-15-137, August 12, 2015.

Lee 2
National HIV/AIDS Strategy and NIH Role

Congresswoman Lee: On World AIDS Day last year, the White House unveiled the Federal Action Plan to implement the updated National HIV/AIDS Strategy. How does the FY17 NIH budget request reflect your agency's role in implementing the new strategy? What new efforts will the NIH be undertaking this year as you work to accomplish the goals outlined in the strategy.

Dr. Collins: The FY 2017 President's Budget for NIH HIV/AIDS research continues the long-term investment that has produced groundbreaking scientific advances, which continue to provide a critical foundation of knowledge, tools, and strategies for achieving the goals of the President's National HIV/AIDS Strategy (NHAS) and the Federal Action Plan. NIH will continue to sponsor critical research in search of solutions to prevent, treat, and ultimately, cure HIV/AIDS. The new NIH HIV/AIDS research overarching priorities and guidelines for determining the use of AIDS funds will optimize the investments in cutting edge research that will advance the NHAS goals.[104,105]

In FY 2017, NIH will support activities aligned with the NHAS Goal 1 to reduce new HIV infections by launching the development and crucial clinical studies of new vaccine candidates, as well as strategies for pre-exposure prophylaxis (PrEP), integrated strategies using multi-purpose prevention technologies, and formative studies to better understand the communities where prevention research is conducted and factors influencing HIV testing, maintaining prevention interventions, and adherence strategies. In support of the NHAS Goal 2 to increase access to care and improving health outcomes, NIH-sponsored studies will advance the development and testing of new and better therapies, including long-acting, sustained release injectable antiretrovirals; initiating treatment immediately after HIV diagnosis; prevention and treatment of HIV-associated coinfections, including Hepatitis C virus and tuberculosis, and comorbidities, including cardiovascular disease, AIDS-defining and non-AIDS defining cancers, and neurologic and neurocognitive disorders; improving engagement and retention in care; and achieving optimal treatment responses. NIH will support key initiatives to achieving the NHAS goal 3 to reducing HIV-related disparities and health inequities including studies to characterize and address the HIV epidemic in U.S. racial and ethnic populations in the South, adolescent men who have sex with men, and sex and gender differences in HIV risk, prevention, pathogenesis, care, treatment, and outcomes. NIH will continue to participate in the Federal Interagency Working Group on HIV and other HHS and trans-departmental efforts as part of its commitment to achieving a more coordinated national response to the HIV epidemic (NHAS Goal 4).

NIH has and will continue to ensure that its investment of AIDS dollars is aligned with the overarching AIDS priorities and achieving the NHAS goals and Federal Action Plan.

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[104] NIH Director's Statement on NIH Efforts to Focus Research to End the AIDS Pandemic, August 12, 2015.
[105] NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding, NIH Guide for Grants and Contracts, NOT-OD-15-137, August 12, 2015.

Lee 3
Sickle Cell Research

Congresswoman Lee: Over 100,000 children and adults in the United States are living with Sickle Cell Disease (SCD) and 1 in 12 African Americans in the United States has Sickle Cell Trait. Despite the numbers, there have been clear funding and research disparities between sickle cell and other similar blood disorders. The National Heart Lung and Blood Institutes (NHLBI) released a report in 2014 on evidence based guidelines for managing SCD, and it highlighted a need for more research that increases the evidence for and availability of a cure for SCD. With a proposed budget of $3.1 billion for the NHLBI in FY2017, what specific Sickle cell disease and trait activities are included in this proposal?

Dr. Collins: The National Heart, Lung, and Blood Institute (NHLBI) places a high priority on funding research on sickle cell disease (SCD) and sickle cell trait (SCT) with promising studies that are achieving important advances. In addition to supporting research conducted by the extramural research community, NHLBI has recently recruited renowned investigators to study SCD in a newly established intramural program devoted solely to SCD research.

NHLBI is funding a major program to promote innovative basic and translational research in the hemoglobinopathies, which include SCD. The Excellence in Hemoglobinopathies Research Awards funded eight groups of extramural investigators to develop new therapeutic and diagnostic options for SCD and the thalassemias.[106] The projects include new therapeutics to elevate patients' level of fetal hemoglobin (the most powerful known modifier of the severity of SCD), new therapeutics for sickle cell pain, novel modulators of inflammation, and treatments for SCD-associated kidney disease.

Research advancing modified bone marrow transplant and gene editing techniques continues to show promise in efforts to ameliorate symptoms and complications of disease. The NHLBI-supported STRIDE study is evaluating the safety and feasibility of bone marrow transplantation in adult patients with and without matched donors.

In addition to funding studies focused on the development of new clinical tools and therapies, NHLBI will be funding implementation research studies to examine strategies to increase adoption of current proven therapies and appropriate medical care for adolescents and adults with SCD. These individuals tend to experience difficulties in accessing high-quality medical care from qualified providers. As a result, adolescents and adults with SCD often fail to receive evidence-based therapies and care that would otherwise improve their survival and quality of life. To rectify this shortcoming, NHLBI has published a Funding Announcement for the Sickle Cell Disease Implementation Research Program. The aim of this program is to identify barriers to care in defined geographical areas (urban, suburban, and rural) and to develop innovative interventions that remedy these barriers. Should the interventions prove successful, they would not only provide quality care to the enrolled research subjects but would also serve as models for further improvements in health outcomes for SCD patients. Thus, the NHLBI research portfolio for SCD is diversified, with funds supporting both early-stage research designed to develop new treatment options and clinical research designed to improve health outcomes based on better use

[106] http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-005.html

of existing therapies. In this way, NHLBI is addressing current pressing needs while laying the foundation for a better future for existing patients and those yet to be born.

In the area of research on Sickle Cell Trait (SCT), NHLBI is supporting studies that may elucidate whether having the sickle cell trait results in any negative health consequences. It is noteworthy that recent cohort studies supported by the Institute showed that the presence of SCT was associated with an increased risk for chronic kidney disease. Yet, further research is necessary to further understand whether SCT predisposes to chronic kidney disease and whether interventions can be developed to reduce the risk of this complication in individuals with SCT.

Because the impact of SCT on health remains unclear, NHLBI is co-funding a Department of Defense epidemiological study that will compare the medical records of individuals with SCT and those without it over a 20-year period to determine whether the trait is associated with particular health outcomes. Using databases from the Armed Forces Health Surveillance Center and the Navy and Marine Corps Public Health Center, the investigators will identify an estimated 16,000 cases of SCT from the rolls of active duty soldiers between 1992 and 2012 and compare the medical records of this group to a group observed during the same time period who do not have SCT. This study has the potential to answer whether SCT has negative health effects and to inform future medical care of individuals with SCT.

Lee 4
National Institutes on Minority Health and Health Disparities

Congresswoman Lee: The Office of Minority Health (OMH) and the National Institutes on Minority Health and Health Disparities (NIMHD) have been critical to identifying racial and ethnic health disparities, and to creating and implementing programs that address those disparities. Without OMH and NIMHD, we likely would not know how serious health disparities and social determinants of health are in this country. I know that the FY2017 NIH budget proposal includes $280 million for the NIMHD. Please explain some of the efforts being done to ensure health disparities research and a focus on social determinants of health will be carried out this year?

Dr. Collins: Health disparities affect many Americans across a wide range of health conditions, including higher infant mortality, higher HIV infection rates, and higher prevalence of certain chronic conditions, such as obesity, diabetes, hypertension, cardiovascular disease, cancer, stroke, liver disease, and many more. Health disparities are multifactorial and addressing health disparities requires input from many disciplines at many levels. The *NIH-Wide Strategic Plan, Fiscal Years 2016-2020*, which was released in December 2015, includes the evidence-based reduction of health disparities as a key cross-cutting activity for health promotion and disease prevention at NIH.[107] The plan states that:

> "efforts will address the importance of understanding social determinants of health, disease, and disability; disproportionate disease risk; and opportunities for progress in prevention. [...] NIH-funded research also will evaluate methods to disseminate evidence-based interventions to promote health and prevent disease—with particular emphasis on comorbid conditions—in a variety of community health and clinical settings, as well as identify barriers to adoption of such interventions. Understanding mechanisms that lead to disparities in health outcomes by race/ethnicity and socioeconomic status will require multi-disciplinary collaboration of population, clinical, and basic scientists."

NIMHD's current scientific planning is generating innovative health disparities topics, such as health disparities in surgical outcomes and health disparities in immigrant populations. NIMHD is also working to expand models of social determinants of health to incorporate more complex behavioral, biological, interpersonal, environmental, and structural factors that impact health.

Collaboration across NIH is critical to ensuring health disparities research at NIH can thrive. NIMHD leads development of the *Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget*.[108] This collaboration across all NIH's Institutes and Centers is a comprehensive document which sets the overarching research for the NIH health disparities agenda. Planning for the *2017-2021 Trans-NIH Minority Health and Health Disparities Strategic Plan and Budget* begins in June 2016.

Currently, NIMHD is leading a trans-NIH working group to clearly define "minority health", "health disparities", "inclusion", and "workforce diversity" as related, but distinct, categories of

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[107] https://www.nih.gov/about-nih/nih-wide-strategic-plan
[108] http://nimhd.nih.gov/about/strategicPlan.html

research projects. These definitions are the keystones for a fundamentally-needed refinement of minority health and health disparities research at NIH. Clearly distinguishing the definition of minority health research from health disparities research can leverage more directed scientific efforts needed to address the growth in diversity of the demographics of the United States. As the diversity of the population increases and the proportion of racial and ethnic minorities approaches 40 percent of the United States population, the burden of health disparities conditions also increases. In addition, NIMHD is leading efforts to develop tools, methods, and metrics to better assess, monitor, and report on health disparities.

NIMHD is uniquely positioned to support science that addresses the improvement of minority health and the reduction of health disparities. However, the allocated funds, even when leveraged, impact only a fraction of the burden of health disparities on the American people.

Lee 5
National Institute of Mental Health, Multiple Sclerosis/BRAIN Initiative

Chairwoman Lee: Roughly 400,000 people are currently living with multiple sclerosis (MS). As you know, MS is a chronic, often disabling disease that attacks the central nervous system, including the brain, spinal cord, and optic nerves. So I was pleased to see the President propose a $45 million increase – for a total of $195 million – to expand the Brain Research through Advancing Innovative Neurotechnologies Initiative (BRAIN), a cross-agency initiative to developing tools and technologies to help scientists understand more about the human brain. This research and development will help fill major gaps that are critical to the treatment, cure, and prevent brain disorders. Please explain how the BRAIN initiative will directly engage patients living with Multiple Sclerosis?

Dr. Collins: The BRAIN Initiative is currently funding scientists to develop new brain imaging tools and techniques capable of examining the activity of millions of nerve cells, networks, and pathways in real time, which will enable a deeper understanding of how the brain functions normally and what goes wrong in diseases like MS. The development of these tools was one of the highest priority goals identified through the BRAIN Initiative planning process, which sought broad public input by directly engaging the scientific and patient communities, including the MS community. These tools will enable a deeper understanding of how brain circuits function in health and disease, improve diagnosis and monitoring of disease in MS and other neurological disorders, and speed the development of new therapies for these diseases. A high-priority result for MS patients and their doctors would be a technology that enables detection of the circuit dysfunction that underlies secondary and primary progressive MS. NIH continues to engage with scientists and patient advocacy communities, including the MS community, to make them aware of BRAIN Initiative plans and progress, and ensure the community will be ready to utilize these tools as they become available for MS research.

TUESDAY, MARCH 22, 2016.

DEPARTMENT OF EDUCATION

WITNESSES

HON. JOHN KING, SECRETARY, DEPARTMENT OF EDUCATION
THOMAS SKELLY, CHIEF FINANCIAL OFFICER, DEPARTMENT OF EDUCATION

OPENING REMARKS BY CHAIRMAN COLE

Mr. COLE. Good morning, Mr. Secretary. It is my pleasure to welcome you on your first visit to the House Subcommittee on Labor, HHS, and Education to present your budget request for fiscal year 2017 for the Department of Education. We are looking forward to hearing your testimony.

And I want to congratulate you again on your recent confirmation. As we all know, watching the Senate: that is no small feat, so well done.

Since the subcommittee last met to discuss the Department of Education budget last year, Congress achieved the significant and long overdue accomplishment of reauthorizing Federal K–12 education programs through the Every Student Succeeds Act. This legislation streamlined and improved many of the Department's programs and devolved much of the authority over K–12 education issues to the States and school districts and was a tremendous bipartisan and bicameral achievement.

The next step is to support States and school districts in their new role by providing sufficient resources to help them build capacity. I have concerns about whether your budget request for fiscal year 2017 for the key formula and block grant programs that support all States and school districts, including IDEA, Title I, and the new Student Support and Academic Enrichment State Grant, is sufficient to successfully implement the new law.

In addition, you propose almost—or over $7 billion in mandatory spending that the Subcommittee has neither the authority nor the inclination to implement. We will have to remain in discretionary allocation that the full Committee ultimately allocates to the Subcommittee.

With regard to higher education, the Department plays an important role not only in assisting students to finance higher education, but also in helping them to prepare for, complete, and succeed in their studies. I was happy that we were able to maintain funding for Pell Grants and provide a significant increase for TRIO and GEAR UP in fiscal year 2016. I look forward to hearing more about your proposals to make higher education more attainable and affordable to students most in need in the upcoming year.

I look forward to having a discussion with you this morning to identify your top priorities for the year so that we can invest the

American taxpayer dollars in the wisest way, given our funding constraints.

As a reminder to the subcommittee and to our witnesses, we will abide by the 5-minute rule so that everyone will have a chance to get their questions asked and answered.

I would now like to yield to my good friend, the Ranking Member of the full Committee, the gentlelady from New York, Mrs. Lowey, for any opening remarks she cares to make.

OPENING REMARKS BY RANKING MEMBER MRS. LOWEY

Mrs. LOWEY. I want to thank our Committee Chair for your leadership of this committee. It is a pleasure to be here today.

Before I begin, Mr. Chairman, I want to note that Tom Skelly, the highly respected CFO at the Department, is making his last appearance before the Subcommittee today. You have been an indispensible resource—42 years in Government service—I understand. We congratulate you on your much-deserved retirement, and we wish you the very best of luck.

Thank you.

Mr. SKELLY. Thank you, Mrs. Lowey.

Mrs. LOWEY. Okay—so, for today's students to be successful in the 21st century economy, we need a renewed focus that will enable them to compete in the global market. It is imperative that implementation of the Every Student Succeeds Act be swift and thorough.

And I know, Secretary King, you are aware of Common Core. I think we have had many discussions about that, and we know that in New York, policies can succeed—or elsewhere—or fail based on their implementation. It is my hope that with the ESSA, we can learn from what has worked and what has failed to ensure that this new law provides students, teachers, parents, and administrators with the tools to provide children with the best education possible.

I know you care deeply, Mr. Secretary, about this mission. I look forward to hearing your testimony on how we can best achieve it.

In December, this committee came together to make sizable investments, particularly in K–12 education. Among those were increases in Title I grants to school districts for students in need as well as increases in IDEA special education funds. Still, much work remains, and we must build on last year's effort.

You come before us today with a budget request that would provide the Department of Education with an increase of 2 percent, or about $1.3 billion. Your budget includes advances in computer science, STEM, and career technical training to help students gains the tools to smoothly transition to the workforce.

I am pleased that the President has proposed measures to increase college affordability, such as year-round Pell and bonus incentives for students to take additional credits. Together, these initiatives will help low-income students, increase graduation rates, and reduce debt, all while allowing them to enter the workforce faster, increasing their earnings and stimulating our local economy.

The President's Pell initiatives are a win-win, and I hope that Congress acts to make these proposals a reality for students. However, as you know, Pell is not available to everyone. That is why

the Federal student loan programs, including Direct Loans, Perkins Loans, and Federal Work Study, are so vital.

Student loan debt is not just a check that is written at the end of the month. It is a weight on the shoulders of those trying to build a career and can make it more difficult for hard-working Americans to save for a home, for retirement, and one day to pay for college for children of their own. I look forward to hearing more from you on how we can increase college affordability and reduce the debt burden on our students.

Lastly, I would be remiss if I didn't mention your proposed cuts to after-school programs. For many students, particularly in underserved areas, funding through the 21st Century Community Learning Centers provides after-school enrichment and a safe place for students to learn and develop their skills. I would like to hear from you what led to this proposed cut, especially when additional after-school programs are badly needed in communities throughout the country.

Thank you.

Thank you, Mr. Chairman.

Mr. COLE. I thank the Gentlelady.

Next, I want to make a point, and then I want to go to my friend, Mr. Fattah, who is effectively Acting Ranking Member today. I know you are aware of this, Secretary, but we have three Members traveling with the President today—so that is why attendance is a little bit sparse.

They are three of our most dedicated Members. They are almost always here, but they trust Mr. Fattah so much that they have left him, single-handedly, to hold us all off. So, with that, I recognize my very good friend from Pennsylvania for whatever opening remarks he cares to make.

OPENING REMARKS BY MR. FATTAH

Mr. FATTAH. I thank the chairman, and I thank him moreover for his leadership on many of the issues affecting education we have worked together on over the years.

One area is GEAR UP, and I would be interested in hearing, I know that the proposed $69.4 billion budget would hold GEAR UP at a hold harmless number from last year. Last year's number was an increase, in part because of many people on the committee support it, but mainly because the chairman was prepared to hold the line on that increase.

I was out in Oklahoma at the University of Oklahoma and saw some of the GEAR UP kids in a pre-engineering program just doing a fabulous job—so I am going to be very interested.

This is the Nation's largest early college awareness program. I authored it some 17 years ago. Millions of young people have benefited. The graduation rates are above the national average, as are the college completion rates.

I am interested in where the Department may go inasmuch as it is a great program, but it is still at the margins. That is, we still have so many of our young people and schools that are not benefitting from a program like GEAR UP, and we still have a need, as the President has laid out, to return the Nation to being the number-one nation in the world producing college-educated adults.

We have a program that works. It works in rural communities and urban communities. It works particularly among populations that we have had challenges with in terms of educational—access to educational opportunity and, therefore, attainment. I am interested in where you sense we can go in terms of creating a college-going culture in communities that heretofore haven't benefited from even our most successful efforts like GEAR UP.

Now I have worked with the administration on the American Opportunity Tax Credit, and I sponsored the bill that created it in 2009. It has helped millions of people and put billions in the pockets of families to pay for college costs. And you know, I know that we have now made it permanent in the tax code, which is a major achievement and a partnership between the Congress and the administration to make another $10,000 available.

It is not coming out of the education budget. It is coming via the IRS, but it is part of the puzzle with the maximum Pell, the tax credit, work study.

But as the Ranking Member from New York, Nita Lowey, said, we also have to deal with loan repayment issues. It may come as a surprise to some, but we tucked into the Affordable Care Act, when we passed it, a loan repayment plan that allowed young people to have parts of their loan forgiven to the degree that they engage in public service; if they join a local police department or they become a teacher or a local public servant in some capacity.

They can have a fifth of their loan retire each year that they serve in a public-spirited opportunity in their local community. I want to hear more about where we are and have that being known to more young people being taken—for them to take advantage of.

And the last question is around—and it is going to be part of your prepared testimony, I understand—this whole question of equity. You came out of the New York circumstance, so you know all too well that young people in our rural and urban communities still have the least of everything that we know they need in order to get an education compared to those in our wealthier suburban communities—so I am interested in the department's efforts in this regard.

We want to welcome you today, and I thank the Chairman.

INTRODUCTION OF WITNESS

Mr. COLE. I thank the Gentleman.

And Mr. Secretary, it is indeed a great pleasure to have you here today, and you are recognized for whatever opening comments you would care to make.

OPENING STATEMENT BY SECRETARY OF EDUCATION JOHN KING

Secretary KING. Thanks so much.

Chairman Cole, Ranking Member Lowey, and members of the Committee, thank you for inviting me to discuss the Department's 2017 budget, the first under the new Every Student Succeeds Act. I look forward to building up on our bipartisan collaboration as we implement ESSA and work to address our biggest challenges in education.

Increasing equity and excellence in public education has been my life's work. Before joining the Department, I led the New York State Department of Education and served with Uncommon Schools, a network of high-achieving charter schools.

I began my career as a high school social studies teacher and co-founded one of the highest-performing urban middle schools in Massachusetts. I am also the proud parent of two public school students. These experiences inform and inspire every decision I make at the Department.

This year, the Agency is focused on three principles, which reflect themes in our budget. First, ensuring every child has the opportunity to access a quality education. Second, supporting our Nation's teachers and elevating the teaching profession. Third, improving access, affordability, and completion in higher education. Allow me to take each of these in turn.

The budget invests in programs to increase educational equity so all children—regardless of background, native language, zip code, or disability—can achieve their potential. For example, the budget ensures our youngest learners get a strong start through President Obama's landmark Preschool for All initiative.

In addition, the HHS budget increases funding for the jointly administered Preschool Development Grants. To help close opportunity gaps, the request provides $15 billion for Title I, which is a cornerstone of the Federal effort to ensure that all students, especially our most vulnerable, graduate from high school prepared for college and careers.

The Computer Science for All proposals would advance comprehensive State and local efforts to offer rigorous coursework for all students, with a focus on those who have been underrepresented in the STEM fields.

The budget also would support community efforts to improve the educational and life outcomes for children and youth. The request increases funding for the Promise Neighborhoods program, for example, as well as Native Youth Community Projects, which support community-driven, comprehensive strategies to improve the college and career readiness of our Native children.

Through our Stronger Together initiative, we would help local leaders create more high-achieving, socioeconomically diverse classrooms and schools. In today's knowledge-based economy, we know we must do more to provide students with rigorous and relevant learning experiences. Consequently, the budget includes proposals for Next-Generation High Schools and Career and Technical Education that will prepare students to transition to postsecondary education and real jobs by engaging in project-based learning, having the opportunity to earn early college credit, and building career-ready competencies.

Recognizing that educators are our Nation builders and vital to our children's success, the budget invests to recruit, develop, support, and retain outstanding teachers and school leaders. The Teacher and Principal Pathways Program would strengthen our pipeline of effective educators, while Teach to Lead grants would capitalize on teachers' leadership for education improvement.

To help educators advance through their careers, the budget supports innovations in human capital management systems and pro-

grams like the Teacher and School Leader Incentive Fund. We also are proposing RESPECT (Recognizing Education Success, Professional Excellence and Collaborative Teaching): The Best Job in the World to rethink ways to structure teaching in high-need schools to attract and retain effective teachers where we need them most.

The programs in our 2017 budget also would make higher education more affordable and help additional students earn quality degrees. America's College Promise would make 2 years of community college free for responsible students. This budget also would drive innovations in Pell Grants by supporting students who take classes year-round, rewarding those who take at least 15 credits per semester, and rewarding institutions with high enrollment and completion rates for Pell Grant recipients.

While this budget is focused on helping to meet challenges, I also want to acknowledge our country's remarkable gains. High school graduation rates are at an all-time high, and dropout rates are decreasing. We have seen the largest and most diverse class completing higher education in our history.

This budget leverages local leadership, the source of strength for our Nation's education system, to help more students thrive from preschool through college. Throughout our proposals and programs, we are committed to using and developing evidence and data to maximize results for students and taxpayers.

The Department's 2017 budget would support local and State-led efforts to ensure that in every community and in every school, students know that their education can provide them with the knowledge and skills to achieve their greatest aspirations.

I look forward to discussing these ideas with you in more detail and would be glad to answer your questions.

Thank you.

[The information follows:]

Biography of John B. King, Jr., U.S. Secretary of Education

John B. King, Jr. was confirmed by the U.S. Senate on March 14, 2016, following his nomination by President Barack Obama. He served as Acting Secretary from January 2016 until his confirmation. As Secretary, Dr. King brings a continued commitment to advancing excellence and equity for every student, supporting educators and elevating the teaching profession, and improving college affordability and completion rates.

Before becoming Secretary, Dr. King had served since January 2015 at the Department as Principal Senior Advisor. In that role, Dr. King carried out the duties of the Deputy Secretary, overseeing all preschool-through-12th-grade (P-12) education policies, programs and strategic initiatives, as well as the operations of the Department. Dr. King carried out this work with a focus on increasing equity, improving educational outcomes for all students, and closing achievement gaps through implementation of key Administration priorities in areas including early learning, elementary and secondary education, special education, English language acquisition, and innovation.

In performing the duties of the Deputy Secretary, Dr. King also oversaw the Department's work leading cross-agency collaboration for President Obama's My Brother's Keeper Task Force, which seeks to address persistent opportunity gaps faced by boys and young men of color and ensure that all young people are able to reach their full potential.

Prior to his arrival at the Department, Dr. King had served since 2011 as the Commissioner of Education for the State of New York. In that role, he served as chief exeeutive officer of the State Education Department and as President of the University of the State of New York, overseeing the State's elementary and seeondary schools (serving 3.1 million students), public, independent and proprietary colleges and universities, libraries, museums, and numerous other educational institutions. Dr. King was one of the Nation's youngest State education leaders at the time of his appointment and the first African-American and Puerto Rican to serve as New York State Education Commissioner.

As Commissioner of Education, Dr. King worked with the Board of Regents to pursue an ambitious education improvement agenda. During his tenure, New York State was a national leader in many facets of education: investing in high-quality early learning; raising standards for teaching and learning; supporting teachers and school leaders through strong professional development, access to rich instructional resources, and innovative educator career ladder models; expanding career and technical education in high-demand fields; and increasing educational opportunity for students in the highest-need communities. Under Dr. King's leadership, New York deepened collaboration between the State's P-12 schools and its institutions of higher education, including strengthening teacher and principal preparation, and raising the bar for teacher and principal certification.

Dr. King brings to his role extensive experience leading urban public schools that are closing the achievement gap and preparing students to enter, succeed in, and graduate from college. Prior to his appointment as Senior Deputy Commissioner at the New York State Education Department in 2009, King served as a Managing Director with Uncommon Schools, a non-profit charter management organization that operates some of the highest-performing urban public schools in

New York, New Jersey, and Massachusetts. Earlier in his career, Dr. King was a co-founder and co-director for curriculum and instruction of Roxbury, Massachusetts, Preparatory Charter School. Under his leadership, Roxbury Prep became one of the highest performing urban middle schools in the State, closed the racial achievement gap, and outperformed not only the Boston district schools but also schools in the city's affluent suburbs. Dr. King began his career in education teaching high school social studies in San Juan, Puerto Rico and Boston, Massachusetts.

Dr. King earned a Bachelor of Arts in Government from Harvard University, a Master of Arts in the teaching of social studies from Columbia University's Teachers College, a J.D. from Yale Law School, and a Doctor of Education degree in educational administrative practice from Columbia University's Teachers College. Dr. King was a 1995 Truman Scholar and received the James Madison Memorial Fellowship for secondary-level teaching of American history, American government, and social studies. Prior to joining the Department in February 2011, Dr. King was appointed by Secretary of Education Arne Duncan to serve on the Department of Education's Equity and Excellence Commission. In addition, Dr. King served on the Board of New Leaders for New Schools from 2005 to 2009. He is also a 2008 Aspen Institute-New Schools Entrepreneurial Leaders for Public Education Fellow.

Dr. King's life story is an extraordinary testament to the power of education. Both of Dr. King's parents were career New York City public school educators, whose example serves as an enduring inspiration. Dr. King's parents both died from illness by the time he was 12, and he struggled to cope with their loss as he moved between family members and schools. He credits New York City public school teachers—particularly his teachers at P.S. 276 in Canarsie and Mark Twain J.H.S. in Coney Island—for saving his life by providing transformative educational experiences and giving him hope about the future. His belief in the centrality of educational opportunity to the American Dream and the vital necessity of second chances for our young people has its foundations in his own experience of overcoming so many challenges and going on to graduate from Harvard, Yale, and Columbia and become a teacher and education leader.

For his leadership on issues of educational equity, Dr. King has been honored with the Ann S. Kheel Award from the New York Urban League, the Eugene M. Lang Lifetime Achievement Award from the "I Have A Dream" Foundation, the New York Immigration Coalition Builders of the "New" New York Award, and the Robin Hood Foundation Heroes Award.

Dr. King lives in Takoma Park, Maryland, with his wife and two children, who attend local public schools.

Mr. COLE. Thank you, Mr. Secretary.

TRIO DEMONSTRATION

Let me begin the questioning. I am concerned about the Department's request to reduce funding for the more traditional grants in the TRIO program to make room for an additional or proposed $20 million demonstration project. As I know you are aware, there is broad bipartisan, bicameral support for TRIO, as these programs are effective in improving access to and the completion of higher education for students from disadvantaged backgrounds.

What is the issue or the concern with TRIO programs that the Department hopes to address through this proposed demonstration project?

Secretary KING. The hope with the demonstration project is really to build on the success of the TRIO programs. We see TRIO and GEAR UP as critical to our Nation's effort to get back to being first in the world in college completion. We think evidence is critical to that, and the demonstration project gives us the opportunity to build in an evaluation process that would generate evidence about what works most effectively in TRIO programs. This would then inform the rest of the TRIO investment.

However, as you point out, it is a relatively small investment in the context of the overall funding level for TRIO.

Mr. COLE. Can you give me a little bit more in the way of specifics in terms of what the evidence is, what are we looking for, and how we go about doing that in the proposal?

Secretary KING. Yes. In many ways, this builds on the work we have done with what is now called the Education Innovation and Research Program within the Every Student Succeeds Act. The idea is that we are to do either a randomized controlled trial or research using quasi-experimental design to try to produce good evidence about best practices that then can inform work that is happening across our programs.

For example, there have been research efforts that have shown that exposing students to other first-generation college students like them who can talk about their experience from a personal perspective is more effective than receiving the same information from folks who didn't share that experience. There is good research evidence that this makes a meaningful difference in students' retention, their grades, and so forth.

So that is the kind of information that we would like to be able to feed into the larger TRIO effort. We think that the small investment of $20 million, in the context of the overall program, is worth it to try and leverage good information about what works.

Mr. COLE. As you know, TRIO has a very active support group and advocacy group of many years standing. Do you know, are they supportive of what you are trying to do? Have they taken a position on this, one way or the other?

Secretary KING. I will have our team follow up. I don't know if there has been a collective response from all the folks who are interested in TRIO.

[The information follows:]

TRIO STAKEHOLDER SENTIMENT

We do not feel that it is appropriate for the Department to characterize the positions of the TRIO community, which is comprised of national and regional organizations as well as educational leaders and individual TRIO alumni, especially when, to our knowledge, none of our stakeholders have made such positions publicly available. However, the Department believes that such a Demonstration would be most successful if it is informed by feedback from the community, and we look forward to continuing outreach efforts in that area.

I will say there has been a lot of enthusiasm for our work on the Education Innovation and Research efforts.

Mr. COLE. Okay. Well, good. We would appreciate any information you found, if you do have a chance to do that follow-up.

NATIVE YOUTH COMMUNITY PROJECTS

Mr. Secretary, in the fiscal year 2016 omnibus, we provided an increase of $20 million for the Native Youth Community Projects to support culturally relevant strategies to improve college and career readiness amongst Native American children. I am pleased to see that you proposed an additional increase again this year.

Can you please give us an update on what you think has been accomplished so far in this program and describe how you propose to build on that with your 2017 request for an additional $31 million?

Secretary KING. Yes. We are certainly early in the process, but what we have seen is that by bringing together tribal communities to think about what it would take to have culturally responsive instruction in the schools, leverage students' Native language, to try to ensure that students are on a path for college and career readiness, that we can see real educational improvement.

We think this is an important investment. If you look at our high school graduation rates as a country, almost every group has seen improvement over the last few years except, in our most recent data, for Native Americans, who did not make improvements. This illustrates that we have more work to do to ensure that Native youth understand that college is possible for them, that jobs are possible for them.

You know, when we have met with Native youth and Native educators who are working on the Native Youth Community Projects, they have talked about the hopelessness you often see in many communities. I know you are familiar with this from your State.

That hopelessness then translates into students not being motivated in school, not sticking through to graduation, not going on to college. So we think this strategy of bringing communities together around college and career readiness can be high leverage. That is why we proposed a significant increase for this activity.

Mr. COLE. Well, I just want to commend you for doing so and appreciate your focus, the department's focus, certainly the Administration's focus on this population in this area. You are to be commended for it.

With that, I would like to go my good friend, the Ranking Member for the Full Committee, for whatever questions she would care to ask.

OPTING OUT OF STATE ASSESSMENTS

Mrs. LOWEY. Thank you, Mr. Chairman.

As you well know, Mr. Secretary, a number of students in New York have opted out of taking State assessments. Under both No Child Left Behind and the ESSA, the department has the ability to penalize school districts by reducing Title I funding if less than 95 percent of students take State assessment exams.

Mr. Secretary, I represent a number of school districts that did not meet the 95 percent threshold despite the participation of the overwhelming majority of students. I am very concerned that if the Department does not work with local school districts, students—the majority of which sat for State assessments—will be punished as a result of a small number of students who opted out of the test.

Will the department provide flexibility to school districts who are putting forth a good-faith effort on participation rates to ensure that needy students are not punished?

Secretary KING. We think it is hugely important for families and educators to have good information about students' progress each year. That is the goal of the assessment system as required in the Every Student Succeeds Act.

We have communicated to States their continuing responsibility to ensure that all students participate in the assessment system, and our experience has been that States are working diligently to try to talk with their districts, with parents, and with communities about the importance of the assessments and the role that they play. We expect States to move forward with that.

There were a small number of States that did not meet the participation requirement last year. We have communicated with those States what their responsibilities are, and our impression is that States are working diligently to address it. So, I am optimistic that States will ensure that the districts get to a better place where we have seen these issues.

Mrs. LOWEY. I hope I am optimistic, and the issue is of critical importance, as you know. I am going to continue to monitor the Department's role to ensure it carries out the goals of the new ESSA, but it is important that we provide more flexibility to those at the local level.

READY TO LEARN AND OPEN EDUCATIONAL RESOURCES

A question about Ready to Learn and Open Educational Resources. You are aware: I am sure, this past fall, the Department published a Notice of Proposed Rulemaking related to Open Educational Resources. The proposed rule is far-reaching, and would require that any intellectual property produced, even in part, with department grant funding be openly licensed and available for use, modification, and dissemination free of charge by other companies, organizations, and individual members of the public.

After speaking to many people, I have concerns about the negative impact this proposed rule would have on public media, which already distributes the content created in part through the department's Ready to Learn grant to nearly every household in the country for free. How does the department plan to address the chal-

lenges this proposed rule would pose to essential partners like public media?

Secretary KING. The context for this proposed rule is that Open Educational Resources can be a lever for equity. One challenge across communities is access to high-quality curricular resources. We see particularly in some of our high-needs urban and rural communities, a lack of access to those materials translating into fewer opportunities for students.

The premise of the Open Educational Resources effort is that where the Federal Government invests funds in the creation of materials, we ought to make those materials broadly available to advance equity. We are in the stage of reviewing public comment on the proposed rule, and we will try to address any of the concerns that we have received from grantees.

As a general matter, I think the reception on the Open Educational Resource rule has been very positive because of the belief that it will be a lever for equity. But we certainly appreciate the important role that public television and public media play in American culture and want to make sure that we are sensitive to those issues. Certainly, our staff can follow up with yours on this issue.

Mrs. LOWEY. Thank you.

Thank you, Mr. Chair.

Mr. COLE. Thank you.

We will go next to Mr. Fattah for whatever questions he cares to pose.

GAINING EARLY AWARENESS AND READINGS FOR UNDERGRADUATE PROGRAMS

Mr. FATTAH. Thank you, Mr. Chairman.

Let us start with GEAR UP. The department is, and rightfully so, focused on evidence and data. Why don't you share with the committee what the evidence and data is relative to GEAR UP?

Secretary KING. The overall results of the GEAR UP program have been very positive. I think you made the point in your opening remarks that the TRIO and GEAR UP programs have both had positive effects particularly on graduation rates, but also on students' readiness to transition to college.

That is why we think they are important programs. That is why the President preserves the funding increases from last year in our proposed budget.

Mr. FATTAH. And how many children do we have in GEAR UP programs per day?

Mr. SKELLY. Five hundred thousand——

Mr. FATTAH. Five hundred thousand.

Mr. SKELLY [continuing]. Students are served by GEAR UP.

Mr. FATTAH. And they are spread through how many States?

Secretary KING. It is—I think it is 39 States?

Mr. SKELLY. Yes, thirty-nine States.

Secretary KING. Yes.

Mr. FATTAH. And with the increase that the committee provided of some $20 million, is there going to be a new competition?

Secretary KING. We do expect to have a grant competition to add additional programs.

Mr. FATTAH. Okay. Now I have worked with Senator Coons on a proposal that the Department, I think, piloted last year or the year before to take a few thousand students and seed small college savings accounts—it is called the American Dream Accounts effort—and to marry it up with online higher ed counseling. This is based on some evidence. It is empirical analysis that shows that poor children, even when they have as small as $100 in a savings account focused on them going to college, their grades improve. The expectations improve for them by their teachers.

And I know we are in the early stages of this, but does the department have any—this pilot program I think now has some 10,000 kids in it through GEAR UP. Do we have any information about that?

Secretary KING. I don't at the moment, but I will have our staff follow up with you on that.

[The information follows:]

STUDENT SAVINGS PILOT PROGRAM PARTICIPATION

We are unable to provide this data because we do not collect student-level data on the GEAR UP program.

STUDENT LOAN FORGIVENESS

Mr. FATTAH. All right. The loan repayment efforts that were embedded in the Affordable Care Act, this opportunity for loans to be forgiven for public service. Can we shift gears and you talk to us a little bit about where that is and how many young people are taking advantage of it?

Secretary KING. Yes. I don't know the precise number of students who are taking advantage. We do worry that, in these public service forgiveness programs, there is inadequate kind of public knowledge and public awareness on the part of students.

One of our goals is to try to increase student awareness of the programs, particularly on teaching. There are a number of teaching loan forgiveness programs, but the participation rate is not as high as we would want. This budget proposes actually consolidating those teacher loan forgiveness programs to create a streamlined program to provide $10,000 of loan forgiveness, up to $25,000 if students have attended what their State rates as a "highly effective" teacher preparation program.

This is a place where we are focused on trying to make sure that students are as aware as possible of their options.

Mr. FATTAH. All right. This is broader than just the teachers, and what we did was we said there were two approaches. One was that you could cap your total repayment or your amount you had to repay to 10 percent of your income over your lifetime, right? Secondly, there was an opportunity to have your student loan forgiven, to the degree that you decided to go into public service as a police officer or a teacher or some other public service profession.

I was wondering whether the department has some sense of whether this is getting out there, or that young people are utilizing it and to what benefit?

Mr. SKELLY. We had a tremendous push in the income-driven repayment programs to let people know about the availability of them and many more students are signing up for them. It is still

a little early for students to have achieved the necessary number of years in public service to get a loan forgiven. So we don't have any hard data——

Mr. FATTAH. Right.

Mr. SKELLY [continuing]. Really worth much—on how many people are getting loan forgiveness, but it looks like it is a very popular option that helps people deal with high student debt if they have got it.

We have a number of proposals in the budget this year to reform some of the proposals. That is because it is possible the public service forgiveness is giving people an inappropriate signal or incentive to borrow more than they need, particularly in graduate school. The undergraduates, not so much, but a lot of people exceed the $57,500 cap available for undergraduate borrowing when they go to graduate school.

We wanted to make sure that folks know they shouldn't be borrowing just because they could and potentially get the loan forgiven after 10 years.

[The information follows:]

PUBLIC SERVICE LOAN FORGIVENESS PARTICIPATION

As of February 2016, there were a total of 359,975 borrowers who could potentially participate in Public Service Loan Forgiveness (PSLF). This figure represents those who have been formally certified based on full-time qualifying employment or conditionally certified based on part-time qualifying employment. Please keep in mind that this number is a total, as we never 'release' a borrower from the total potential PSLF population, so it may include some borrowers who are no longer holding employment, have since paid in full, etc.

Through the end of 2022, the Department estimates that 331,000 borrowers will receive Public Service Loan Forgiveness.

Mr. FATTAH. Right. I will stop there, Mr. Chairman. I think we need to do a lot more to let young people know about what is available. Maybe we will do it after the reform, all right?

Thank you, Mr. Chairman.

Mr. COLE. Thank you.

We will next go to my good friend, the gentleman from Tennessee, for whatever questions he cares to ask.

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

Good morning, Mr. Skelly, and Mr. Secretary, good morning, sir.

Secretary KING. Good morning.

STUDENT LOAN SERVICING

Mr. FLEISCHMANN. Good to see you. Secretary King, I would like to ask you a series of questions, sir, regarding student loan servicing.

The contracts that the Department has in place with the 10 national nonprofit and for-profit servicers specify that servicer performance will be measured semi-annually in the areas of customer satisfaction and default prevention, and these results will determine future loan volume allocations twice a year.

I have a two-part question. The first question, sir, is what rationale and under what authority is the Department using to unilaterally reduce the allocation window from September to July? And then secondly, doesn't this recent announcement directly contradict the language included in your servicing contracts, which requires

the Department to allocate student loan volume through services based on performance and capacity through fiscal year 2016?

Secretary KING. Thanks for the question.

Certainly our goal in servicing is to make sure that we serve borrowers' interests well and serve taxpayers' interests well. The 2016 Appropriations Act required us to reallocate loans for this year using existing metrics of performance between the not-for-profits and the TIVAS.

That process took place. We have done a loan reallocation. However, one of the challenges is that our existing metrics actually do not make an apples-to-apples fair comparison between the different servicers. Our next step is to develop metrics that more accurately assess performance across the different types of servicers based on the mix of loans that they have.

The mix of loans that you have affects many of these performance indicators, so we are gathering input from the not-for-profits and the TIVAS on those metrics now, and we will develop new metrics in advance of the next academic year. By July, we expect to have new metrics in place for the allocation going forward, consistent with what is required in the 2016 appropriation.

Mr. FLEISCHMANN. Okay, sir. As a follow-up, last week Federal Student Aid announced it was creating new performance metrics for loan allocation "because of the significant variation in the composition of loan portfolios between student loan servicers."

Several questions. What variation is FSA talking about, sir?

Secretary KING. The key issue is the nature of the loans that are given. For example, if you are a servicer and you have loans of currently enrolled students who are not yet in the process of paying back their loans, that is very different from having loans from students who may be high-risk borrowers. We want to make sure that our methodology accounts for variations in the loan portfolio.

Mr. FLEISCHMANN. Okay. Why is the department creating new performance metrics when it just completed such a process in 2014? As a follow-up to that, what new performance metrics is the Department considering using going forward?

Secretary KING. As we do the next round of loan distribution, beginning this summer, we want to use the best metrics to compare performance—again to protect the interests of both borrowers and taxpayers. We haven't determined what those new metrics will be. That is the process we are in now. We are gathering feedback from both the not-for-profits and the TIVAS on what those metrics should look like.

Mr. FLEISCHMANN. Is the Department taking such steps to circumvent the language included in the Consolidated Appropriations Act, and wouldn't it be more appropriate to incorporate such new metrics as part of the upcoming recompete instead of changing the rules of the game midstream, sir?

Secretary KING. Well, the challenge is that the 2016 Appropriations Act changed the methodology for this year from prior years. This limited us to existing metrics that don't necessarily adequately measure the differences in the loan portfolios. We want to make sure before the significant tranche of new loans takes place this summer—August/September, some of the highest volume

months—that we have the best possible metrics, focused again on performance for students and taxpayers.

Mr. FLEISCHMANN. Thank you, Mr. Secretary.

Mr. Chairman, I will yield back.

Mr. COLE. Thank you very much.

We will next go to my good friend, the gentlelady from Alabama, for whatever questions she cares to offer.

Mrs. ROBY. Thank you, Mr. Chairman.

STATE AUTONOMY IN STANDARDS AND CURRICULA

Congratulations, Secretary, on your confirmation, and I look forward to getting to know you and, hopefully, being able to work together.

As you know, the ESSA includes provisions that specifically prohibit you and your staff at the Department of Education from using funding grants or special policy waivers to influence or coerce States into adopting certain standards or curricula. And as you may or may not know, I proposed that language when I was on the Authorizing Committee in a standalone bill, and I worked for 3 years to get it in the final bill.

It was borne out of frustration over department officials habitually exercising undue and inappropriate influence over State education decisions throughout the former Secretary's tenure. So we both know old habits die hard, and it is not hard to imagine bureaucrats thinking, "Hey, we know better than Congress. We are going to keep doing what we think is best, despite the specific language that is included in the current bill."

Mr. Secretary, how can you assure this Committee and the Congress that your Department will comply with this very, very important provision of the law? And how will you change the culture at the Department to prevent your team from falling into the same bad habits of telling the States what to do?

Secretary KING. Two important elements of the Every Student Succeeds Act have important implications for your question. One is the requirement that States have standards in place to ensure students are ready for success after they leave high school.

In many States across the country, and I know you are familiar with this, we see students arriving on college campuses only to be told that they need to take remedial courses, which really is a euphemism for high school classes, because they don't have the academic skills they need for success in college.

We hear all the time from employers, as I am sure you hear this from your constituents who say they are struggling to find employees with the skills that are necessary. So ESSA importantly requires States to have standards that reflect college and career readiness. We think that is critical.

Second, ESSA requires that standards are the province of States, for States to determine. We agree with that. The Department's position during the last 7 years and today is that standards should be determined by States, but those standards should be high and should point towards college and career readiness.

I think ESSA strikes the right balance, and we intend to adhere to exactly what ESSA requires: the standards are the province of the States.

Mrs. ROBY. Well, thank you for your response.

I really appreciate hearing your commitment to that very important provision of the law. I know, though, a lot depends on rulemaking, and we need to ensure that those rules comply with the intent of Congress. And so as a Member who fought very hard for these provisions in the law, let me state very clearly again that the intention is to stop Federal coercion in education decisions, not just on Common Core.

I know that that is what the debate seems to center around a lot. It is not just about Common Core, but it is the next policy that the Department wants to push in the next year or 5 years or whenever. So I do appreciate your commitment to that. We will see how much we can fit in in a minute and 22 seconds.

COMPETITIVE VERSUS FORMULA CAREER AND TECHNICAL EDUCATION GRANTS

There is the administration's request for $1.2 billion for career and technical education. It is an increase of $77 million over fiscal year 2016 appropriation. The request would provide $1.1 billion for State formula programs and $75 million to fund a grant competition for American Technical Training Fund.

So rather than funding a large competition grant, it seems to me that the funds would be better used to support State formula grants, which would ensure more students are able to benefit from the CTE experience. So many of my constituents benefit from this. Can you just address the competitive grant versus——

Secretary KING. Sure. The goal of the American Technical Training Fund is to incentivize partnerships between higher ed institutions, school districts, and employers and workforce investment boards to provide high-quality career and technical education experiences. We think that kind of cross-sector partnership is critical to driving quality programs.

I was just at Alabama A&M last week, meeting with them on the STEM programs they have developed in partnership with NASA and Lockheed Martin. And you can see the strength of those employer-higher ed institution collaborations.

Our goal in this program is to foster that alongside the kinds of career and technical education programs that are supported by the traditional Perkins program.

Mrs. ROBY. We will continue this. My time has expired. So I will yield back, but we will continue this if there is another round.

Thanks.

Mr. COLE. I thank the Gentlelady.

We go next to my good friend, the Gentlelady from California, Ms. Roybal-Allard.

Ms. ROYBAL-ALLARD. Thank you, Mr. Chairman.

And welcome, Secretary King.

INDIVIDUALS WITH DISABILITIES (IDEA) VERSUS DEMONSTRATION FUNDING

Each year, children and families are shortchanged when the Federal Government does not meet its full commitment to special education under the Individuals with Disability Education Act. While school districts across the country have a serious need for addi-

tional resources, IDEA is consistently funded well below the 40 percent Federal cost share that was promised under the bill's authorization.

Once again, I am disappointed that the President's budget request only funds the Federal share of education for students with disabilities at 16 percent. Given the tremendous need that exists for students with disabilities, can you please explain why the President's budget freezes funding for IDEA State grants while requesting $465 million for programs that are unauthorized and unproven?

Secretary KING. Let me first say that I share your commitment to the important role of IDEA in supporting the success of our students with disabilities, as does the President. The budget maintains the $415 million increase from 2016 for IDEA.

The budget also includes an increase for IDEA preschool and IDEA infants and families, so there are IDEA increases.

One of the constraints in the budget process was to try to balance advancing priorities with maintaining the caps that were agreed upon in last year's budget agreement. The IDEA budget reflects that, that we, again, maintained last year's increase and then have an increase for preschool and infants and families.

Ms. ROYBAL-ALLARD. The fact is, though, that the President's budget does not reflect a dedicated effort to meet our Federal obligation to special education and instead has requested robust funding for new and unproven programs. And that is a big concern.

STUDENT SUPPORT AND ACADEMIC ENRICHMENT

As you know, the Student Support and Academic Enrichment Block Grant, Title IV–A under the Every Student Succeeds Act, consolidates into a single block grant several programs that protect the health and safety of students, promote well-rounded enrichment opportunities, and invest in education technology.

Again, I am deeply concerned that the President's budget proposes to fund this program at barely $500 million, which is less than one-third of its authorized funding level. If the President's budget request is implemented, school districts will be seriously compromised in their ability to invest in K–12 services, ranging from advanced placement courses to high-quality digital learning.

Competitive grant structures risk leaving many under resourced school districts without any Federal support. Can you please justify your less-than-adequate funding request for Title IV–A and your recommendation to turn the program into a competitive grant?

Secretary KING. We think the new version of Title IV under the Every Student Succeeds Act has a number of very important purposes, including, as you described, supporting well-rounded education, school counseling, education technology, and efforts by districts to offer Advanced Placement courses. The preexisting programs that are folded into Title IV were funded in the 2016 Appropriations Act at $278 million. We propose Title IV funding at $500 million. That is a $222 million increase over last year's spending.

It is less than the authorized level. Again, we were trying to, in our budget, both advance the President's priorities and stay within the budget caps that were agreed to in last year's budget agreement.

But we are certainly open to working with you and others on the Committee as we move forward in the budget process because we do believe that Title IV has very important elements. The proposal around competitive awarding of the grant is to give States the option to award the grant competitively because we worry that without that competitive element, you could have a distribution in the State through a formula methodology that results in school districts receiving $10,000, which may not be enough to offer a meaningful program in school counseling, arts education, or Advanced Placement courses.

So we propose giving States the option to make the grant competitive within the State around State priorities with a $50,000 floor so that we can ensure that the Title IV grant has a meaningful impact for students.

Ms. ROYBAL-ALLARD. I recognize that argument, but on the flip side of that, it also leaves a lot of very needy school districts and areas—that don't have the resources—with the inability to compete and be competitive for those grants. That is the flip side of what you are saying.

Unfortunately, this funding continues the cycle of inadequately funding necessary supports for a lot of students and leaves out a lot of schools, particularly those that I represent.

I see, Mr. Chairman, that my time is just about up, I will wait until the next round.

Mr. COLE. I have enjoyed the questions. They are great questions.

If I can, I will go to my good friend, the gentleman from Arkansas, who is also the Vice Chairman of the Committee, Mr. Womack.

Mr. WOMACK. Thank you, Mr. Chairman.

Mr. Secretary, Mr. Skelly, welcome once again. Congratulations, Mr. King, on your appointment and your confirmation.

CAREER AND TECHNICAL EDUCATION AND DEMONSTRATION

My colleague from Alabama opened the door on career and technical education, and I would like to go back into that subject for just a minute and save her questions later for another topic, if she would like to do that.

First of all, I am a huge believer in career and technical education, and it is my opinion, only my opinion, that our country has maybe even duped an entire generation of young people to believe that the only real road to success is a 4-year degree, going to your local college or university and getting that 4-year liberal arts degree, perhaps. And we left a lot of opportunities for these kids begging.

In fact, when I travel my district, one of the first things I hear from my job creators is the skills gap and the fact that we had an opportunity to put a lot of kids in that pipeline and just did not, and a lot of these skills are just simply not able to match the job requirements.

I want to go back to the fact that there is level funding, the $1.2 billion in level funding and the $75 million request for a new competitive grant program and get your thoughts as to why we would be opening up a new unproven program of $75 million when we are not able to meet the demands across the rest of the spectrum?

So can you just kind of articulate on that, and then I have one other question.

Secretary KING. Yes. Again, I think our goal there is to try to create a best practice model through a relatively small, targeted competitive grant that would incentivize strong partnerships.

We also would like to see Perkins Career and Technical Education Act reauthorization in a way that advances this notion of partnership. In my experience in New York, one of the things we worked on was creating partnership high schools, where high schools were partnered with community colleges and employers. Students would graduate with high school diploma and associate's degree, first in line for a job at those employers.

We created those all across the State, and what we found was there is huge demand, just as you are describing, from employers across industries—from advanced manufacturing to pharmaceuticals to the tech industry. We think that notion of partnership should drive reauthorization of the Perkins CTE program.

The President also has a Next Generation High Schools proposal, which would aim to get high schools to think differently about their design so that they can do exactly what you are describing—help students see that it is not necessarily a question of college versus career. It is the idea that postsecondary training is essential, and that it can lead you on a career path that might bring you back to school multiple times to hone your skills.

That career could be the hook that gets a high school student interested and focused on their future.

DEPARTMENTAL COLLEGE RATINGS

Mr. WOMACK. On another subject, in our fiscal environment, we have been taught that data and evidence-based approaches are critical to improving our education system, and we are all forced to do more with less. Everybody gets that, and I am a big supporter of State and local control when it comes to education.

But I think most of us can agree that there are some areas where the Federal Government can play an effective role, and I believe one of those areas is research and creating transparency through data. I am glad to see the Department of Education withdrawing its troubling plan to rate colleges. It demonstrates a fine line between providing students and institutions with more data and trying to generate a "one size fits all" system for evaluation.

DATA TRANSPARENCY

I would argue that consumers are probably more suited to judge whether an institution is right for them based on their unique circumstances rather than a bureaucracy up here.

I mention this because I noticed in your budget proposal that you request funding for an initiative launched this year, InformED, that will make the Department's data and research across education spectrum more available and actionable for internal users and for the public. Can you explain in greater detail in the last minute that I have behind this new initiative and tell me your plans for making this data actionable?

Secretary KING. Yes. As you say, data can inform decision-making at the local level, State level, and at the Federal level. With the

college scorecard, our approach was to make transparent the Department's data and—while protecting transparency—make that data available to nonprofits and others who wanted to use it to inform consumers.

What we have seen, for example, is a program called Pell Abacus, which helps students see within a minute how they might calculate what their actual costs would be at a given college. I was at a high school recently with students, watching as they discovered that a college they thought would never be accessible to them, based on their financial aid package, actually could be within reach. That is a powerful way that data can be leveraged.

The InformED proposal seeks to do that kind of work across the department. The bulk of the funding, I think $13 million of the $15 million is really for States to improve their data quality, data management so that we can pull that data to the Federal level in a way that helps it inform States, districts, and ultimately students and families.

Mr. WOMACK. Thank you, Mr. Chairman.

Mr. COLE. I thank you, and—oh, the gentleman from Maryland is gone. Okay. Well, I will move on and recognize myself then.

TITLE I FORMULA AND SCHOOL IMPROVEMENT ALLOCATION

Mr. Secretary, several education advocacy organizations are concerned about the Department's funding request for Title I grants to local education agencies because they believe it would result in a reduction in Title I allocation in many schools. In a sense, it is sort of building on the point that my good friend from California made.

Are these groups correct in that, and if so, you know, why does the request shortchange district and instead invest in some unauthorized competitive grant programs, as opposed to something sort of tried and true like Title I?

Secretary KING. Let me give some context to how we approached the Title I allocation. Our Title I proposal is actually $350 million above the authorized level because we do think Title I is very important in getting resources to our highest-needs districts.

What we propose is to divide that $350 million between formula dollars and school improvement dollars that would focus on the schools that are struggling. For districts that have significant numbers of struggling schools, they will likely see level funding or an increase because of that school improvement focus.

But because States will determine which schools are most in need of improvement, and States are the ones who develop those lists, it is not possible for us to project exactly what the implications will be for any given district. It will depend on how many schools they have that are deeply struggling.

Mr. COLE. Well, not to push this point too hard, but as I am sure you are aware, there is a great deal of unease and uncertainty because of that, because there isn't a predictability there, and there is concern that some of these schools will literally just fall through the cracks or will have something done at a State level that really doesn't direct the money to where it is needed. So I think that is something that a lot of folks have considerable concern about.

EVERY STUDENT SUCCEEDS ACT IMPLEMENTATION

The Every Child Succeeds Act represented a significant shift of control over K–12 education policies and programs from Federal to the State level. How does your budget request address this shift and assist in building capacity in States to take over these new responsibilities?

And wouldn't a larger investment in block and formula grants, as opposed to the new competitive grant programs included in your budget, be a better way to help States to succeed under the new law?

Secretary KING. We certainly think that, like the increases that we saw in Title I last year, the significant increase we proposed in the Title IV programs will be important to Every Student Succeeds Act implementation. We also have held public hearings and have gathered significant public comment on implementation. We have begun negotiated rulemaking in two areas based on input from States and districts as well as civil rights organizations and community organizations.

We intend to implement the law in a very collaborative way, gathering feedback throughout as we develop guidance and regulations. Driving our work on guidance and technical assistance will be what we hear from districts and States about what they need.

We do think some of the specific competitive grant requests here advance key priorities within the Every Student Succeeds Act, but it is worth saying that 94 percent of what we propose is directed toward formula dollars. The vast, vast majority of what is funded in the President's budget is through formula, but we do think there are places where competitive grants can highlight or incentivize particular practices that will help drive educational improvement.

Mr. COLE. Well, and this is hardly your fault, but there is some concern—certainly, I have concerns—that because Congress was late in getting this legislation to you, you know, frankly, the President and, with all due respect, you will only be there for a certain period of time. A few months, really. I am very skeptical about new initiatives when the people that are implementing them aren't going to have the timeframe to actually be there.

Do you have any concern of that yourself?

Secretary KING. We think the proposals we have made really build on the last 7 years of work, build on the bipartisan agreement in the Every Student Succeeds Act, and point toward important priorities that are shared bipartisan priorities. We propose, for example, an increase in the Preschool Development Grant Program because I think there is strong bipartisan consensus, not only in Washington, but in State capitals, around the importance of investing in early learning.

We propose a program around computer science because I think everyone understands, again in a bipartisan way, that computer science is a part of our future competitiveness and that we ought to be helping districts and States think about how to support their students in achieving around computer science so that they are ready to compete for the 21st century jobs that will rely on computer science.

Mr. COLE. Great. If I could, I will recognize my good friend from Pennsylvania, Mr. Fattah.

Mr. FATTAH. Thank you, Mr. Chairman.

EQUITY AND LOCAL CONTROL

I want to revisit this issue around equity, and I know my colleague from Alabama talked about standards, and you said that, you know, standards should be left to the States. I want to return us to a different President, President Nixon.

He said this issue about local control is an injustice wrapped up in a virtue, right? That in the Nixon school finance commission, in its summary, it said that as long as we have a property-based funded school system, poor children in our country are going to disproportionately fail.

The reason for it is that if you are funding schools on a property tax, then poor communities aren't going to be able to put—they are going to have a higher millage, but they are going to put less money behind each child.

So we have in the classrooms of the poorest children in our country today—this has been true since Nixon was President. They have in the main teachers who in the major subjects haven't a major or minor in the subjects that they are teaching—math, science, English—because these school districts can't afford to compete with their wealthier suburban districts for, you know, the teachers who are certified in math, right?

They have, in many of our States, double the classroom size. They have textbooks that haven't been printed in these children's lifetime. When we stand here and we talk about, well, you know, it is a local matter. It is, and it is an unfortunate local matter, right? That is to say that our States, you know, the politics of the statehouse is that the poor communities and the rural communities in Appalachia and big cities, poor communities get the short end of how these things get worked out.

Even when States set up important standards like teacher qualifications, they then grant waivers. Everywhere you can find a predominant group of poor children, the State waives the requirement, right, rather than create an impulse to actually get qualified people in the classroom.

When Education Trust did the study in California, and they found 57,000 teachers who had not majored or minored in the subjects they are teaching, right? Now I am not blaming the teachers—these are good people. But at my alma mater, Overbrook High School, a young lady shows up. She has got a degree in art history. The principal says, "Look, I don't have anybody teaching geometry. You have to go teach geometry."

At the end of the school year, that young lady quit. Those kids did not learn a lot of geometry. Down the street at the middle school, at Sulzberger, 14 substitute teachers teaching math during the course of one year. It is impossible for these children under those circumstances.

I don't want us to pretend like, well, if we leave it to State governments, poor children will get a quality education. That has never been the history in our country, and if the Federal Government doesn't insist, to some degree or another as, a referee, that

we have to have some form of equity, it is not going to happen in any of our States.

FEDERAL ROLE IN EDUCATIONAL EQUITY

I just want the record to be clear on this matter that, yes, we have a system of local control of schools. It has never served poor children—and particularly children who come from generational, intergenerational poverty—well. It won't today, it won't tomorrow, we, at some point, if we want to get more of our children headed in the right direction, we are going to have to do something more about it.

Secretary KING. I certainly share that view. You know, I served on the Equity and Excellence Commission that you helped to create, and that commission tried to make the point that the fate of all of our children is bound up together. As we think about local control, we have to remember that all of our children are diminished if there are other children who do not have access to opportunity.

We think the implementation of Every Student Succeeds Act requires a strong civil rights role for the department in ensuring equity. It is important that the law requires equitable access to effective teachers and that the law requires transparency around per pupil spending and access to advanced coursework and access to early learning.

We expect to fulfill that civil rights responsibility.

Mr. FATTAH. And I think it can be done, and I think we can—we have local—we have a basketball team in Philadelphia. They are not doing all that well these days. About as well as the one in Oklahoma. But the court is the same size. The rim is at the same level, right? The ball has got the same——

I mean, we can create some level of equity so that children have an opportunity to succeed. You know, the Sixers have an opportunity to play well. They just haven't gotten there yet, all right?

Thank you, Mr. Chairman.

Mr. COLE. They just don't have Kevin Durant. [Laughter.]

Mr. COLE. With that, we will go to my good friend from Maryland for whatever questions he cares to pose to the Secretary.

Mr. HARRIS. Thank you very much.

And thank you, Mr. Secretary. Welcome.

OPPORTUNITY SCHOLARSHIP PROGRAM (OSP)

I am just going to concentrate on one program. It is the one I have asked the person who sat in that chair for the past 3 years about, which is the Opportunity Scholarship Program. Just, you know, the opportunity for low-income individuals to get a chance.

The first thing I am going to say, I am glad that, again, on page 9 of your—of the budget book, you know, there is this effort to promote greater use of evidence and data. Actually, on page 6 of your testimony, it says, "Finally, we extend our commitment to improving student outcome by increasing funding for programs based on evidence of success."

So, I am going to ask you, does the Department of Education intend on increasing funding for the OSP? Because I think the evidence is pretty good that it is successful. I mean, a graduation rate

of 90 percent, as opposed to 64 percent in a regular D.C. public school, is pretty good evidence of success. I mean, a 26 percent increase in graduation rate.

Is the Department, in accordance with your testimony about using evidence and data to increase programs that work, are you in favor of expanding the Opportunity Scholarship Program?

Secretary KING. We are committed to implementing the program as required by law but don't believe that vouchers are a scalable solution to the challenges we face as a country.

Mr. HARRIS. So you are unwilling to expand the program?

Secretary KING. Again, we will implement——

Mr. HARRIS. Now let me—let me refer to——

Secretary KING [continuing]. The program according to the law.

Mr. HARRIS [continuing]. What the Washington Post, you know the Washington Post has editorialized about this and has called the claims made by opponents of expansion "specious claims." Just in case you don't know the meaning of "specious," it is superficially plausible, but wrong.

So do you believe the data is just wrong?

Secretary KING. I don't believe that vouchers can be the answer to the challenges we face at scale.

Mr. HARRIS. Well, let me follow up with that. Thousands of families, again in that Washington Post editorial. I am going to take them at their word that there are thousands of families on the waiting list. Has the Department over the past few years actually studied what happens to the children who don't get into the program versus the ones who do?

Because we know the ones who do graduate at a 90 percent rate. What happens to the children who don't get into the program? What is their graduation rate?

Secretary KING. There was an IES comparative study, I believe in 2010, that showed a 12 percentage point difference in graduation rates——

Mr. HARRIS. That would be——

Secretary KING [continuing]. Between the participating students and the nonparticipating students.

Mr. HARRIS. That would be an improvement in the graduation rates. That is right?

Secretary KING. That is right. That is right.

Mr. HARRIS. So, let us say there were 1,000 children on the waiting list in a year. That would be 120 children who actually graduate that year if they had been given an opportunity scholarship. Do you believe that data? And that is old data.

Secretary KING. The IES study was well designed, and there is an ongoing evaluation. I would note that the District of Columbia district schools have also seen a significant improvement in graduation rates over that time period, and there are very strong charter schools in the District of Columbia.

Mr. HARRIS. The District's——

Secretary KING. Not all, but some of the charter schools are performing quite well.

Mr. HARRIS. The District's improvement rate was from 56 percent to 64 percent. Of that 100 students, you have helped 8 of them. Whereas the data shows that you would help 12 with the

OSP. So I am going to go to your testimony. You said, "We extend our commitment to improving student outcomes by increasing funding for programs based on evidence of success."

There is evidence of success, and what you are telling me is you don't want to increase funding. Is it just some programs that have evidence of success? Is it we pick the science and we pick the studies, and if it is politically untenable to perhaps go against some vested interest, we are not going to support it?

OPPORTUNITY SCHOLARSHIP PROGRAM CARRYOVER

Anyway, so I want to ask you what about the carryover dollars? I mean, we actually—there actually are dollars out there that could expand this program. My understanding is that the carryover dollars are not being allowed to be spent now by the—by Serving Our Children, which is now the administrator of the program.

Is that the position of your department that carryover dollars are not allowed to be spent on expanding this program, which has proven successful to help needy, low-income children actually graduate? Is that the position of the department?

Secretary KING. Just to be clear, the evidence of success is an important factor, but another important factor is scalability, and we believe public school choice, the district and charter options in D.C., are the more scalable option.

That said, the carryover funds are dedicated to ensuring that the students who are currently enrolled in the program will have the opportunity to continue. We don't want to see an eventuality where students have begun in a school, and there isn't funding available, so they are forced to change schools.

So we have set aside the carryover funds to ensure that the currently enrolled students are able to continue.

Mr. HARRIS. I yield back. I will yield back. My time has run out, and I will just continue in a second round.

Thank you.

Mr. COLE. We will go next to the gentlelady from Alabama.

Mrs. ROBY. Thank you, Chairman.

STATE CONTROL AND CURRICULA

Before I move on to a different issue, and I appreciate the gentleman from Arkansas talking about the career and technical education, I do want to tie a bow around the local control box. The language is very explicit in ESSA that the Federal Government, the U.S. Department of Education cannot use Federal funds to coerce States into adopting certain curricula and standards.

We have agreed on that, and you committed to upholding that portion of the law. But I want to also make sure, to get one step further, that you have no intention and under your leadership the people that work for the U.S. Department of Education will not use, per the law, grant programs or waiver programs to then coerce States into adopting certain curriculum.

I just want to make sure that our understanding is the same, that the law is explicit in its language that you cannot do that.

Secretary KING. Yes. As we discussed, standards and curriculum are the province of State and local decisions. I will again say that we have an important civil rights function.

Mrs. ROBY. Sure.

Secretary KING. For example, if in a given district, English language learners were not allowed to access programs on an equitable basis, the Department would have a civil rights responsibility to intervene.

Mrs. ROBY. But you can't use waiver programs or grant programs to require the State of Alabama to adopt certain standards or curriculum?

Secretary KING. That is right. The Every Student Succeeds Act requires them to adopt standards that——

Mrs. ROBY. I just want to make clear that when it comes to curriculum and standards that the U.S. Department of Education cannot use waiver programs—because what ends up happening and what we have seen happen is that because of what happened in the past under the old law is that States ended up spending precious dollars to comply with waiver programs to adopt because the Federal Government in the past has been able to coerce States that could otherwise be implemented—used right in the classroom.

Now with parents and teachers and administrators on a local level in the driver's seat, those dollars can be best spent on our children, and the States can make the decisions about those curriculum and standards. But I wanted to specifically address the waiver and grant programs, and I think we are clearly on the same page.

ON-TRACK PELL BONUS

I want to move to the administration's proposal for the On-Track Pell Bonus, which would give $300 to Pell Grant recipients who enroll in 15 credit hours per semester in an academic year. The objective is to encourage students to complete 60 credit hours within a 2-year period and 120 credit hours in 4 years.

So where the goal behind this program is commendable, I am concerned that this Pell bonus might encourage students to enroll in more credits than they can handle just to receive the $300 bonus. Furthermore, I don't see how this program helps nontraditional students who are unable to take 15 credit hours because they have got a work schedule and/or family that they take care of.

This idea seems to promote quantity over quality and like many things that we do around here could lead to some very negative unintended consequences. Can you tell this committee in a minute and 30 seconds that the On-Track Pell Bonus would not lead to abuse or diminished learning outcomes for students who feel pressured because of this incentive to take on more than they can handle just to get that $300 bonus?

Secretary KING. The goal of the President's proposals around college completion addresses the challenge that we see. Many of the students who are defaulting on their debt are students who start, but don't finish. They have—they don't have a degree, but they do have debt. They can't pay it back because they can't get a good job because they don't have the degree.

So there is a set of programs that would work together. There is good evidence that incentives to take 15 or more credits make a difference for college completion. A number of efforts around the

country, including University of Hawaii, have very strong evidence around a focus on 15 credits.

We also propose summer Pell, allowing students to access Pell dollars during the summer, which, for the nontraditional student, can be essential because that is an opportunity for them to continue their coursework over the summer and stay on track to on-time graduation. We also propose an institutional bonus that would incentivize colleges and universities to focus on completion support.

I was just at Georgia State last week, same day I went to Alabama A&M. They have increased their graduation rate by 22 points over the last decade while nearly doubling the number of students who are Pell-eligible through a focus on supporting students through to completion—academic advising, support services, good counseling on which courses to take and how to fulfill their credit requirements for their major.

We think this package of efforts will help us address our completion challenges.

Mrs. ROBY. My time has expired, but I would just say that I have concerns that this would not only lead to people, individuals taking on more than they can handle, but also there is an opportunity here for abuse to take place, as well as diminished learning outcomes.

As a committee, I hope that we will continue to look into this. I yield back.

Mr. COLE. Thank you.

Just for informational purposes, some of us have had an opportunity to have two rounds. Some of us have not. We are going to move to those people that have only had an opportunity to have one round. We will start, if we may, with our Distinguished ranking member of the Full Committee.

Mrs. LOWEY. Well, thank you very much.

STUDENT LOAN DEBT

Because this issue is so important, although there are about three or four hearings going on at the same time, I did want to come back. Because this student loan debt, which has reached $1.2 trillion nationwide for 40 million borrowers, making the average student loan burden $29,000 upon graduation, is a major challenge for all of us.

I want to say at the outset, I think it was 3 years ago or three cycles ago that we took away the third cycle of Pell Grants. When you visit the community colleges, as I do all the time, these kids are now working three, four, five, six jobs. If they could get another cycle continuing the three, four, five, six jobs, they could get out there and work with a degree.

I want to emphasize this again, ask our distinguished chairman maybe we can do something through the appropriations process. You are shaking your head. So I know you agree.

In 1980, Pell Grants covered 77 percent of the cost of a 4-year college program. Due to the rising cost of college in the 2015–2016 school year, Pell Grants covered just 29 percent of the cost, forcing students to take on additional debt, which we have been talking about.

This is why I was very pleased that the budget request includes the maximum value for Pell Grants and I am glad in the request you are asking for the third semester, maybe trimester of Pell eligibility and provide a bonus to students who take additional credits, which, together, would help students graduate more quickly with less debt and enter the workforce faster.

To me, it is a win-win. Third cycle, let them get that education, let them get out.

I am concerned that the current level of student loan debt is absolutely unsustainable. In addition to your Pell expansion proposals, I would like to know what the Department is doing to reduce student loan debt and make our higher education more affordable. As Congress is preparing to debate a Higher Education Act reauthorization, what more can we do to ease the financial burden on those trying to pay for college or a vocational training?

Thank you.

Secretary KING. It is a very important question. You know, one of the things that we are seeing that is promising, as we discussed earlier, was students enrolling in the income-based repayment program. We propose streamlining that income-based repayment process so that students can enroll in programs that cap their student debt payments at 10 percent of their income.

We would like to see rapid expansion of that effort, and we are reaching out to students so that they are aware of that possibility. That would be helpful. There are a number of proposals, including in the RED proposals around students' ability to refinance, we think would be potentially helpful to students if done in the right way.

The President has also proposed America's College Promise, as you know, which would guarantee for hard-working students that they would be able to go to 2 years of community college for free or the first 2 years at a historically Black college or university or a minority-serving institution. We think that can be a powerful lever.

In the structure of that program, we also require States to meet the national average commitment, and the amount that the State gets is tied up with how close they are to that national average commitment. The intention there is to incentivize States to maintain or increase their investment in public higher education.

As you know, one of the reasons why we have seen the shifting of cost to students is in many States around the country, we have seen a retreat from investment in public higher education.

Mrs. LOWEY. Thank you, and I hope to continue the discussion. With my one minute, I just wanted to get another issue on the record because I think it is so important, Title VI and anti-Semitism.

TITLE VI AND ANTI-SEMITISM

The International Education and Foreign Language Studies Program within Title VI advances national security, foreign policy, and economic interests. I really have very great concern about reports that some recipients of these funds are disproportionally focused on or are biased against Israel. In 2014, the department revised many

Title VI program performance measures by focusing on quantitative metrics.

How did these reviews affect the International and Foreign Language Studies Program? What step is the department taking to ensure that Federal investments are not perpetuating an anti-Israel bias? And, I just want to say, the reports I have been getting, there is a bipartisan caucus, as you probably know and are a part of, on anti-Semitism. And what is going on on the college campuses, I have personally witnessed it, it is truly outrageous.

So, Mr. Chairman, if you would give the distinguished Secretary a minute just to tell us what you can do, what we can do, and I know many of us are working together to address this.

Secretary KING. Yes. In terms of the international programs, international language and education programs, we can follow up with more detail on those programs.

[The information follows:]

TITLE VI AND ANTI-SEMITISM

We fully support strategies to promote diversity and pluralism in education. We are committed to ensuring that our Nation's schools and institutions of higher education are free from discrimination and harassment based on their race, religion, or national origin.

In December 2015, Secretary Duncan and I signed a joint letter to all of our universities and school districts that focused on tolerance, celebrating diversity, and protecting students from bullying and harassment based on religion or other issues of prejudice. In November, we convened campus leaders from around the country—university and college presidents, faculty, legal experts, and student leaders—to tackle the issue of racial harassment on campuses and lay out solutions to foster supportive educational environments.

Over the past year, the Department revised the performance measures for the International Education and Foreign Language Studies programs authorized under Title VI of the Higher Education Act of 1965, as amended, and the Mutual Educational and Cultural Exchange Act of 1961, commonly known as the Fulbright-Hays Act. The new performance measures use higher quality data, and are designed to increase transparency and accountability for the IFLE program while aligning with the institutional-level goals of the programs they serve. Additionally, the selection criteria for these programs ensure that recipients provide a full understanding of areas, regions, or countries in which the foreign language being taught is commonly used, as required by the Higher Education Act. We feel confident that Title VI/Fulbright-Hays projects reflect diverse perspectives and a wide range of views that will generate debate on world regions and international affairs—and that appropriate procedures are in place to report, investigate and resolve any exceptions to this requirement. Furthermore, the Department is committed to responding to any allegations that our Title VI/-Fulbright-Hays program recipients are not meeting their legal obligations.

In order to accomplish this goal, we work with our colleagues in the Department's Office for Civil Rights, as well as with grantees and institutions through increased performance monitoring, site visits, and/or increased technical assistance, as appropriate. We are very committed to setting the right tone around this and will respond to any complaints of intolerance, prejudice, and harassment in our schools and on our campuses. We are eager to continue to work with you and others on the Committee on this issue.

I would say important to us is that in all of those programs, we are supporting the celebration of diversity and pluralism and how we approach those.

One of the first things I did on becoming Secretary is also the last thing Secretary Duncan did, was we signed a joint letter that went to all of our universities and school districts around issues of tolerance and religious tolerance and celebrating diversity and protecting students from bullying and harassment based on religion or other issues of prejudice.

We are very committed to setting the right tone around that, and certainly our Office for Civil Rights responds to complaints we get, whether it is from higher education institutions or districts, around intolerance, prejudice, and harassment that may occur on campuses.

We had a convening last year with higher education institutions focused on campus climate and issues of racial and ethnic harassment. We are eager to continue to work with you and others on the committee on this issue.

Mrs. LOWEY. Thank you.

Thank you, Mr. Chairman. The reports I have gotten are really outrageous. New York City public colleges, UCLA, we saw those reports. I think this is an issue that we should pursue together, as we are, Democrats and Republicans. Seeing what we can do through the programs, which we fund, to address this.

Thank you.

Mr. COLE. I thank the Gentlelady.

We will next go to the Gentlelady from California for any questions she cares to ask.

ADULT EDUCATION FUNDING

Ms. ROYBAL-ALLARD. Mr. Secretary, in California alone, 5.6 million individuals need adult education services. However, under Title II of the Workforce Innovation and Opportunity Act, the State is only able to serve about 500,000 with adult education, skill training, and workforce preparation.

While Congress intended Title II of the Adult Education and Family Literacy Act of WIOA to receive additional funding each year, and this is reflected in the legislation's graduated authorization levels, the budget request for WIOA adult education State grant program is only level funded from fiscal year 2016. Why has the Administration chosen not to request funding that would allow adult education State grants to meet their full authorized amount under the Workforce Innovation and Opportunity Act?

Secretary KING. Again, this is a place where one of our challenges is how we pursue our priorities within the caps that were agreed to in last year's budget agreement. We do propose an increase in adult education funding because we think that is hugely important.

We are working very closely with the Department of Labor on WIOA implementation. The President also proposed on the mandatory side $5.5 billion that would be directed towards programs that are focused on adult education, training, disconnected youth, and trying to make sure our disconnected youth are connected to education and job readiness.

All of the mandatory proposals in the President's budget are paid for in the budget and would result in a net reduction in the deficit. We do believe that that set of proposals that we made jointly with the Department of Labor would get at exactly the issues that you were describing.

Ms. ROYBAL-ALLARD. Well, let me just explain my frustration with the way this program is not being funded at the level that it should be. In my district alone, only 51.7 percent of my constituents 25 and older are high school graduates. Programs under the Adult Education State Grant Programs, such as Workplace Literary Programs, English Literacy Programs, and Civics Education are absolutely essential.

So I would again urge that the administration prioritize proven programs that are badly needed, as opposed to unauthorized, unattested proposals as it has a tendency to do when it presents its budget.

In closing, I just want to associate myself with the Ranking Member's statement about the value and the importance of year-round Pell Grants, and I was pleased to see that the Pell for accelerated completion proposal was in the President's budget request because it really is critical. In fact, the year-round Pell has a very strong return on Federal investment.

Secretary KING. Absolutely. Thank you.

Ms. ROYBAL-ALLARD. I yield back.

Mr. COLE. I thank the Gentlelady.

We will next go to the Gentleman from Maryland for whatever questions he would care to ask.

Mr. HARRIS. Thank you very much.

OPPORTUNITY SCHOLARSHIP PROGRAM (OSP)

First, I want to associate myself with the Full Committee Ranking Member's comments on the anti-Semitism that prevails on some college campuses, and I would hope that as the Ranking Member suggests, that since we fund a lot on those college campuses, we ought to have a say when they deny diversity because of your religious background, in this case, again, anti-Semitism.

Let me go back to the Opportunity Scholarship funds because I just don't understand what the evidence is that these aren't scalable. I just don't—I mean, I am not talking about doubling the problem. But you know, you can expand it 5, 10 percent.

I mean, is it that there aren't schools to accept these students? Because I find that hard to believe. What is the evidence that it is not scalable?

Secretary KING. Well, the reality nationally is that there is not the private school capacity——

Mr. HARRIS. Mr. Secretary, we are not talking about nationally. We are talking about the District of Columbia. We are talking about the Opportunity Scholarship Program. What is the evidence in the District of Columbia that this program is not scalable? Because you do understand, there have been more students in this program in the past.

I mean, in fiscal year 2016 is the lowest number of students in the past 5 years in the program. What is the evidence that it is not scalable?

Secretary KING. Well, both nationally and in the District of Columbia, it is clear that private school capacity is not sufficient to replace the important role of public education. So our belief is that——

Mr. HARRIS. Mr. Secretary——

Secretary KING [continuing]. The District's——

Mr. HARRIS [continuing]. I am going to have to interrupt you here. I am not talking about replacing public education. I am talking about an expansion of the program. I am not talking about replacing public education. We are going to—if we are going to have a serious discussion, you can't set up a straw man that I am suggesting replacing public education.

What is the evidence that if we merely go back to the levels of 4 fiscal years ago that we are not helping dozens of students who would otherwise not graduate based on the evidence? We have evidence. Yes, the public school system is getting better. But we have a 90 percent graduation rate in the OSP program.

OSP SCALABILITY

What is the evidence that it is not scalable to increase it by 10 percent? Is there evidence? Do we have evidence?

Secretary KING. Well, as we discussed, the original question was about student access to current funding. We will ensure that students are added in a way that spends current funding.

A separate issue is the carryover, and our view on the carryover is that that should be preserved so that the students who are enrolled have the opportunity to complete their educational program within the schools that they are enrolled in.

We will add students this year—I don't know the precise number, that will depend on attrition and so forth—to make sure that we are spending current dollars. We will preserve the carryover for the long term.

If the question is as a public policy matter, do we think it is a good idea to expand voucher programs? No, because we don't believe, as I said, that they are a scalable solution to the challenges we face, and we would prefer to see those resources invested in public school choice, quality district and charter options.

Mr. HARRIS. Mr. Secretary, I fully get that. I am just going to point page 6 of your testimony where you say, "We extend our commitment to improving student outcomes by increasing funding for programs based on evidence of success."

Let me summarize what you have said today. There is evidence that the graduation rate is higher, right? The IES study, the graduation rate is higher.

There is no evidence that it is not scalable to previous levels, none at all. Zero. You have no evidence of that.

So, when I read your testimony, you want me to believe that if you see the scientific study, which the IES study we could argue is scientific study, based on evidence, you say you want to increase funding in your testimony, written testimony, but your verbal testimony is different.

Let me just point out one issue with the program is that if a poor family has tried to do right for their student, and they have scraped by and they are working two, three jobs to pay that private

school tuition, $7,000, $8,000, $9,000 in a lot of cases, they are not eligible for this.

To be eligible for this program, is it true that they would have to—their child would have to drop out of the school they are in to then enter the lottery to be eligible for funding to go back into that same school? Because income is the prime determinant, but if you happen to be in a—not in the public school system, you are not eligible for the lottery at this point in time?

Is that a correct summary of the way things are run?

Secretary KING. Well, the original intent of the program was to create opportunity for students who otherwise wouldn't have that opportunity, and so the funding is awarded in a way that respects that intent. Otherwise, you would have the risk of merely funding students who were already enrolled.

Mr. HARRIS. These are all—I mean, let us get it straight. The income level is $22,000. To make a $7,000 or $8,000 payment to a school for tuition, you are scraping by. You are a parent who is trying to do what is right. As usual, the Government kind of punishes you for that.

I get it, Mr. Secretary. I yield back.

STUDENT SUPPORT AND ACADEMIC ENRICHMENT BLOCK GRANTS

Mr. COLE. Mr. Secretary, I was surprised, and this touches on a point that Ms. Roybal-Allard made earlier, but I was surprised that your budget request included only $500 million for the newly authorized Student Support and Academic Enrichment State Grant. That is less than a third of the authorized level.

The program is intended to be a flexible funding stream that allows States and school districts to invest in those areas that are most needed to improve the quality of education. I was disappointed that the request seeks—I was also disappointed that the request seeks to change the local allocations from a formula basis to a competitive basis, which would further shortchange many school districts and, frankly, in my view, circumvents congressional intent.

Again, I understand the resources are limited here, and it would be a challenge under any circumstances to fully meet the authorized level. But the funding at the requested level seems to me to significantly curtail its potential usefulness to support school districts.

Why does your—is it simply a math problem, you know, a cap problem that we are this low on this? Again, it seems to me there are other areas where you have requested funding that, frankly, I would rather see the money here in these kind of things than perhaps in some of the other areas.

I want to give you an opportunity to elaborate on that.

Secretary KING. Sure. You know, again, we were—we see this as a significant increase over the preexisting program. The four programs that were funded previously were only at $278 million. Taking it up to $500 million is a significant increase.

We do think there is an opportunity for more discussion in a bipartisan way about how to move forward with the Title IV program. The competitive grant component would be an option for

States. We are not requiring—we are not proposing requiring States to make it competitive.

The concern, as I mentioned earlier, was if the formula delivers a grant that is just too small to do anything meaningful, then that is a missed opportunity. We see this as an opportunity for States to identify priorities within the many available uses of Title IV dollars and then to have a competitive process.

States could weigh in that process, you know, attention to rural issues. They could weigh in that process attention to perhaps pooling of resources across smaller districts. We want to make sure that folks have an opportunity to advance the purposes of Title IV around a well-rounded education, school counseling, advanced placement courses, so forth.

Mr. COLE. Okay. Well, thank you for the explanation.

I will go to my good friend from Pennsylvania next.

STUDENT LOAN REPAYMENT

Mr. FATTAH. Yes, I just want to circle back on this loan repayment thing. I got my facts straight now.

In the portion of the Affordable Care Act that was entitled the Student Aid and Fiscal Responsibility, which was a separate bill altogether. We just included it on the train that was going along, and Senator Kennedy and former chairman George Miller and others worked on this. It says basically that for new borrowers, starting in 2014, will be able to have their payments capped at 10 percent of their discretionary income and that, furthermore, that if for 10 years of public service work, they could have their loans forgiven, right?

This doesn't affect people who already have loans, who are already in the process. But it may be helpful for families and students who are matriculating through higher education now or contemplating it to understand that there will be a circumstance in which managing their debt would be a lot more plausible and even more affordable to the degree that they followed the others into public service.

I just want to make sure that the record is clear, and I think it would be very helpful if the Department could make sure that families know about this. Because at least as for myself, I have a 17-year-old who is looking around at colleges, and you know, some of them are a little pricier than others, but it is an important consideration, I think, for families as to this.

I think even as we think about the Pell Grant, we also have to think about the other things that the Congress and the administration has done together, including the American Opportunities Tax Credit, which I was proud to author, but is another way where we are helping families and many of them at incomes, you know, in which they might not think they could get help, but they are receiving, you know, dollar for dollar, a reduction on their higher ed cost, up to $2,500.

I want to thank you. I would be glad if you want to respond to that, you can.

Secretary KING. Yes, just I would say on the income-based repayment portion, there I think we have seen very significant growth.

I think we are well over now 4 million folks who are participating in income-based repayment and see a path to adding many more.

On the loan forgiveness, public service loan forgiveness, we will get back to you with the details that we have on students participating now and what we project over the next few years.

Mr. FATTAH. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. Thank you.

Mr. Harris, you are recognized for whatever additional questions you would care to pose.

OPPORTUNITY SCHOLARSHIP PROGRAM (OSP)

Mr. HARRIS. No, I just want to thank the Secretary, and welcome to the job. You know, as you probably figured out, I have some passion for the Opportunity Scholarship Program. I think we really have to provide educational choice.

I think the evidence is that when we do, everyone benefits. That I believe that the increased graduation rate in the public school system in D.C. is partly because there actually was an educational choice alternative. And I think that that is part of the solution.

Again, I hope to work with you on some way to be able to bring the numbers up to their historic numbers in that program and you know, again, just give these children of low-income families a chance at the American dream.

Thank you very much for coming before the Subcommittee.

Secretary KING. Thank you.

Mr. COLE. I will recognize my good friend from Pennsylvania to make an additional point.

ROLE OF FEDERAL INVESTMENT IN EDUCATION

Mr. FATTAH. I met with the Secretary Hite—I mean Superintendent Hite—from Philadelphia yesterday, and he was focused, and I know this has been mentioned earlier, on this apprenticeship program. We had your counterpart, the Secretary of Labor in last week, and we talked about apprenticeship efforts. We have some wonderful programs in Philadelphia that have been federally funded.

I know the chairman took some issue with that, but they are doing great work. They are helping young people who are not going to college, but to find their way into careers that allow them to make a living capable of raising families.

So, thank you, and just wanted to put that in the record.

Thank you, Mr. Chairman.

Mr. COLE. Well, thank you, my friend.

First of all, Mr. Secretary, you got through the first one without too much problem. So very fine job.

Secretary KING. Thank you.

CLOSING

Mr. COLE. Mr. Skelly, I want to join our Ranking Member of the Full Committee and just thank you for 42 years of wonderful service to help educate young people and put this country in the right

direction. You had a wonderful career to be very, very proud of, and you have earned your retirement.

We have probably kept you working for a few extra years since you put a child through Grinnell. Believe me, having gone there, that is an expensive proposition. We just thank you for your wonderful service to our country.

Mr. FATTAH. I agree. Thank you.

Mr. SKELLY. Thank you very much, Mr. Chairman.

Mr. COLE. Okay. With that, we will conclude the hearing. Mr. Secretary, again, it was great to have you.

Secretary KING. Thank you.

Coordination between the Departments of Education and Health and Human Services

Mr. Cole: The Every Child Succeeds Act authorized the Preschool Development Grants program in the Department of Health and Human Services (HHS) starting in FY 2017, though it is currently operated in the Department of Education. Would you please tell us how the Department will coordinate with HHS on the administration of the Preschool Development Grants program?

Dr. King: The Department has long worked with the Department of Health and Human Services to help States better coordinate and improve the quality of their early learning systems; indeed this was the focus of the successful Race to the Top Early Learning Challenge program, which was implemented jointly by the two agencies. Similarly, the Department partnered with HHS to administer the Preschool Development Grants program (PDG), which was launched in 2014 to build state and local capacity to implement preschool for four-year-olds from low-and moderate-income families. PDG has made grants to 18 States, to help over 200 communities provide an estimated 120,000 children access to high-quality preschool through the first three years of the program. In addition, the Departments formalized their relationship in a Memorandum of Understanding and created the Early Learning Interagency Policy Board (IPB) to facilitate work to reduce fragmentation, and unwarranted overlap of goals or activities; improve the quality, effectiveness, and coordination of federally-funded early learning programs; increase the coordination of research, technical assistance and data systems; and maximize resources.

The President's 2017 Budget funds Preschool Development Grants at $350 million to support both the final year of the first cohort of 18 States and new grants under the program's authority in ESSA. Under ESSA, the program will continue to be jointly administered by ED and HHS and the new grants will focus on improving the overall quality of state preschool programs while improving coordination across early learning systems and increasing parent choice and knowledge about these programs. In administering the reauthorized program, ED and HHS will focus on strengthening partnerships among the two agencies, state governments, and local providers of high-quality preschool services.

Student Support and Academic Enrichment State Grants

Mr. Cole: The Department's budget proposes to allow states to allocate funds for the Student Support and Academic Enrichment State Grants on a competitive basis, instead of on a formula basis as directed by the Every Child Succeeds Act. It would seem that states and Local Educational Agencies would incur some costs associated with running these competitions and putting together applications, diverting resources that would otherwise be available to directly improve education for students. What are the potential costs of running this program as a competition?

Dr. King: The Department believes that providing States with the option to make competitive subgrants under the Student Support and Academic Enrichment Grants program is more likely to ensure effective uses of funds by local educational agencies (LEAs), but would leave the subgranting method to States' discretion.

A competitive subgranting process should generally not result in significant additional administrative costs for a State or its LEAs, which may be supported by program funds. In establishing criteria for selecting LEAs for competitive subgrants, a State could rely on the application requirements in section 4106 of the program statute – including requirements that the LEA describe its proposed activities, the objectives and intended outcomes of those activities, and its proposed evaluation of the activities based on those objectives and outcomes. Additional State and LEA costs related to preparing and evaluating subgrant applications based on criteria stemming from those requirements should not be significant. In establishing other criteria or parameters for selecting LEAs for subgrants, States would have flexibility to consider State and local resources and needs.

Even if funded at the full authorized level, the Student Support and Academic Enrichment Grants program would provide formula allocations that for the majority of LEAs could be too small to support meaningful uses of funds. We estimate that, at the fiscal year 2017 authorized funding level of $1.65 billion, at least 53 percent of LEAs would receive a formula allocation that is less than the $30,000 award that under statute triggers a needs assessment. Allowing States the option to make competitive subgrants would help ensure that LEAs receiving awards have sufficient funds to carry out activities likely to advance the purposes of the program, and the additional time and effort that LEAs put into competitive applications are likely to increase the quality of their subgrant projects. In addition, under the Administration's proposal, States that choose to make competitive subgrants could prioritize one or more of the program's authorized activities, which would help ensure that program funds can be used to address the State's most pressing needs.

Student Aid Enforcement Unit

Mr. Cole: The Department's budget request describes a new Student Aid Enforcement Unit that was created this year to increase oversight of the Department's higher education program activities. However, the responsibilities of this new unit seem like activities that the Department was already conducting within the existing programs and administrative structure. Given this, why did the Department create this new administrative unit?

Dr. King: As part of the Obama Administration's aggressive action to protect students and taxpayers, the U.S. Department of Education is creating a Student Aid Enforcement Unit to respond more quickly and efficiently to allegations of illegal actions by higher education institutions. The Enforcement Office (EO) is a new unit within Federal Student Aid (FSA). The goal of this office is to focus oversight on high-risk institutions participating in Title IV programs.

The EO will work with multiple Federal and State agencies to identify potential misconduct or high-risk conduct of institutions, proactively use enforcement tools to gather information, and use available actions to seek remedies. The EO will also include enforcement as it relates to the Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act and the Drug-Free Schools Communities Act. Finally, the EO will ensure that students who have been affected by misrepresentation or otherwise defrauded by their institutions will have access to a transparent and fair loan discharge process. Moreover, it is expected to enhance the Department's enforcement capabilities relating to abuses in student solicitation and enrollment. These new capabilities aim to reduce improper disbursement of federal funds by enhancing the efficiency and integrity of the federal student aid process to better protect students and taxpayers.

The Department remains strongly committed to investigating violations that harm students and taxpayers and taking swift and immediate action as necessary. The EO will support more reviews of high-risk institutions by responding to concerns raised by states' and other federal agencies' investigations of such institutions, as well as complaints by students.

The creation of the new Enforcement Unit builds on steps the Obama Administration has taken over the past seven years to hold schools accountable for a providing a quality education, including:

- Developing a wealth of consumer tools to help provide families with clear information to make a smart college choice;
- Establishing gainful employment regulations to help ensure that students at career colleges don't end up with debt they cannot repay;
- Creating a federal interagency taskforce to crack down on bad actors through investigations and enforcement actions;
- Enforcing the ban on incentive compensation to protect students from aggressive recruiting practices; and
- Proposing to close the 90/10 loophole so institutions do not take advantage of service members.

Avoid Duplication of Efforts

Mr. Cole: How will the Department avoid duplicating efforts and complicating program oversight?

Dr. King: The new unit will work closely and collaboratively with existing program compliance personnel to leverage knowledge about institutions and enhance the targeting of limited resources, while providing dedicated resources for in-depth investigations. The new unit will communicate regularly with compliance staff to ensure that resources are not duplicated.

The Enforcement Unit will consist of the following four divisions:

- **Investigations Group:** to identify potential misconduct or high-risk activity among higher education institutions and protect federal funding.
- **Borrower Defense Group:** to provide legal analysis, support and advice concerning claims of borrowers of Direct Loans. The unit will analyze claims to make determinations of injury, investigate institutions in connection with borrower defense claims and coordinate with federal and state agencies regarding those claims.
- **The Administrative Actions And Appeals Service Group (AAASG):** to impose administrative actions such as Emergency, Termination, Limitation, Suspension or Fine actions. This group will continue to resolve appeals by program participants from final audit and final program review determinations, initiate debarment and suspension actions, and issue school revocation and denials of re-certification.
- **Clery Group:** to ensure institutions comply with the Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act, requiring colleges and universities participating in federal financial aid programs to disclose campus crime statistics and security information.

The new unit will collaborate with, and incorporate evidence gathered in investigations by, partner state and federal agencies in establishing cases against institutions of higher education as warranted. The unit will also collaborate with the Program Compliance Unit regarding evidence which may impact ongoing program compliance reviews. Moreover, the new Enforcement Office will utilize a broad set of interventions and tools, including subpoena authority, document demands, and interrogatories and interviews to enforce against violations of Federal law.

Proposal to Reduce Funding for the Fulbright-Hays Program

Ms. Roby: The Mutual Educational and Cultural Exchange program, commonly referred to as Fulbright-Hays, was designed to build mutual understanding between the United States and other nations through education and cultural exchange. This program has served as a vital vessel for training US personnel in uncommon languages and cultures, which has improved our defense readiness for over fifty years. As the House Armed Services Committee[1], the GAO[2], and the Department of Defense[3] itself have repeatedly concluded, there is a significant and longstanding shortage of language and cultural expertise in the military and our intelligence community. The Department of Defense has nearly 7,000 unfilled language slots, and in 2011, had only 28% of all language-required slots filled at the specified level of language proficiency[4]. These shortages put our Nation and our service members at risk.

Given these long-term vulnerabilities, why are you proposing slashing Fulbright-Hays by 69 percent when that program is central to our efforts to train the language and cultural specialists who are needed to keep the American public safe in an increasingly dangerous world?

Dr. King: The 2017 Budget Request stays within the cap established by Congress. In order to stay within the cap, the Administration proposes to decrease funding for the International Education and Foreign Language Studies (IEFLS) Overseas Programs. The amount requested for 2017 would be sufficient to cover all continuation costs. In addition, the request proposes to maintain level funding for the IEFLS Domestic Programs, which are significantly larger than the Overseas Programs ($65 million for the Domestic Programs compared to the fiscal year 2016 level of $7 million for the Overseas Programs). While current participants and graduates of the Overseas Programs are important sources of information and expertise on many issues that dominate the international environment, the Domestic Programs are key to maintaining a broad skill base and a long-term national capacity in language and area studies in about every region of the world, with a focus on the less commonly taught languages. Foreign language development has been the major focus of the Title VI Domestic Programs since their inception, with a focus on addressing national security needs. The Domestic Programs focus their resources on those areas of the world often neglected in the curricula of institutions of higher education, and on the foreign languages spoken in those areas; many of these languages, particularly the less commonly taught languages (LCTLs), would not be taught in the United States or at advanced levels without Title VI support. The Title VI Domestic programs are key to the teaching and learning of languages vital

[1] House Armed Services Committee, Subcommittee on Oversight & Investigations, "Building Language Skills and Cultural Competencies in the Military: Bridging the Gap," December 2010, <http://democrats-armedservices.house.gov/index.cfm/files/serve?File_id=5F9D55F9-7B8A-4461-8C5A-4B5FB08E9A7F>.
[2] Sharon L. Pickup, Director of Defense Capabilities and Management, U.S. Government Accountability Office, testimony before Subcommittee on Oversight and Investigations, House Armed Services Committee, June 29, 2010, <http://www.gao.gov/assets/130/124930.pdf>.
[3] Laura Junor, Deputy Assistant Secretary of Defense for Readiness, in testimony before the Senate HSGAC, "A National Security Crisis: Foreign Language Capabilities in the Federal Government," May 21, 2012, <http://www.hsgac.senate.gov/download/?id=9FA456A7-679E-4349-B20B-CEF4CB324280>.
[4] Laura Junor, "A National Security Crisis."

to the national interest. And the programs serve as a national resource that can be drawn on by the entire Nation.

Evaluating the Capacity of Student Loan Servicers

Mr. Dent: The Department is currently working on revising the allocation of new loan volume to the student loan servicers, pursuant to language from the FY2016 Omnibus. Specifically, what criteria is the Department using to evaluate the capacity of the loan servicers to absorb increases in loan allocations? Do these criteria include factoring in the different information technology systems of the student loan servicers?

Dr. King: As required by the Consolidated Appropriations Act of 2016, as part of our allocation process we are assessing the capacity of each servicer to manage and process new and existing borrower accounts. We have experience working with each of our servicers and are already familiar with their systems and capabilities. Regardless, we have requested, received, and conducted an initial review of capacity plans from all of our servicers to assess the reasonability and risk of each servicer's staffing, training, information technology system, and other resource planning. We are in the process of reviewing these submissions in more detail. Based on our experience and our initial assessment of the capacity plans, we are confident that all of our servicers can manage and process projected borrower account allocations for the next few months, while the volume of new accounts is relatively low. While we continue the process of completing and documenting our capacity assessment, we will monitor each servicer's performance closely and can modify or discontinue allocations on short notice if any issues arise. Our plan is to complete and document the capacity review, as well as any adjustments or changes to the metrics, by June 30, 2016.

Private Collection Agencies

Mr. Dent: The Department of Education has delayed awarding the renewal contract to collect on student loans, while also recalling outstanding loans from second tier student loan vendors. Why isn't the Department delaying the recall until after a new contract is awarded?

Dr. King: We are pacing our recalls around the expiration of the current Private Collection Agencies (PCA) contracts in April 2017. Accounts are only recalled when no payments (excluding those made through Treasury Offset) have occurred during the previous 90 days; this ensures that no borrower starts the nine loan rehabilitation payment series with a given PCA to then have it recalled mid-stream. We believe this would adversely impact some borrowers. At the same time that we are recalling accounts from the outgoing PCAs, we are placing them with six small business contractors who were awarded contracts in 2014 and five incumbent PCAs whose contracts were extended. We anticipate five more small businesses becoming eligible to receive accounts by June 2016, at which time there will be a total of sixteen PCAs eligible to receive accounts. We believe these 16 PCAs will have sufficient capacity to handle the volume of accounts in question.

Federal TRIO Programs

Ms. Roybal-Allard: The President's budget requests $900 million for federal TRIO programs to enable the Department to provide funding for nearly 3,000 TRIO projects serving secondary and postsecondary students and adults, while also supporting a new TRIO Demonstration initiative to support the implementation and dissemination of evidence-based college access and success strategies.

Could you describe the intended objective of the TRIO Demonstration initiative and its recommended $20 million funding level?

Dr. King: At $900 million in fiscal year 2016, the Federal TRIO programs represent a significant annual Federal investment in student support services designed to help low-income and first generation students move through the academic pipeline. The Administration's 2017 request of $900 million would support nearly 3,000 projects nationwide serving over 800,000 students, including middle and high school students served through the Talent Search, Upward Bound and Upward Bound Math and Science programs; postsecondary students served through the Student Support Services and McNair programs; as well as the adults served through the Educational Opportunity Centers and Veterans Upward Bound programs.

The Administration's request for a small amount of funding to support a TRIO Demonstration Initiative reflects our objective of maximizing the return to that annual investment by building evidence of effectiveness around specific strategies designed to improve college access and success within the Federal TRIO programs. Such strategies, if proven effective, could be adopted more broadly by other TRIO projects. Under our request, the Department would allocate no more than $20 million to the TRIO Demonstration initiative to support the implementation and rigorous evaluation of interventions designed to improve college access and success. The funding would be available only to existing TRIO grantees and would either support additional students or provide additional support to students already served by TRIO projects.

Statewide Family Engagement Centers

Ms. Roybal-Allard: In the President's budget request, no funding was requested for the Statewide Family Engagement Centers (SFECs) yet Congress has authorized a minimum of $10 million to be set aside for these centers as part of the Every Student Succeeds Act (ESSA). If Congress appropriates the authorized funding level, what do you anticipate the level of demand will be for this competitive grant?

Dr. King: The SFECs would be similar to the Parental Information and Resource Centers (PIRCs) program that previously was authorized by the ESEA as amended by NCLB and last funded in fiscal year 2010. The PIRCs program funded centers in virtually every State, and given the continued strong emphasis on parent and family engagement in ESEA programs such as Title I, we would expect demand for additional grant assistance in this area if Congress appropriates funding for the SFECs program.

However, it is important to note that the current requirement that LEAs spend 1 percent of their Title I allocations on parent and family engagement already results in an annual investment of more than $140 million in such activities. In addition, State educational agencies may use their Title I administrative funds, as well as the 5 percent State share of school improvement funds reserved under section 1003 of the ESEA as amended by the ESSA, to support activities aimed at strengthening parent and family engagement in education.

Public Service Loan Forgiveness Program

Ms. Roybal-Allard: 50 Members of the California Congressional delegation wrote to urge that the Department resolve an issue that has arisen which would unintentionally prevent physicians at many California nonprofit healthcare facilities from being eligible under the Public Service Loan Forgiveness program administered by your agency. Due to a provision in California state law that precludes such physicians from direct employment at certain nonprofit hospitals and facilities, it is essential that the Department modify its regulations to permit our physicians to participate, just as their counterparts do in the 49 other States.

What is the timing of initiation of a rulemaking, if that is necessary, to solve the unforeseen consequences of the Department's 2008 regulations regarding direct employment in this unique context?

Dr. King: The eligibility requirements for Public Service Loan Forgiveness were developed through a negotiated rulemaking process and reflect the consensus that was reached by the negotiating committee. At no time during the negotiation was the issue raised that currently impacts California doctors. While we are not in a position to take up this issue through negotiated rulemaking at this time, we will keep these concerns in mind as we consider the agenda for future negotiated rulemaking committees. Alternatively, we believe this concern could be resolved through state action; for instance, other states with similar rules, such as Texas, have established a non-profit co-op to which their doctors belong, making them eligible for PSLF.

WEDNESDAY, MARCH 23, 2016.

CENTERS FOR DISEASE CONTROL AND PREVENTION

WITNESS

THOMAS FRIEDEN, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. COLE. Good morning. It is good to have you here, Dr. Frieden. And it is my pleasure to welcome you to the Subcommittee on Labor, Health and Human Services, and Education to discuss the fiscal year 2017 Centers for Disease Control and Prevention budget request.

I am looking forward to hearing the testimony of Dr. Frieden. I look forward to discussing in greater detail priorities that I know we all share, such as reducing opioid abuse, antibiotic resistance, and chronic diseases in our country.

I also want to better understand the steps the CDC is undertaking to address Zika.

Last year, Congress provided CDC with a 4 percent increase, double the request. This year, the administration has proposed a 3 percent decrease for fiscal year 2017. I would like to talk more today about the reason for this proposal and the impact it may have on public health.

I understand two more countries now have met the World Health Organization criteria to be considered free of the Ebola transmission. We know the CDC has been actively engaged in the Ebola fight and are glad to hear about such progress.

Many other public health threats face our Nation, and we want to give you the resources you need to combat them. I want to caution you, however, that we also want to ensure that precious taxpayer dollars are not wasted on politically motivated activities outside the mission of the CDC, such as promoting gun-control or lobbying local communities to ban the consumption of certain products.

Today, we welcome Dr. Thomas Frieden, the CDC director, to the subcommittee. Although we will continue to work with you throughout the year, this may be the last time you appear before our subcommittee during this administration. In fact, I want to publicly thank you for the splendid, splendid work that you have done and how well you have worked with every member of this committee and with Congress in carrying out your important functions.

You genuinely represent the finest traditions in public service. So we are so happy to have the opportunity to work with you.

As a reminder to our subcommittee and our witness, we will abide by the 5-minute rule. But before we begin, I also want to announce some housekeeping. We will be voting sometime during this

hearing, so I want to go as far as we can in terms of opening statements by everybody. When the vote occurs, we will recess and then we will come back immediately after the vote. So you do not have to worry about juggling back and forth. We will recess the hearing, so people have an opportunity to put their questions to Dr. Frieden.

I am pleased, obviously, we have the big chairman here today. So if I may, I am going to yield to him for his opening statement, and then I am going to go to the ranking member for her opening statement.

Mr. ROGERS. Mr. Chairman, thank you very much for your recognition.

Dr. Frieden, welcome to the subcommittee, and your 2017 budget request for CDC.

CDC performs a critical mission to protect Americans from a host of health threats, both domestic and foreign. Your request of $7,039,000,000 constitutes a 3 percent reduction from last year's enacted level, largely taken from immunization funds and flexible Preventive Health and Human Services Block Grant funding.

At the same time, like a number of agencies within the Department of Health and Human Services, you have requested to add $30,000,000 in new mandatory funding outside the purview of this committee. Behavioral health is a topic meriting discussion and our support, but it must take place within the confines of our discretionary authority.

I look forward to working with you so this committee can adequately fund your mission for fiscal year 2017.

I want to start off this morning thanking you and your colleagues at CDC for your tremendous work to help build a healthy work force through the prevention and treatment of serious health concerns in my region and across the country.

As you know from having traveled in my district, we have lost around 10,000 coal mining jobs in the past few years. To help build a stronger economy for Appalachia, I have been working with both the current Kentucky Governor Matt Bevin and his predecessor, Governor Steve Beshear, on a regional development initiative known as Shaping Our Appalachia Region, SOAR.

As we build a network across the region to strengthen and expand the economy, it is important to understand the vital role of having a readily available and healthy work force. Currently, Kentucky is plagued with some of the Nation's highest rates of heart disease, cancer, diabetes, kidney disease, and others.

I appreciate your visit to my district for 3 straight days a couple years ago and for the wonderful work your CDC team members are doing on the ground in Eastern Kentucky working with SOAR. By helping coordinating what is called a health hackathon with MIT scheduled for later this year, and assisting with substance abuse, heart disease, and diabetes health disparities, the CDC is truly making a difference in helping my region address serious health concerns.

Another longstanding challenge in my region, as you know, has been the abuse of prescription medications. As the abuse of opioids, including heroin, has spread to new heights across the Nation, you have rightly characterized this emerging threat as an epidemic, and I thank you for dedicating your personal attention and re-

sources to addressing this terrible problem that has taken too many lives and touched too many families.

In particular, I salute you for working to produce new guidelines for prescribing opioids for chronic pain, just in the last few days. These science-based and data-driven recommendations constitute a landmark achievement.

A poll conducted since you released the guidelines last week indicates that they earned tremendous support from both the patient and prescribing community.

For too long, a narrow focus on opioids as a cure-all for pain and runaway prescribing have directly led to many of the 40 deaths each day, I am told, from opioid overdoses. For the first time, thanks to you and your colleagues, doctors will have clear recommendations for what factors to consider before prescribing opioids, how much they should prescribe when warranted, how often they should check back in with their patients after sending them home, and how to respond if their patients succumb to addiction.

So your guidelines are a major step forward, and I congratulate you and thank you for a signal achievement.

I am anxious to see that the medical community follows through now with these recommendations and prescribes responsibly.

In particular, I am glad to see you acknowledge the breadth of options for treating pain outside of opioids. As your recommendations reflect, addictive painkillers like oxycodone are certainly appropriate when a patient faces serious pain and has exhausted other options, but it should not be the default option.

I am so glad that you emphasize the importance of the continual interaction between doctor and patient. This relationship can and should be the start of an honest conversation at each step of the process. Fully embracing this may well save tens of thousands of lives each year.

I know that this message will be well-received when you address the National Rx Abuse & Heroin Abuse Summit next week in your current home of Atlanta. And I thank you again for taking the time to focus on these important issues. And I am pleased to say that you will be joined at the summit this time by the President of the United States, who will be addressing this national summit, I think the best summit there is on prescription drug abuse and heroin abuse, in Atlanta, the fifth annual.

Finally, you and I have spoken extensively about your request for Zika virus prevention and preparedness. I just came back along with Chairman Cole and others from a visit to South America, including Brazil, where we met with various leaders and health officials about the spread of this virus.

Our committee has made countless inquiries to the administration about the use of currently available dollars to address this crisis, and I hope you came prepared with some answers in that regard today.

Just to reiterate the position of our committee, when we received the request from the administration for a supplemental, we consulted and checked into the records. And when we wrote you a letter, it was to explain that we stand ready to help. We think there are available funds that are unobligated from the Ebola campaign

that could be quickly utilized in an emergency basis to get the fight against Zika going, giving us time then to see what else might be needed down the road, in which case we can consider a supplemental, if necessary, or take care the problem in the 2017 regular order bills.

So that is sort of where we are, and we stand ready to help. I want to make that clear, that we are here to help you.

We are trying to find out now from the administration what monies are available for this purpose; whether or not they are being used; and if so, how much and where; and what is the bottom-line request or need that we can try to fulfill.

Thank you, Mr. Chairman.

Mr. COLE. Thank you, Mr. Chairman.

We have been joined by the ranking member of the full committee, my good friend, the gentlelady from New York. She is recognized for whatever opening comments she cares to make.

Ms. LOWEY. I want to thank my good friend, Chairman Cole, and Ranking Member DeLauro for holding this hearing.

I also want to thank you, Chairman Rogers, for your leadership for quite a few years on opioids. It is your leadership that is really making a difference, so I thank you very much.

And I thank Director Frieden. For nearly 7 years, you have guided the CDC with a steady hand from one public health crisis to another. We appreciate your dedication, your skill, your service, and your testimony today.

It was just a year ago that we were discussing how the CDC's efforts mitigated the tragic losses due to Ebola. A year later, we are faced with yet another public health emergency, as the Zika virus is growing through South and Central America and the Caribbean.

Our mission to eradicate Ebola is not yet complete, and the CDC's efforts to combat Zika, in addition to other infectious diseases, are pushing public health infrastructure resources to the breaking point.

Last month, the administration requested an emergency supplemental to combat Zika. Sadly, Congress has sat on its hands while the number of Zika cases continues to rise. The World Health Organization estimates Zika could eventually affect as many as 4,000,000 people. As you know, this is particularly dangerous for women who are pregnant or who could soon be pregnant, causing birth and development defects that could result in miscarriage or death.

The world is looking to the United States to lead on combating Zika, and I hope Congress will face the seriousness of this threat and act without delay.

At a time when CDC's resources are already stretched thin, you come before us with a budget that would reduce CDC's overall program level by 3 percent. I am really very concerned about your proposed cut to chronic health and cancer screenings, particularly at a time when diabetes, heart disease, and more risks not only the health of the patient, but the health of our Nation's economic well-being.

I was pleased to see a proposed increase for combating the opioid epidemic, as well as a $15,000,000 increase for Global Health and an additional $40,000,000 to combat antibiotic resistance, which

causes more than 23,000 deaths annually and poses a serious risk to the future of our health system.

Finally, the budget once again includes $10,000,000 for gun violence prevention research at the CDC. As you know, I have been working to advance this research for 20 years, having authored the first amendment to strike the prohibition from this bill in fiscal year 1997. Since then, hundreds of thousands of Americans have died as a result of firearms. Since 2001, nearly 10,000 children were wounded or killed as a result of an accidental shooting.

Even Congressman Dickey has changed his mind and called for the removal of his rider and for funding this important public health matter. I am baffled, frankly, that Congress cannot come together and find a bipartisan path forward on gun violence research.

This is not about confiscating firearms or restricting the sale of weapons. This is pure and simple about looking to public health experts for research on how to make our communities safe.

I do hope, Mr. Chairman, that, this year, we may be able to solve this issue once and for all. We are talking about research. Thank you very much.

Mr. COLE. I thank the gentlelady.

Now I move to my good friend, the ranking member of the subcommittee, the gentlelady from Connecticut, for whatever remarks she cares to make.

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

I would like to welcome Dr. Frieden this morning and add my thoughts and appreciation for the great work that you have done over the years. It has been an honor to work with you and with the Centers for Disease Control. Thank you so much for your commitment, your personal commitment.

This morning, we discuss the 2017 budget request for the Centers for Disease Control and Prevention. The CDC is the first line of defense in protecting Americans from public health emergencies. It is vital to the well-being and safety of American families, and it is an essential part of our country's defense and its security apparatus.

Most of CDC's funding supports core public health infrastructure across the country, including State and local health departments, public health laboratories, and nonprofit and community-based organizations. The CDC also plays a primary role in responding to emerging public health threats.

One year ago, we were in the midst of a worldwide response to the Ebola outbreak in West Africa. CDC ultimately deployed more than 2,000 staff to West Africa to respond to the Ebola threat, protecting American lives, as well as those in West Africa.

Right now, we are facing three public health crises on three fronts, and the CDC is critical to confronting each of them to protect American families and children—the Zika virus, the opioid epidemic, and the lead poisoning crisis in Flint, Michigan.

Unfortunately, Congress is dragging its feet, leaving Americans at risk.

The Zika virus is affecting thousands of pregnant women and causing their babies to be born with severe birth defects. It is infecting travelers returning to the United States. And it is even being transmitted sexually.

We are about to send hundreds of American athletes, men and women, to Rio for the Olympics, and thousands more will attend as spectators. We are sending blood supply to Puerto Rico.

We need to act quickly on the administration's request for emergency supplemental appropriations to defend against this serious threat.

Some of my colleagues have expressed a desire to shift unobligated funds Congress has provided for Ebola to respond to Zika. I strongly oppose that idea because of the activities we would have to forgo if we shift funds away from Ebola to Zika. And I hope that Dr. Frieden will discuss these today.

We need to be able to respond to multiple public health threats at the same time. That is why this Congress and the last Congress, I proposed funding the Public Health Emergency Fund to enable the Federal Government to immediately respond to public health threats. It is modeled on the Disaster Relief Fund, which is at $7,300,000,000.

This fund enables a rapid Federal response following a natural disaster. If we can act quickly to respond to floods, hurricanes, and other natural disasters, we should be able to act quickly to respond to public health emergencies.

I might add that, since 2010, when it has come to the CDC cooperative agreement efforts with State and local governments, we have cut that fund from 2010 to 2016 by 8 percent. Our hospital preparedness program from 2010 to 2016 has been cut 39 percent. Then we wonder why we are not prepared.

Before I move to fiscal year 2017, I want to take a moment to review the fiscal year 2016 omnibus. Last year, we provided an increase of $308,000,000 for CDC. That is about 4.5 percent over the 2015 level, including a critical investment of $160,000,000 to address the threat of antibiotic resistance, which has the potential to threaten the entire health care system. And we provided an increase of $50,000,000 to respond to the opioid and prescription drug crisis.

Of the over 47,000 drug overdose deaths in 2014, heroin was a factor in 10,574 deaths, and opioids were involved in 20,808. Sadly, opioid deaths are likely undercounted. Thousands more people are addicted or are in recovery.

Responding to this crisis, I was pleased to see that the CDC released new prescribing guidelines, helping providers and clinicians to strike a balance between pain management and patient safety. We must work to find alternatives to opioid prescriptions and only use them when appropriate.

It is our responsibility to address this need, and Congress should support the President's request for $1,100,000,000.

I am concerned we were unable to fund other high-priority areas of health in 2016. The majority of last year's increase, about 83 percent, was allocated to three programs—antibiotic resistance, opioid abuse prevention, and the Strategic National Stockpile. That means that only one-sixth of last year's increase was allocated to support the rest of CDC's critical work.

Chronic disease prevention was cut by 22 percent, including a 3 percent cut to tobacco prevention. Prevention of HIV/AIDS, hepatitis, STD, and tuberculosis was increased by less than one-half of

1 percent. And environmental health was increased by less than $3,000,000, including an increase of only $1,500,000 for the Childhood Lead Poisoning Prevention Program.

Given what we are seeing play out in Flint, Michigan, we need to support this program. I am disappointed that the administration's proposal for this year would not fund lead poisoning programs in all 50 States. We can and we must do better than this.

Do we not understand that children and adults are at risk of lead poisoning all over the country? And according to the CDC, in the United States, more than 500,000 children under the age of 5 have elevated blood levels. That is unconscionable that we would cut back on this program.

That brings us to the 2017 budget request. There are good proposals in this budget. There are modest increases for antibiotic resistance and prescription drug abuse prevention, as well as a request for $10,000,000 for gun violence prevention research.

These are important initiatives, and I will support them. But I am overall concerned that this proposal cuts CDC's program level by $194,000,000 below current levels. I see that once again, the budget includes cuts to cancer screenings, immunizations, minority outreach, occupational health, as well as complete elimination of the Preventive Health and Health Services Block Grant.

These programs are critical to American families and they are too critical for American families to sacrifice. That is why this subcommittee's allocations that will be released next month will be so important.

I hope my colleagues on the other side of the aisle will join us in urging an increase for Labor-HHS in fiscal year 2017.

When I look at this budget, and I read the mission of the Centers for Disease Control and Prevention, I cannot help but feel that we are nickel-and-diming the Centers for Disease Control, an agency whose mission is the defense of the American people. The initiatives that you lead have the power to defend American children and families from life-threatening health crises. We need to treat the CDC funding level with the gravity that it deserves.

I thank the chairman.

And I look forward to your testimony, Dr. Frieden, and today's discussion. Thank you.

Mr. COLE. Thank you.

Dr. Frieden, you are recognized for whatever opening statement you care to make.

Dr. FRIEDEN. Thank you very much, Chairman Rogers, Chairman Cole, Ranking Members Lowey and DeLauro, for your very kind words about CDC. I greatly appreciate that. It is an honor to lead the Nation's leading public health agency, the agency that is responsible for protecting the country, our first line of defense in public health.

We work 24/7, and we have the world's top experts in most of the diseases that affect Americans. We support States, tribal nations, communities, health care providers, universities, and other groups to protect the Nation's health security.

And we greatly appreciate the committee's support in fiscal year 2016. I think you appropriately recognized that CDC and public health is a best buy, that when we invest in prevention and in sup-

porting communities, we can not only improve health and save lives, but also save money.

Thank you, in particular, for the emergency funding for the Ebola and Global Health Security supplemental last year.

EBOLA

Ebola is not over. Just last week, a new cluster of cases occurred in a remote area of Guinea, Nzérékore. I have been there. It is difficult to reach. It is difficult to get to. We have had, so far, six confirmed cases. We have more than 100 high-risk contacts who are being tracked. We have more than 1,000 potential contacts who are being tracked. We have 84 of our own top doctors, scientists, nurses, other staff there responding.

So Ebola continues. It has an unfortunately long tail of this very challenging epidemic that we have been fighting now for 2 years.

There has been, though, enormous progress. We have helped these countries establish systems. The last seven clusters have been promptly identified and promptly stopped. To do that, we need a large infrastructure, and we need to continue to strengthen the country's own capacity to detect and respond.

Much more is needed for us to understand how Ebola is spreading. We still do not know all the details of what is causing these recurrent clusters. To better deploy countermeasures such as the vaccine, which is going to be used in this and other responses, to finish our own vaccine and therapeutic and other trials that are being done in West Africa and elsewhere, these investments pay off.

GLOBAL HEALTH SECURITY

I recently returned from Tanzania where the Global Health Security investments are helping to improve response to a massive cholera outbreak.

I also visited Ethiopia, where a devastating drought is causing severe health problems, and the Global Health Security approach is being used to mitigate the health impacts there.

In Benin, Togo, and Nigeria, we are fighting Lassa fever, another hemorrhagic fever analogous to Ebola that can also spread through rodents and other measures.

In an indication of how much the world has changed, we had, tragically, a death of a medical missionary from Lassa fever. His organization called me at night a week ago. We were then able to medically evacuate a second medical missionary to Emory University Hospital, where he is under treatment.

That did not get anything like the coverage that the evacuations got 1.5 years ago. That is a reflection of the progress I think that we are making regularizing and realizing that the new normal is that we are tightly interconnected as the world, and an outbreak anywhere is potentially a threat everywhere.

It would be dangerous to let down our guard now. It would be dangerous to let down our partners now. There are many risks out there, whether it is Ebola or Lassa or MERS or SARS or the next HIV.

We are dealing now with a very large yellow fever outbreak in Angola. This could spread throughout Africa and potentially to Asia and outstrip available vaccine supply.

There are also new epidemic threats, many of which we cannot predict with certainty. There are tickborne diseases that can cause severe and fatal illness that we are now identifying as more widely disseminated because of the Global Health Security support.

Drug-resistant pathogens have the potential to undermine our work. We are focused on keeping America safe and healthy.

Investments in CDC are a best buy. Congress and this committee supported our request for advanced molecular detection some years ago. Those resources are saving lives.

They are improving our detection of diseases such as listeria, where we have been able to get contaminated products off shelves faster and save lives. They allowed us to accelerate our production of a Zika diagnostic test.

They are also enhancing our response to diseases such as the outbreak of HIV in Indiana related to opioids. We were able to rapidly sequence that and understand what was occurring.

And we can better respond to and prevent diseases, such as improving our flu vaccination production.

I also want to thank you for your support for initiatives in 2016 that are continuing in 2017, with the continued increase in antibiotic resistance funding requests. This is crucially important to protect modern medical care and reduce the number of deaths, so we can rapidly detect outbreaks, respond effectively, and prevent them wherever possible.

OPIOID OVERDOSE PREVENTION

Also, thank you, Chairman Rogers, for your long-term leadership on the battle against opioid overdose. We continue to struggle to make progress in this field, and it will require all of us in society doing more to get to a better place with our relationship with these dangerous medications and illicit substances.

We know of no other medication used routinely for a nonfatal condition that results in death so often. Our recent guideline emphasizes that for patients and physicians to begin an opiate is a momentous decision, and it needs to be taken with a full understanding of the risks and the benefits that this involves.

We also have a proposal to increase funding for Indian country programs. We would be delighted to discuss this further going forward.

ZIKA

Zika is an emergency, and there is much that we still do not know about it. We are learning more literally every day. We have already been able to get two new diagnostic tests approved through the Emergency Use Authorization at FDA.

Our staff are working literally around the clock. We have produced more than 500,000 test kits. We have more than 800 staff working on the Zika response now. We are scraping together money from wherever we can find it to respond effectively.

But a robust response, I do believe, will take emergency funding. If you look at the definition of emergency—unanticipated, poten-

tially catastrophic, permanent damage—I cannot imagine a situation that meets this more than Zika.

Unanticipated. There has never before been a mosquito-borne illness that can cause a birth defect. We have never seen that before.

Potentially catastrophic. Each child affected can cost more than $10,000,000. And it is a horrific tragedy for the families that are involved. And we do not know the full range of illness. Microcephaly is a horrific birth defect, but that may be just part of the spectrum of severe problems these infants may face.

And permanent. These are lifelong disabilities that they will be facing.

So I want to thank you very much for your support of CDC and our work to protect Americans, and I will be happy to answer any questions that you have.

[The information follows:]

CDC Congressional Testimony

Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies

CDC 24/7: On the Front Lines of America's Health Defense

Wednesday, March 23, 2016

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, Chairman Cole, Ranking Member 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 health protection agency and an operating division of the Department of Health and Human Services. We thank this committee for its generous support throughout the 2016 appropriations process and its continued support of our ongoing emergency Ebola response in West Africa and our Global Health Security work around the world. With your help, CDC is strengthening public health at home and abroad and protecting Americans from threats wherever they arise.

Today I would like to focus on how CDC works 24 hours a day, 7 days a week to protect Americans from health threats and save our nation health care dollars through prevention. Additionally, I will discuss our priorities for FY 2017, including the Good Health and Wellness in Indian Country initiative, which is targeted at specifically promoting the health and wellness of a population that has historically borne a disproportionate burden of death, disease, disability, and injury compared to other populations in the United States.

Working to Provide Health Security 24/7

CDC helps save lives by preventing, detecting, and controlling the growing risks of infectious disease outbreaks, emerging infectious and other diseases, drug-resistant bacteria, and natural and man-made hazards and disasters. We provide emergency response support, technical expertise, and rapid development of prevention solutions, including means to rapidly diagnose health threats, and deliver vaccines and other medical countermeasures.

CDC focuses on high-impact, sustainable programs, including building a public health workforce that is prepared, diverse, and flexible. For instance, CDC assigns fellows for the Public Health Associate Program (PHAP) to serve on the front lines in state and local public health departments. Most PHAP fellows have stayed in the public health field. Health departments througbout tbe United States depend on CDC's expertise and support to provide basic services that protect Americans. CDC's disease detectives—EIS officers—have significant impact on improving the public's health. They support more than 100 field investigations each year in the United States and around the world. About 80 percent of all CDC funding is awarded through grants and contracts to help

accomplish our mission to promote health and quality of life by preventing and controlling disease, injury, and disability. CDC is also committed to continuous improvements in laboratory science and safety, as well as the quality of its public health laboratory services.

Today's Emerging Health Threats

Zika is an emerging health threat; we face a rapidly changing situation involving numerous health risks in this country and abroad. Zika virus, carried by the *Aedes* mosquito, causes understandable concern among people throughout the Americas, including those here in the United States, most notably pregnant women. Every day, CDC is discovering better ways to prevent, detect, and respond to Zika and its potential adverse health outcomes. We are committed to ensuring that the American people have access to the most accurate, timely information about Zika virus and the current outbreak. There are, however, many unanswered questions about the Zika virus, including the following: the nature of maternal-to-child transmission; what cofactors may play a part in various consequences of the virus; its relationship to microcephaly, Guillain-Barré, and other consequences; level of risk including symptomatic versus asymptomatic transmission; and duration of infectivity in semen. We need to dramatically accelerate optimal vector control strategies, improved diagnostics, and vaccine discovery. While we continue our work 24/7 to answer these critical questions, we will not be able to do so without the resources requested in the Administration's FY 2016 emergency supplemental request.

Many areas of the United States have the type of mosquitoes that can become infected with and transmit Zika virus, the same type of mosquito that spreads dengue and chikungunya. Although we cannot predict with certainty the impact of Zika virus in the United States, we believe we will see additional cases in the United States based on our experience with dengue and chikungunya, which have caused relatively small, localized outbreaks in parts of the Southern United States, and Hawaii. For the Commonwealth of Puerto Rico as well as the U.S. Virgin Islands and American Samoa, the outlook is different. There have already been several case reports of local transmission in all three territories, and experience suggests that Zika virus may spread rapidly in those areas.

Our primary concern at this point is to protect pregnant women from Zika virus infection to prevent microcephaly, strongly suspected to be linked to Zika virus infection during pregnancy. This newly discovered

consequence of Zika emphasizes that our health security as a nation depends on stopping outbreaks where they start, before they reach our shores.

Improving Global Health Systems to Protect American Health Security

Infectious diseases do not respect borders, as we have witnessed previously during the West Africa Ebola epidemic, Middle East Respiratory Syndrome Coronavirus (MERS) outbreaks, measles, and ongoing challenges from highly-pathogenic strains of influenza. We all are connected by the air we breathe, the water we drink, and the food we eat. We cannot predict when, where, or how the next epidemic may strike, but we do know that if our partner nations are unprepared, these outbreaks will cost more lives and resources. We appreciate Congress' continued strong support for the five-year commitment to the Global Health Security Agenda, which enables us to provide sustainable assistance to other countries so they can detect, stop, and prevent the spread of infectious diseases. Maintaining these investments in sustainable Global Health Security is critical to stopping outbreaks before they reach our shores.

Fighting Antibiotic Resistance

Antibiotic resistance (AR)—when bacteria do not respond to the drugs designed to kill them—threatens to return us to the time when simple infections were often fatal. Today, AR causes more than 23,000 deaths, more than two million illnesses, and up to $20 billion in health care costs in the United States each year. We face a fundamental threat to modern medicine: if antibiotics are rendered ineffective by resistant bacteria, we will lose the ability to treat sepsis (blood infection) or cancer, provide organ transplants, or save victims of burns and trauma. Routine surgical procedures, such as hip and knee replacements, would be far riskier, and common complications of life-saving treatments such as chemotherapy could prove fatal. A simple cut of the finger could lead to a life-threatening infection. If antibiotics lose effectiveness, we may have no means to treat otherwise treatable illnesses and our entire health care system would take a huge step backwards.

Thanks to a significant starting investment by this Congress in FY 2016, CDC is dramatically scaling up solutions outlined in the National Action Plan for Combatting Antibiotic Resistance to build robust networks to track and

stop the spread of AR threats, protect the effectiveness of antibiotics we already have, and spur development of new interventions that can transform the way public health responds to AR. The FY 2017 request includes an increase of $40.0 million for year two of the Antibiotic Resistance Solutions Initiative. This increase expands support to states, building on AR capacities started in FY 2016, to expand the nation's ability to detect, respond to, and prevent AR infections across healthcare settings and in the community in up to 50 states, 6 large cities, and Puerto Rico.

Curbing the Prescription Drug Overdose Epidemic

Together, we have witnessed a deadly epidemic unfolding in states and communities across the country. Deaths from drug overdoses have been rising steadily over the past two decades and have become the leading cause of injury death in the United States. The growth in drug overdose deaths is fueled in large part by a quadrupling in the number of deaths involving prescription opioid pain relievers. As the nation's health protection agency, CDC has applied public health principles to identify the connection between inappropriate opioid prescribing and overdose deaths. The prescription drug overdose epidemic is driven in large part by fundamental changes in the way healtheare providers prescribe opioid pain relievers: 245 million prescriptions were written for opioids in 2014, approximately enough for every American adult to have their own bottle of pills. As the amount of opioids prescribed increased, so bas the number of deaths.

States are at the front lines of this epidemic. Thanks to strong Congressional support in FY 2016, CDC is supporting HHS's targeted initiative aimed at reducing prescription opioid and heroin related overdose, death and dependence and focus on three priority areas: (1) providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions; (2) increasing use of naloxone, the life-saving drug to reverse overdose; and (3) expanding the use of medication-assisted treatment, which combines the use of medication with counseling and behavioral therapies to treat substance use disorders. CDC is equipping states with the resources and expertise they need to reverse the epidemic and protect their residents, families, and communities. With these funds, CDC is supporting states, particularly those with the highest burden of deaths, to respond to this epidemic by: 1) improving data quality and surveillance to monitor

and respond to the epidemic; 2) scaling up effective public health interventions; and 3) enhancing and maximizing the effectiveness of prescription drug monitoring programs. CDC's FY 2017 budget requests an increase of $10 million to support newly released opioid prescribing guideline dissemination and adoption throughout our primary health care system and to continue to bring to scale interventions we know work. CDC will develop and deliver the clinical decision support tools and training to fundamentally change prescribing for chronic pain. We will also scale up prevention practices in hospitals and health systems and continue to identify new promising prevention practices that can be brought to bear on this epidemic across the nation.

Fighting Health Disparities

Across our nation, CDC data has consistently shown that Native Americans and Alaska Natives have far too often suffered disproportionately high rates of chronic disease like obesity, diabetes, and heart disease in addition to high rates of suicide, prescription drug overdose, and motor vehicle injury. In FY 2017, CDC requests $15 million in dedicated funding for a Good Health and Wellness in Indian Country initiative to enable CDC to comprehensively address the leading causes of death and their associated risk factors in this community, and further incorporate the culturally driven wellness practices that build resilience and strengthen social and emotional well-being. In addition to funding interventions in Tribes and Tribal Organizations, the initiative will provide support for Tribal Epidemiology Centers to increase their ability obtain area and Tribe-specific data on health and disease, health behaviors and health status, and environmental factors such as access to healthy foods and physical activity opportunities. Finally, we will emphasize strategies developed or adapted by Tribal communities that address a documented health need while honoring and strengthening connections to heritage and traditional practice. This budget request also includes a new approach to the REACH program, which will incorporate lessons learned from prior community grant programs, resulting in a stronger, more robust REACH that builds on the growing evidence base.

Keeping Americans Healthy, Safe, and Competitive

Over the past year, CDC and our nation have addressed difficult challenges to protect our health security as we have seen the Ebola epidemic enter a new phase of careful monitoring, and the Zika outbreak begin. CDC will

continue our vigilance on all fronts to detect and quickly respond to numerous, unpredictable emerging disease threats. We will protect Americans from the leading causes of death and disability that threaten our economic productivity and global standing. Thank you for your continued support of CDC's important work serving our nation; I am happy to answer your questions.

Mr. COLE. I thank you very much. As I know you are aware, again, we have votes soon, and the chairman and ranking member have multiple committees, so I am going to go first to them for whatever questions they would care to pose.

So, Mr. Chairman, you are recognized.

Mr. ROGERS. I thank you, Mr. Chairman, for that courtesy.

OPIOIDS

Dr. Frieden, your medical expertise and forward-leaning approach is what helped put the wheels in motion for the new guidelines for prescribing opioids. I am truly grateful for your commitment and your actions in this fight that we are in.

A Harvard University poll conducted since you released the guidelines for prescribing opioids shows that Americans are overwhelmingly in favor of your recommendations. I, for one, am pleased that these guidelines clearly address the problem holistically, an approach that I have long advocated, as have you.

There are a couple things I want to try to clarify with you.

I am pleased that consultation of the prescription drug monitoring programs in all States except Missouri is a key recommendation for prescribers. PDMPs are an essential tool for good medical practice, because it allows a physician or pharmacy to find out whether or not a prescription they have been presented has already been filled in some other place, to prevent double-filling of the prescription.

Yet, doctors are not using the PDMPs. It is there for them, and all they have to do they do is contact that State computer number and find out if this person that is in to see them has already been to a doctor and prescribed medicine. That is a huge source of the pills that we find available for young people to overdose on.

First, not all States are interconnected with one another with the PDMPs. We still have a problem. And they are not real-time. They are getting better. And interoperability is available in some States, but not all.

But nevertheless, what steps can we take at the Federal level to be sure that doctors consult PDMPs?

Now in Kentucky, the State Legislature passed a law requiring doctors to consult PDMPs before they prescribe.

Is that the answer? Or is there a better answer?

Dr. FRIEDEN. Thank you for your question, Mr. Chairman. And again, thank you for your leadership on this issue.

I have a lot of sympathy for the physician who is often harried, overworked, facing a patient who is in pain. There is no objective measurement of whether that patient is in pain. And I fully agree that PDMPs have tremendous potential, and that potential is not being fully met.

There is a pilot that was done some time back that I think is encouraging in this regard. This was the integration of the prescription drug monitoring programs and electronic health records, so that doctors do not need to sign onto two different systems, and it pops up right immediately in their EHR system.

I think that would be a very important area to pursue. As with so much with this terrible problem, I do not think there is one simple answer. I do think that States that try things, as Kentucky has

done, trying those things, evaluating, seeing what works, and scaling that up is going to be critically important.

So I think the goals are clear, as you exactly outlined. You used interoperable, real-time. I would add actively managed by the State.

We need to work together both at the State and Federal levels, and with private industry, including the electronic health record vendors, to make sure that that happens.

Mr. ROGERS. Let me ask you about naloxone. Guideline eight says, "Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose are present."

Is that suggesting that doctors co-prescribe naloxone along with opioids in these higher risk cases?

Dr. FRIEDEN. Yes.

Mr. ROGERS. Are you at all concerned that this might actually have the unintended consequence of giving a patient false sense of security that could lead to more cavalier behavior?

Dr. FRIEDEN. We are aware of that concern. But what we have seen so far is that many of the overdoses are unintentional. In fact, the overwhelming majority are unintentional.

One of the things that was so striking to me in the evidence review running up to the release of these guidelines was the astonishingly high rate of overdose in people at higher doses. Once you got to over 90 or 100 MME per day, you increased about ninefold the risk of overdose. When you were at more than 200 MME per day, the risk of overdose in just a few years was about 1 in 32. This is just an astonishing level.

These are very dangerous medicines. The fact that we do have essentially a method of reversal suggest that they need to be used.

So I would see these things in parallel. We need to reduce the use of medications. But for those on them, we need to increase the safety with which we use them.

Mr. ROGERS. Thank you.

Mr. Chairman, my time is expired. Thank you.

Mr. COLE. Thank you, Mr. Chairman.

We will now go to the ranking member of the full committee, the gentlelady from New York.

ZIKA

Ms. LOWEY. Thank you, Mr. Chairman.

And welcome, again, and thank you for all your good work, Dr. Frieden.

In addition to the budget request, the administration requested more than $1,800,000,000 for an emergency supplemental to combat the Zika virus. Nearly half of this funding would support the CDC's efforts to respond to the virus, including enhanced mosquito control, rapid response teams, surveillance in domestic cases, and improved diagnostics and laboratory capacity.

This is a huge task, and much of South America and the Caribbean, including American citizens in Puerto Rico and the U.S. Virgin Islands, are looking to Congress for leadership to tackle this public health emergency.

How will the CDC work with physicians and public health experts to get the best information into the hands of Americans and, in particular, women who are pregnant or could be pregnant in the near future, so they are protected from the dangers associated with the virus? And if supplemental funds are not provided, how would the CDC's response capabilities to both Ebola and Zika be curtailed?

Dr. FRIEDEN. We are doing everything we can to respond to Zika. We are currently at our highest level of activation, Level 1, for the Zika response. We have, as I mentioned earlier, more than 800 staff working on Zika. We have already dedicated essentially all of our dengue branch, which is located in Puerto Rico, to Zika.

We have been working really on three different fronts. In the continental U.S., where dozens of States have mosquitoes that can sometimes spread viruses like Zika, and about a dozen or little over a dozen States in the south of the U.S. have the particular mosquito that is most efficient at spreading this type of virus.

It is possible that, come summer, we will have a situation where a woman gets pregnant and through bad luck is bitten by a mosquito that is infected by Zika and may have an affected child. We want to do everything in our power to prevent that from occurring.

The second front is in the U.S. territories. Puerto Rico, as you indicate, these are American citizens. Unfortunately, through a bad roll of the dice, if you will, they have an environment that is both a natural environment and a human environment that is extremely conducive to the spread of Zika.

We know that when chikungunya infected Puerto Rico, within 2 months of the introduction, it was all over the island. Within 8 months, nearly 1 in 5 adults were infected.

If this occurs with Zika, which it may well, we could see thousands of affected pregnancies there. So we are really doing everything we can to protect pregnant women, to support vector control so we can optimize the control for mosquitoes—this is a very challenging mosquito to control—and to increase access to voluntary effective contraception for women who choose to delay pregnancy.

The third front is international. Since they are at the front lines of this, we can both help them and learn more about what is occurring. We have teams on the ground in Brazil, and I thank the committee for meeting with our team there, and in Colombia. And they are really very robust and productive partnerships there that will help us learn more and help them control better.

I am concerned that, if we have to, we will take every dollar we can find to work on the Zika response. But there will be implications. All of the dollars allocated were allocated by you, by Congress, for specific activities. We are aware that there are tradeoffs.

With the Ebola and Global Health Security supplemental, when I look at the international components of that supplemental, all of those dollars are planned to be used.

In fact, I received last night a request from an Ambassador in an African country where we had hoped to be able to put a staff person, but we do not have the resources to do it. Nothing related to Zika, but just because the Ebola and Global Health Security dollars do not meet the entire need to protect Americans and keep us safe by strengthening systems in countries that most need it

around the world. This was the Ambassador to Benin, which is currently experiencing an outbreak of Lassa fever, another hemorrhagic fever.

So I am challenged with recognizing that we do not have all the resources in place to protect Americans as well as we could, should, and would like to. Now we have this new unanticipated challenge of Zika that we are really scrambling to respond to as effectively as we can.

Ms. LOWEY. Thank you very much.

Thank you, Mr. Chairman.

Mr. COLE. I thank the gentlelady. We are going to now put the committee in recess, so members can go have the opportunity to vote. We will resume immediately after votes. Again, we apologize for the inconvenience.

[Recess.]

Mr. COLE. We are going to go ahead and reconvene the hearing, if we can. Obviously, we will have members coming back from votes. We have some that may be disappearing home.

So regardless, again, Dr. Frieden, we apologize for having to interrupt the session. We appreciate your patience.

INDIAN COUNTRY

I am going to pick up a subject that we are just visiting about before we reconvened the hearing. I want to thank you again for some of the work that CDC is doing in Indian country, particularly, as you mentioned in your testimony, the Good Health and Wellness in Indian Country program. We appreciate that. However, it is one program. As you know, we have multiple issues with this population.

I would like, if you could, discuss that but also discuss what your thoughts are on where the CDC could be helpful in funding other programs in Indian country on issues like suicide, motor vehicle accidents, cancer, HIV, the whole range. This population obviously has a higher incidence of all these things than the rest of the population.

So I would appreciate your focus and any thoughts you have on things we ought to be doing or considering.

Dr. FRIEDEN. Thank you. As you well know, Mr. Chairman, as you have highlighted, these are really some of the most stark health disparities that we know of in this territory.

Indian nations have a great degree of diversity with some having health statuses that are relatively good and others shockingly bad. What we have tried to do with the modest proposal in the 2017 budget is indicate what could be done to strengthen capacity within Indian country through tribal epidemiology centers, through more information on what the burdens are and what the potential ways to address them are, and then to implement prevention programs, working in conjunction with communities.

That means sometimes building on traditional practices that are healthy, whether it is food, physical activity.

We have also seen some very positive results reducing motor vehicle risks by working with communities, getting communities engaged in reducing alcohol-impaired driving and improving adherence to safety belt and car seat use.

So I think this involves the importance of getting data there and involving the communities in the solution, and recognizing that with hundreds of tribes, we have the challenge between going deep or going broad, whether we work with a few tribes and document what works well, or try to get a widespread effort.

I think our approach is to try to get data, so we understand both where the burdens are and what are the programs that are likely to work best, and then engage communities in solutions. There are some communities that have ample resources, and it is a question of dedicating them to things that make the most difference, like cardiovascular prevention. There are other communities where there are dire needs for everything from safe water to very fundamental issues of health care access.

And in far too many communities, as we were just discussing, there is a problem of substance abuse and suicide. These are areas where solutions are not quick and they are not simple. But there are things that we can do to support communities, support parents, support families in reducing risks.

Mr. COLE. We appreciate that and would ask you to continue those efforts. As you know, in many cases you work directly with State and local health departments, and quite often tribes are just simply left out of that equation by States. So having Federal involvement here to make sure there is some equity and those communities are given ample attention I think is very important.

HEART HEALTH

Dr. Frieden, in the minute or so I have left, the American Heart and Stroke Association—remain our number one most expensive killer. They cost us roughly $1 billion a day. This committee significantly expanded resources in those areas last year, increasing the amount by about $70,000,000. That includes a $10,000,000 increase that doubled the National Diabetes Prevention Program.

Could you explain to us how those funds are being awarded and again look ahead a little bit and tell us what we ought to be thinking about this year in that very important area?

Dr. FRIEDEN. Thank you very much, and thank you for the support there. Heart disease and stroke, as you know, are leading killers. They are largely preventable, probably more than half of all the heart attacks and strokes that occur in this country could be prevented with today's technologies. Our flagship project in this area is the Million Hearts program. We think we can prevent 1,000,000 heart attacks and strokes over a 5-year period by implementing programs that are community-wide and also individual.

One of those key areas is control of hypertension. High blood pressure is the single leading killer, the single thing that could save the most lives if we do a better job in our health care system, and yet we are only at about 52 percent control in the country as a whole.

We have a system to recognize leaders in hypertension control. Treatment does not have to be expensive. It does not have to be complex. It can be done by a health care team that involves nurses and pharmacists, and community outreach workers. I think this is one of the areas that has the most potential for progress.

We also appreciate your support for the National Diabetes Prevention Program, and I think we will be hearing more about that today from Secretary Burwell.

Mr. COLE. Thank you very much.

I now want to go to my good friend, the ranking member of the subcommittee, the gentlelady from Connecticut.

ZIKA

Ms. DELAURO. Thank you, Mr. Chairman.

Dr. Frieden, you have been showing a series of slides that depict the rapid expansion of chikungunya, that infection in Puerto Rico. It starts in a few pockets, spreads rapidly, covers the entire island.

My understanding is that public health experts are expecting the Zika virus to spread in the same way. I have heard also from your CDC colleagues, as well as Dr. Fauci at NIH, and they predict that clusters of Zika infections will reach Florida, Texas, and parts of the Gulf Coast. It really is only a matter of time, which is why, as you know, I support the administration's request and the $828,000,000 that it proposes for CDC.

And I wholeheartedly agree with Leader Pelosi that Congress should stay in session until we have dealt with emergency funding for Zika.

Let me pose a series of questions, so that you can get them down.

How many States are you expecting to be at high risk for transmission? Is the plan limited to the Gulf Coast States? What about States that are too far north for the Aedes aegypti mosquito?

Second, Puerto Rico is now importing its blood supply, because the danger of Zika-infected blood is high. What does that say about the risk of Zika to the health of the population? What will happen to the blood supply in Gulf Coast States when Zika is more prevalent in the coming months? Can you talk about your work with State and local health departments?

My understanding as well—this is the fourth question—FDA recently issued an Emergency Use Authorization for a PCR assay, a diagnostic tool that enables doctors to tell if an individual is infected with chikungunya, dengue, or Zika. How many labs will get access to the test? Is the CDC distributing this assay across the country or to the Gulf States or Puerto Rico?

The Kaiser Foundation, in 2014, said there was a total of 783,000 births in Gulf Coast States—Texas, Louisiana, Mississippi, Alabama, and Florida. Given the risk factors along the Gulf Coast, is there an estimate for how many pregnant women in those States are expected to be infected by Zika virus in 2016?

Sorry.

Dr. FRIEDEN. Okay, I will see how quickly I can do that.

First, the number of States at high risk. There are the Aedes aegypti States, and the surveillance for mosquitoes is not perfect. It is not up-to-date. That is one of the problems with vector control, that we do not know definitively where it is. But there are at least 13 States that have Aedes aegypti.

Aedes albopictus also can spread Zika. It is probably a less efficient vector, and there are more than 30 States.

We tier our support to States based on their risk from mosquitoes and the number of travelers that they are likely to receive.

There are more than 40,000,000 travelers to and from the Zika-affected areas in the U.S. each year.

In terms of blood supply, we are hopeful that within a month or so, there may be a way of testing blood for Zika that would allow blood supply to resume in Puerto Rico. In terms of the Gulf Coast States, if there are clusters, we are in active discussion with the Food and Drug Administration, which is the regulatory authority, about what would happen in that circumstance.

Ms. DELAURO. But that is potentially at risk, the blood supply in those States, as it is in Puerto Rico?

Dr. FRIEDEN. There could be a risk, although we think the risk would be dramatically lower than in Puerto Rico.

In terms of local and State governments, we have a Zika action plan summit in Atlanta on April 1. We have more than 30 States that will be coming, and we will be working hard with them on what their preparation plans are, what the needs are, what can be done now.

We have a tremendous degree of interest and expertise from the States, and we work closely based on the risk.

The supplemental, as you know, has as its largest component the $453,000,000 of the $828,000,000 that would be support to State and local and support within the continental U.S.

There are two different Emergency Use Authorizations from the Food and Drug Administration.

We have superb laboratorians. They have done just phenomenal work around the clock. On March 17, we had the second EUA. This is a Trioplex Real-time PCR that can tell Zika, dengue, and chikungunya. Also, earlier than that, on February 26, we had an IgM, the CDC MAC-ELISA test, which is an antibody test.

The MAC-ELISA test is currently up and running in six States. We would like to get it up in as many States as wanted through the Laboratory Response Network the CDC coordinates. There are 28 labs that are already using Real-time PCR with materials provided by CDC.

So we are getting these out as rapidly as possible. Our lab in Fort Collins is working nightshifts around the clock 7 days. So the quicker the States can do it, the better for us.

Ms. DELAURO. Across the country, just the Gulf, or Puerto Rico? It is going to be across the country?

Dr. FRIEDEN. Across the country.

Ms. DELAURO. Okay. The last question.

Dr. FRIEDEN. In terms of the number of pregnant women——

Mr. COLE. Can we make this pretty quick?

Dr. FRIEDEN. I do not have an estimate.

Ms. DELAURO. Can we get an answer to that and can we get a list of the States, your first tier, your second tier, that are going to be in jeopardy?

Dr. FRIEDEN. We can get you a list of States.

Ms. DELAURO. Can we get the number of births in these States that we can anticipate here, based on prior data and prior statistics?

Dr. FRIEDEN. The number of births, we can get you. The number that might be infected would be hypothetical.

Ms. DELAURO. No, the number of——

Dr. FRIEDEN. Yes, we can do that.
[The information follows:]

Answer to Representative Delauro's Inquiry: List of states by tier of Zika risk, number of births in these states.

States that have previously experienced local transmission of dengue and chikungunya (Hawaii, Florida and Texas) would be presumed to be at higher risk of local transmission of Zika virus. This week, CDC has updated and released new maps of the United States that show the approximate and potential locations of the two species of mosquitoes that are associated with Zika transmission. Currently, there have been no identified cases of local, mosquito-borne transmission of the Zika virus in the continental United States. The updated maps reflect the latest data that have been collected by CDC and its state and local partners and show where these mosquitoes are now or have been previously found within the continental United States. These maps do not show the numbers or density of mosquitoes within each area, and they don't indicate the risk of potential disease spread or risk of infection. Based on this map, states with potential *aedes aegypti* located within their borders are listed below, with the number of live births in each state in 2014.

Alabama	59,422
Arizona	86,887
Arkansas	38,511
California	502,879
Connecticut	36,285
Delaware	10,972
District of Columbia	9,509
Florida	219,991
Georgia	130,946
Hawaii	18,550
Indiana	84,080
Kansas	39,223
Kentucky	56,170
Louisiana	64,497
Maryland	73,921
Mississippi	38,736
Missouri	75,360
Nevada	35,861
New Jersey	103,305
New Mexico	26,052
New York	238,773
North Carolina	120,975
Ohio	139,467
Oklahoma	53,339
Pennsylvania	142,268
South Carolina	57,627
Tennessee	81,602
Texas	399,766
Utah	51,154
Virginia	103,300
West Virginia	20,301

Mr. COLE. Thank you very much.

I am advised that our good friend from Virginia has an appointment and is going to have to leave early, so Mr. Harris is graciously allowing me to skip down to recognize Mr. Rigell for his questions.

HOSPITAL ACQUIRED INFECTIONS

Mr. RIGELL. Mr. Chairman, thank you.

And, Dr. Harris, thank you very much. I appreciate it. I will try to reciprocate, if I can.

Dr. Frieden, thank you for being here and for your testimony to us today. I count it as one of the privileges of public service, certainly in the House of Representatives, to be able to interact with you and engage you on these matters.

I want to just call your attention to a remarkable company that I visited in my district. It may seem a bit self-serving to bring this up, but I left there just really wowed by what they are doing, optimistic about what they are doing, and inspired, because I think this is what we do as Americans. We innovate. We discover. We push the boundaries.

The company is called EOScu, and they have a preventative biocidal surface. It is the only synthetic hard surface that has been recognized by the EPA for health claims. It continually kills harmful bacteria within 2 hours of exposure.

So we are looking at these uses in a hospital environment, for the bed rails, for the sinks, anywhere.

My first question is just a general one. Are you familiar with the technology and maybe even perhaps the company, EOScu? And if not, just generally, the potential for this course of action, the potential that it represents?

Dr. FRIEDEN. I am not personally familiar. My staff may be. We are looking always for new technologies, particularly because hospital-borne infections, as you indicate, are severe problems.

[The information follows:]

REP. RIGELL: EOS SYNTHETIC ANTIBACTERIAL SURFACES

CDC is committed to protecting patients and healthcare personnel from infections, promoting safe, quality care across the continuum of care, and addressing the role of the environment to reduce the spread of antibiotic resistant bacteria. CDC is always looking for new evidence based-technologies that reduce the risk of transmission of pathogens from the environment to patients in healthcare settings. CDC was not specifically aware of EOS, but we are aware of several other surface technologies being developed to prevent healthcare-associated infections. CDC values engagement with industry including hearing about innovations that can improve patient safety. Each year, CDC hosts several Vendor Days which allow industry to visit CDC and discuss their healthcare products and technologies with CDC scientists. CDC will contact EOS with information about this opportunity.

If we look, for example, at C. difficile, there are 500,000 infections and 15,000 deaths per year in the U.S. And new technologies, including better ways to sanitize hospital environments, are important.

Mr. RIGELL. Well, I am glad that I have this opportunity just to bring this company to you and your staff's attention. Again, it might seem a bit self-serving, but as the chairman often points out, I am not seeking reelection. It is just an exceptional company doing really wonderful things. So I hope it is looked at by the CDC.

PROSTATE CANCER

I want to pivot to another organization that I just consider such a privilege to represent, and that is Hampton University and specifically Dr. Bill Harvey. He is going to be coming appear today, and the chairman was kind enough to agree to an appointment to meet with him.

I have come to know him and respect him over the years. He leads a historically Black university, Hampton University, which is a real treasure to us in the Hampton Roads southeast portion of Virginia. Several years ago, his leadership resulted in the formation of the Hampton proton therapy center.

One of the things that they are really focused on there, and not exclusively, but prostate cancer. It disproportionately affects African-American men. The numbers that I have seen, they are between 1.6 and 2.4 times more likely to be diagnosed with prostate cancer.

In the couple minutes I have here, I wanted to just ask your general assessment of that particular cancer, how it disproportionately strikes our fellow Americans in the African-American community, and the potential I believe—and I would like to understand your view—on what proton therapy represents for that.

Dr. FRIEDEN. Thank you very much. You are absolutely correct that prostate cancer is a serious problem and disproportionately affects African-Americans.

Unfortunately, the current state of our science on the prevention and treatment of prostate cancer is inadequate.

When objective groups have looked at this, there is no clear benefit for early screening or early detection. There is a fair amount of debate about that, and some groups believe that there is a benefit for early screening and early detection, but I think the weight of scientific evidence suggests that, unfortunately, that may not be the case.

That being said, it is critically important that more research is done on understanding the different types of prostate cancer and what therapies may make the most sense.

In our minds, I think we have a model of cancer. That model of cancer is: It is small. It grows. If it grows too big, it is too late.

That model works for certain skin cancers, for cervical cancer, for colon cancer. That model does not work for breast cancer and prostate cancer, which are very heterogeneous entities that work differently in different people, and for which research will be needed, but currently public health interventions are limited.

Mr. RIGELL. Well, I am encouraged just as a fellow American that there are good, hardworking Americans really cross the land, certainly in Virginia's Second Congressional District, who are pushing the envelope in these matters from a biocidal hard surface to the good work being done in proton therapy specifically at the proton center there related to Hampton University.

I thank Dr. Harris. I thank the chairman for the time. Thank you.

Mr. COLE. Thank you very much. We will next go to my good friend, the gentlelady from California.

LEAD POISIONING PREVENTION

Ms. ROYBAL-ALLARD. Thank you, Mr. Chairman.

Dr. Frieden, I would like to go back to the issue that was raised by Congresswoman DeLauro, and that is lead poisoning prevention.

This is an issue that impacts millions and millions of families in this country. I would like to use an example in my own district, because while the entire country is rightfully focused on that tragic lead poisoning of an entire community in Flint, Michigan, not many people know about the battery recycling plant in my 40th Congressional District that had been emitting lead, arsenic, and other dangerous pollutants for over 20 years.

When the Vernon, California, plant was officially closed in 2015, State officials revealed that the lead contamination extended as far as 1.7 miles from the plant and may have contaminated schools, parks, and as many as 10,000 homes.

Last week, the California Department of Toxic Substances Control reported that more than 99 percent of the roughly 1,000 properties tested so far have lead levels high enough to require cleanup.

Many experts in the public health community believe that Flint and Exide may represent the tip of an iceberg, and that children in many communities across the country are at risk of exposure to lead hazards from various sources.

Now I know that you know that lead is a poison that affects virtually every system in the body, and it can cause irreversible damage to the developing brain, the nervous system, fetuses and young children. Lead poisoning lowers IQs, limiting the opportunity for children to reach their full potential. It increases learning disabilities, attention disorder, and behavioral disorders. And lead-poisoned children are six times more likely to drop out of high school and are more likely to enter into the juvenile justice system.

The medical and special education expenses alone can equal $5,600 for each child with serious lead poisoning, and lead poisoning results in an average loss of lifetime earnings of $723,000 per child.

The reason I have outlined this is because this is the impact that we are seeing in the community that I represent that is impacted by this lead poisoning.

For that reason, I am particularly concerned about the lack of adequate funding for the CDC Healthy Homes and Lead Poisoning Prevention Program, which provides critical surveillance and monitoring of elevated blood lead levels and community education to prevent and mitigate childhood lead poisoning.

With the increased number of children who are now above the updated lead reference level of 5 micrograms per deciliter, what has the CDC done since 2013 to increase support to the States it funds? And do you believe that your budget request for $17,000,000 will be sufficient for CDC to provide critical surveillance in every State in the country?

Dr. FRIEDEN. Thank you very much.

Confronting and reversing and preventing lead poisoning has been a priority for CDC for a long time. In fact, as you may know, it was the NHANES survey of NCHS at CDC that identified lead as a huge problem and led to the elimination of lead from gasoline

as well as the elimination of lead from paint in this country, and that has resulted in a steady decrease in lead poisoning.

But this is a far from finished effort. There are still far too many children and far too many adults affected by lead poisoning.

As you know, there was a large reduction in the CDC lead poisoning prevention program several years ago. It was partially restored several years back. And both in terms of lead poisoning and larger environmental health tracking programs, we have a very strong program, the world's best environmental lab, terrific health professionals. We are not able currently to support all States in monitoring lead levels and intervening at the level of resources that we have.

Ms. ROYBAL-ALLARD. You are not able to?

Dr. FRIEDEN. No.

Ms. ROYBAL-ALLARD. And yet the fact remains that there are millions of homes and families who are exposed to this, probably in every State in this country.

Dr. FRIEDEN. That is correct.

Ms. ROYBAL-ALLARD. The Advisory Committee on Childhood Lead Poisoning Prevention provided scientific and technical advice to the CDC and HHS, but its charter expired in October 2013. In light of Flint, Exide, and other incidents, do you believe that a new charter should be established?

Dr. FRIEDEN. What we did at CDC was to involve our Board of Scientific Counselors of our National Center for Environmental Health, which is superbly led by Dr. Pat Breysse, to have a subcommittee on lead. We feel that is the appropriate way to manage it. That incorporates input from scientific experts and the community. It is a FACA operating under the FACA responsibilities and can address any issue related to lead and lead poisoning.

Mr. COLE. The gentlelady's time is up.

Ms. ROYBAL-ALLARD. Okay. I apologize.

Mr. COLE. We will come back.

Ms. ROYBAL-ALLARD. Okay.

Mr. COLE. With that, my good friend from Maryland, Dr. Harris, is recognized.

SODIUM

Mr. HARRIS. Thank you very much.

I have a couple different areas I am going to touch on.

First, in regard to the sodium dietary guidelines, my understanding is that the CDC may be engaging in a systematic review of the scientific literature regarding sodium intake in advance of developing a new DRI.

My question is, as you look at the systematic review, is this going to be a review of all-cause mortality or is the predominance going to be using blood pressure as some kind of proxy for things that happen, with particular reference to the study that shows that in some people actually restricting sodium leads to an increase in all-cause mortality?

Dr. FRIEDEN. The systematic review will look systematically at all dated related to health.

Mr. HARRIS. So all-cause mortality will be considered in it, I take it?

Dr. FRIEDEN. I believe so.

COMMUNITY PREVENTIVE SERVICES TASK FORCE

Mr. HARRIS. Okay. Let me ask you a question about something that has come up with some wording that was in the omnibus bill, and that has to do with the Community Preventive Services Task Force, which I think, if I am correct—I think it is correct—that the language in the report stated quite clearly the committee does not provide support for the community guide or the operations the Community Prevention Services Task Force.

Can you affirm that since no funds were provided through the Prevention and Public Health Fund, because that is where we restricted it, use from that fund, that the task force is not being funded in this fiscal year?

Dr. FRIEDEN. We would have to get back to you on the details of that. The task force is an authorized activity by Congress and has support not only through the prevention fund.

Mr. HARRIS. So you may be using funds from other areas to fund that, despite Congress' intent not to provide support for it.

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

[The information follows:]

Rep. Harris Inquiry: Community Guide funding

Prior to FY 2014, PPHF funding was allocated by the Secretary of Health and Human Services, with some funds being allocated to the Community Guide activity. Starting in FY 2014, Congress directed the transfer of PPHF for specific activities, and no longer included the Community Guide in those transfers. CDC continue to support Congressionally mandated activities related to the Task Force on Community Preventive Services through our Public Health and Scientific Services budget authority.

Community Guide Funding History: Fiscal Years 2009-2015

Fiscal Year	PHSS Budget Authority (BA)	Prevention and Public Health Fund (PPHF)*	Funds received from other CDC programs and Federal Agencies for specific activities	Total Funding
FY 2015	$4,144,000	$0	$1,558,000	$5,702,000
FY 2014	$4,030,000	$0	$1,095,000	$5,125,000
FY 2013	$1,465,000	$7,400,000	$68,800	$8,933,800
FY 2012	$800,000	$10,000,000	$200,000	$11,000,000
FY 2011	$1,400,000	$7,000,000	$0	$8,400,000
FY 2010	$1,754,000	$5,000,000	$660,000	$7,414,000
FY 2009	$1,773,000	N/A	$860,000	$2,633,000

* Starting in FY 2014, PPHF Funds were directed by Congress, and no PPHF fund were directed to the Community Guide.

Mr. HARRIS. Okay. Because that raises a concern. If there is this money sloshing around CDC that can be used for something that Congress actually took a specific position against, I hope that it can slosh around to help you with Zika.

STRATEGIC NATIONAL STOCKPILE

With regards to the biodefense community, I have to ask a question about coordination between BARDA and then, of course, once things reach approval stage, things kind of get shifted for stockpiling to CDC. Is the coordination adequate to make sure that things do not get dropped in the pipeline, things that BARDA has expended a fair amount of effort in developing, actually get acquired at some point?

Dr. FRIEDEN. I think we have very good coordination with BARDA. We have had a very positive relationship along a whole host of activities.

Just to give you an example, when we were working on the vaccine trials for Ebola in West Africa, BARDA staff actually traveled to West Africa and helped us with the implementation of those trials. So there is very good coordination between ourselves and BARDA.

I think the bigger challenge is that there are a great number of needs and limited funds.

Mr. HARRIS. Sure. With regards to the SNS, because the SNS, the role kind of expanded from this idea where it is going to help us stockpile for bioweapons and now it is kind of everything, natural disaster response, things like that, providing medical things.

Is that going to be a problem in terms of having adequate resources to do what it was initially established to do, which is to stockpile against bioweapons?

Dr. FRIEDEN. I think really, if I step back, our commitment is to use every dollar that is entrusted to us to protect Americans as effectively as possible.

With the SNS, we look at an all-hazards approach: What are the things most likely to harm Americans? And what can we do that has the most impact at mitigating those harms? And how can we ensure that we are not just putting stuff in a warehouse somewhere, but that in the event of an emergency, they would actually be able to be deployed and used to protect Americans?

That is, in broad strokes, our approach to the SNS.

Mr. HARRIS. But it appears to me that perhaps a shift has occurred from where it is stockpiling specific therapeutic measures to stockpiling general medical supplies to——

Dr. FRIEDEN. I do not think that is the case.

Mr. HARRIS. Then what was deployed, for instance, after Superstorm Sandy, because things were deployed from SNS? And that was not an infectious disease. That was not by a bio-response.

Dr. FRIEDEN. There are some Federal medical units that can be provided in a disaster that would be basically the framework for responding to an emergency. We have also looked at things like respirators, because when we do models of what could be a worst-case scenario, there is likely to be a shortage of ventilators that could be critically important.

[The information follows:]

Rep. Harris: Is SNS expanding beyond its mission of preparedness for bioterrorism to an all hazards approach? Is this consistent with the initial intent of SNS or current authorities?

In 1998, Congress appropriated funds for the CDC to acquire a pharmaceutical and vaccine stockpile to counter potential biological and chemical threats that could affect large numbers of persons in the civilian population. The program was originally called the National Pharmaceutical Stockpile program, but on March 1, 2003, became the Strategic National Stockpile (SNS) program and now includes not just drugs but medical supplies and medical equipment required to protect America's public health and safety from multiple hazards (terrorist attack, earthquake, emerging infectious disease threats such as flu, Ebola, Zika). As defined in 42 U.S. Code 247d–6b, the Secretary is "directed to maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency."

Mr. HARRIS. I understand the ventilators. Again, I am concerned that the initial intent just has been expanded to this disaster mitigation.

I yield back. Thank you.

Mr. COLE. Thank you very much.

I will now go to my good friend from Pennsylvania for whatever questions he cares to pose.

ZIKA

Mr. FATTAH. Thank you very much, Mr. Chairman. And thank you, Doctor, for all the work that you are doing.

Obviously, there is a lot that we can talk about that is very beneficial, but usually when we are talking to the CDC, we are talking about more challenging circumstances, so I want to return to the Zika virus.

This is a mosquito, the one that is transporting this virus, that we have seen before in the Philadelphia area, many, many years ago, bringing an epidemic to our city. So we know that it can do so very effectively.

I know there is first a concern about young women and pregnancy. I have seen reports that there could even be other challenges for people who do not fall into that category. So I wonder if you could just spend a minute and talk to the committee about what we think the health consequences are. And then I want to ask a question about what more we could be doing.

Dr. FRIEDEN. Thank you.

With regard to Zika, we are literally learning more every day. It is a mosquito-borne virus spread by primarily two different mosquitoes that are present in the U.S.

From the best of what we understand, for the vast majority of people, it has few symptoms or none at all. When it does cause illness, it tends to be for about a week with rash, fever, red eyes, joint pain, and then it resolves.

But we have seen two consequences that are concerning.

One is Guillain-Barre syndrome. That is a form of paralysis that is usually temporary. It follows many different types of infections, so that is not particularly unprecedented. We have seen this after influenza, after Campylobacter, and intestinal infection, and after

others. We anticipate that this will be confirmed as a post-infectious complication of Zika.

What is really unprecedented is the birth defects that we are seeing in Brazil now being reported in Colombia and Panama, that we saw in one woman who lives in Hawaii, who traveled to Brazil during the first trimester of her pregnancy.

We do not yet know many things. We do not know what proportion of women who are infected with Zika will deliver a Zika-affected child. We do not know what proportion of infants who do not have microcephaly will have a severe neurological complication.

But CDC's laboratories have actually identified the Zika virus in the brain tissue of infants who died in the first 24 hours of life with severe microcephaly. This indicates to us that it is what is called a neurotrophic virus. It targets the brain.

We are very concerned that, in addition to microcephaly, there may be many other consequences of Zika for infants who are infected.

In addition, there was a recent article in the New England Journal that suggested that it was not just the first trimester, which we would think might be the most susceptible. But in fact, even in the second and third trimester, there were some severe complications of the Zika infection.

Mr. FATTAH. So now the game plan is to detect this in a variety of ways, all the way up to and including developing male mosquitoes. Talk to us about us line of attack here.

Dr. FRIEDEN. In public health, we use basically an approach of find it, stop it, prevent it. So those are the three ways that we work.

We find it by doing better diagnostics, and CDC labs have worked around the clock to get test materials out around the country, around the world, so that we know what is happening.

Stop it. Stopping Zika is not easy. It spreads in the same way that dengue spreads. If you look at how dengue has spread in many communities, it is explosive and very difficult to stop. Efforts to mitigate dengue have been hard.

So it is a matter of mosquito control, and the four aspects of that are outdoor mosquitoes, indoor mosquitoes, larval or baby mosquitoes, and adult mosquitoes. For each of those four areas, there are things that we can do. One of CDC's roles is to figure out what works best.

It would be States and localities that are implementing mosquito control activity, but what we can do is identify best practices and help to spread those. In addition, in places like Puerto Rico where Zika is likely to spread widely, we want to ensure that if a woman decides to delay pregnancy, that access to voluntary effective contraception is available to her.

Mr. FATTAH. Thank you, Mr. Chairman.

Mr. COLE. Thank you very much.

We now go to the gentlelady from Alabama for whatever questions she cares to pose.

Ms. ROBY. Thank you, Mr. Chairman.

And thank you, Dr. Frieden. It is good to see you again. I know oftentimes in our visits over the years, we have talked about my children, and I am very blessed today to have Margaret Roby—you cannot see her behind the chair—with me. But that has certainly been the inspiration for a lot of our discussions, my two children. So again, I appreciate your willingness to be here.

I am sure the chairman of the full committee touched on this, but all of us on this committee share a very deep concern about the opioid epidemic raging across our country.

I have just recently become even more aware. I very recently watched the video that was put out by DEA and the FBI, *Chasing the Dragon*, which really just brought it home for me to see not only the mother of a child who lost her life but also a mother who lost everything in her life because of her own addiction.

So it has really hit home, having not walked through that with a family member or anybody close with me, which I think you have to do really deeply appreciate it. But that is a very powerful video, and I encourage everybody on the committee to watch that. It is easy to find.

I am encouraged as well by the recent CDC guidelines for prescribing opioids for chronic pain. I hope these new guidelines will help limit access of individuals who try to game the system to get ahold of these prescription drugs.

While this development will attempt to decrease the overuse and abuse of opioids over time, we have to focus in on the impact of overdoses occurring every day. I was stunned to learn that, in 2014, there were 47,000 overdose deaths in the U.S.

For years, organizations have offered opioid overdose prevention services with training and kits containing naloxone, a drug used to treat a narcotic overdose in emergency settings.

So my question is, could you began by addressing the possible safety concerns of providing naloxone to untrained individuals? And how are fellow drug users expected to help someone suffering from cardiac arrest, which I understand is a very real potential byproduct of this drug as it is being administered as a result of reaction to the drug? And what steps are CDC, in collaboration with other agencies such as DEA and FDA, taking to address any concerns about nonmedical personnel administering naloxone?

I know from the testimony from the administrator of DEA that all of their personnel are trained not just how to administer the drug, but also how to address any issues as a reaction to the drug.

So if you could just start talking about that, that would be great.

Dr. FRIEDEN. Thank you.

Naloxone is a very specific reversal drug, so it reverses an opiate effect on the human body. I have used it in patients I have cared for. It has a dramatic impact on reversing overdose.

Overdose is life-threatening. Someone stops breathing. So every moment matters.

Communities around the U.S. have tried different things, and we encourage communities to try things and rigorously evaluate them.

One thing that has been expanding is naloxone access in even ambulances, because not all ambulances have it. So that should be universal, in my personal view.

The FDA has been very helpful in approving a new formulation of naloxone that is intranasal, so it does not require injection. That makes it easier for a layperson to provide.

Training, as you say, is very important. We have seen communities around the U.S. provide naloxone. There are now problems with the cost of naloxone, and there are efforts being used to reduce the cost.

But they report a large number of reversals, and the recommendation is you just do not give naloxone. You give naloxone and call 911 at the same time, because the person needs emergency care. But that may buy you the 5 or 10 minutes that may make a difference between life and death or between permanent brain damage and not permanent brain damage.

So I think the optimal use of naloxone is something that communities need to work out. There are a complex set of issues, including Good Samaritan laws and issues of reporting of drug paraphernalia and law enforcement. But as communities work through those consistent with their values and their service availability, it has a role, I believe, in reducing the risk of fatal overdose.

Ms. ROBY. Are there more specific things that CDC is doing to work with these community organizations?

My time is running short, so maybe you can get back to me.

I think all of us have a shared concern about how we, as Members of Congress, could help people at the local and State level have access to not just prevention and how to deal with this opioid epidemic, but also tools and solutions such as this that can be utilized in the moment that someone is suffering from that.

Dr. FRIEDEN. Yes. We will get back to you. We work through States. With the support from Congress, we are able to support all States in opioid response. One component of that is naloxone access.

[The information follows:]

Rep. Roby: How does CDC work with states/communities on naloxone?
Through CDC's Prevention for States program, several awardees including Arizona, New Mexico, North Carolina, and Rhode Island, are using funds to evaluate the impact of recently passed naloxone access legislation. Other states are planning to use a portion of their funds to educate the public and providers on naloxone use and administration in cases of opioid overdose. Specific examples include the following:

- Kentucky is planning to enhance prevention education of drug overdose risk, appropriate prescribing, and naloxone use for prescribers and law enforcement in high-drug overdose counties.
- Oregon is planning to use EMS data to track Narcan/naloxone EMS response and administration as a potential means of evaluating local opioid overdose prevention efforts.
- Eight states (Ohio, North Carolina, Rhode Island, Massachusetts, Minnesota, Kentucky, Oklahoma, and Washington) have conducted activities related to Naloxone through CDC's Core Violence and Injury Prevention Program (Core VIPP). Activities from the states include: conducting surveillance, distributing Naloxone kits, increasing access to Naloxone, and educating health care providers, law enforcement, and the public about Naloxone. Training on naloxone focuses on 1) how to recognize an overdose (what to look for; 2) how to provide rescue breathing; 3) how to administer naloxone; and 4) how to monitor the patient post naloxone-administration, based on SAMHSA's toolkit: http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742

Specific state examples highlighting Core VIPP program activities include:

Ohio: The program is working in collaboration with Project DAWN (Deaths Avoided with Naloxone) programs throughout the state. These are naloxone distribution programs that provide training, educational materials and doses of naloxone to any individual requesting assistance. The VIPP program has also helped educate and inform changes in the Medicaid system to activate codes for reimbursement and eliminate pre-authorization for Naloxone, as well as providing education to inform policies and regulations allowing third party prescribing of Naloxone and standing orders (a physicians' orders that can be exercised by other than health care workers).

North Carolina: The program conducted a study of overdose deaths in North Carolina and found that over 60% of opioid overdose deaths occur before emergency medical services arrive. This information was used to inform policies and programs to increase access to Naloxone. Community access to naloxone has increasingly become a standard overdose prevention strategy; and, NC now has the second largest distribution in the country. Under prescriptive authority of the program's Medical Director, staff have distributed over 11,000 overdose rescue kits resulting in over 1,236 reported overdose reversals (lives saved) as of October 2015.

Rhode Island: The program has focused on expanding access to Naloxone and providing training to health care providers, law enforcement and school nurses. The program has also promoted Naloxone use and distribution to high-risk patients in hospital Emergency Departments and by law enforcement agencies. They have been instrumental in informing regulations requiring all schools to have Naloxone on site, and informing all state-run treatment facilities of the requirement to offer Naloxone to patients upon release.

West Virginia: The West Virginia University Injury Control Research Center (WVU ICRC), one of CDC's Injury Control Research Centers, has also made naloxone distribution a program focus. The WVU ICRC conducted research and a pilot study on take-home naloxone distribution programs to determine if naloxone distribution could be an effective approach to overdose prevention in a rural setting. WVU ICRC is currently conducting analysis of the program.

CDC is also conducting research in the area of naloxone. Recently, two articles related to naloxone have been published. One of these articles found an under-use of naloxone in rural communities as naloxone is less often administered by EMT-basics, who are more common in rural areas. The other article looked into EMS' ability to recognize drug overdose and found that patients without clear signs of illicit drug use were less likely to receive naloxone in EMS resuscitation attempts. CDC is also partnering with SAMHSA to evaluate the upcoming SAMHSA naloxone grant program.

CDC, along with other federal partners, has committed funding toward an AHRQ systematic review around the treatment of suspected opioid overdose patients in the prehospital setting. CDC hopes this review will serve to provide a basis for evidence-based guidelines to inform naloxone administration by emergency medical personnel and increase naloxone use in prehospital settings.

Ms. ROBY. Okay, great. Thank you so much.

Thank you, Mr. Chairman. I yield back.

Mr. COLE. Thank you very much.

I have been advised that your schedule is a little flexible. If that is the case, what we would like to do, since we missed so much time because of votes, is give every member about 3 more minutes to ask any additional questions they might have, so if you can indulge us, Doctor?

Dr. FRIEDEN. Sure.

Mr. COLE. Very good. Then I will go first.

I am going to ask you a series of three interrelated questions, if I may.

CDC BUDGET

First, obviously, we increased your budget last year by 4 percent, which was about double, if I recall, of the administration request, because we thought that was important, and all of us on a bipartisan basis appreciate the good work. This year, the budget is being reduced by 3 percent.

So I am going to ask you, one, can you give us the rationale for the reduction?

Two, I know you are working, as NIH has been working, on a strategic plan to sort of prioritize your work, so could you give us your top three priorities looking forward in the context of this budget?

And three, I am going to ask you a happier question, which is, if we found extra money, what would you do with it, beyond what is in your budget?

Dr. FRIEDEN. Thank you very much, Mr. Chairman. And thank you so much for your support in the 2016 budget.

As with any budget proposal, the administration had difficult choices to make. In fiscal year 2016, the House was very supportive of CDC, and I hope to see that again in the end with the budget.

CDC is a best buy and investing in public health saves both lives and money.

In terms of a strategic plan or top three:

Antibiotic resistance, we have to continue to make progress. The bugs are dividing every minute, and we need to be able to try to get ahead of this very concerning trend.

The second is prescription drug overdose. We really appreciate the support. As just mentioned, this allows us to support every State in the country or offer support to every State in the country. And we want to continue to extend that and improve prescribing patterns. And our support for Indian country we would really like to expand.

If we had additional resources, well, there is a lot that we would like to do. The way I look at public health is I break it into four quadrants, basically. There are the infectious diseases in the U.S. There are the infectious diseases globally. There are the chronic diseases in the U.S., and the chronic diseases and injuries globally. So those are the four areas.

In each of those areas, there are best buys. There are things where we can save many, many lives through the efforts that we implement.

I think we indicated in antibiotic resistance, for example, that $264,000,000 a year over 5 years would allow us to save $7.7 billion, prevent more than 30,000 deaths and 600,000 hospitalizations. So we would like to fully implement that program, if resources were available.

Furthermore, on issues of preventing cardiovascular disease, we have shown that some of the programs that we have are remarkably cost-effective. We can save a life for less than $3,000. There are not a lot of programs that can do that. And yet, they are not fully funded for whole-year activities. If we are able to do that, we could save many more lives and much more money.

I think also our work on health-care-associated infections is an unsung success story, but a very partial one. We continue to lose tens of thousands of Americans to infections that they pick up in hospitals each year. We would like to work very closely with States and health care facilities to drastically reduce health-care-associated infections.

Mr. COLE. Thank you. I noticed your very capable staff was shoving answers up there when the idea of additional money came up. So I look forward, offline, to talking to you about those.

Dr. FRIEDEN. And I forgot to mention our buildings, which are in desperate need of repair.

Mr. COLE. With that, we will go to the gentlelady from Connecticut.

CHRONIC DISEASES

Ms. DELAURO. Thank you, Mr. Chairman.

Let me pick up on this chronic disease prevention and antibiotic-resistant drugs.

Eighty-six percent of annual medical costs in the U.S., 70 percent of deaths, can be attributed to chronic disease. A hundred million Americans live with one or more chronic conditions.

We had a $66 billion increase for defense and nondefense, and we actually cut funding for chronic disease prevention at CDC by $22,000,000, or about 2 percent. Shortsighted, in my view.

Talk about the threat of chronic disease, what will happen to health care spending, if we fail to address chronic disease, which is largely preventable.

And I would like to get to antibiotic-resistant question as well.

Dr. FRIEDEN. Chronic diseases are largely preventable with current technologies. I mentioned the Million Hearts campaign, hypertension control. Our Tips from Former Smokers campaign is truly a best buy. It is saving tens of thousands of lives a year. Our tobacco control program is helping to drive down tobacco use rates in kids and others. And our injury prevention control program also has been a real success story.

We should be able to invest in programs like prevention of senior falls, document what works and then scale that up. Those are extraordinarily not only expensive, but they undermine independence of seniors all too often.

So this is a crucial area where we can protect Americans from threats.

Ms. DELAURO. What I will do is follow up with you on where are one or two places which, if we could increase funding in terms of chronic diseases, what would make sense.

ANTIBIOTIC RESISTANCE

Antibiotic-resistant bacteria, we know all the dangers on this. I just want to ask you about your work with the USDA.

Antibiotic sales for food animal production are significant and increasing. They account for 70 percent of total medically important antibiotic sales by volume, a 23 percent rise since 2009. Animal feed and the development of bacteria that cannot be killed now by antibiotics, what are we doing in this area? What kind of collaboration do you have with USDA, so that we can look at scaling back in this effort?

Dr. FRIEDEN. We work closely with both USDA and FDA. We have a weekly conference where we review clusters that may reflect outbreaks of infectious disease.

One of the things that does concern us is that we are seeing a continuing increase in the volume of antibiotics used in animal husbandry.

We had a summit at the White House last year and had more than 150 commitments from organizations to do a wide range of things, including reduce use in animals. I think one of the things that is crucially important is to track the actual numbers—what gets measured can get managed—and see if that reduction is occurring.

Ms. DELAURO. Do we have oversight capability, knowing what they have done?

Dr. FRIEDEN. I cannot answer that question. We would have to get back to you.

[The information follows:]

REP. DELAURO: WHAT OVERSIGHT DO WE HAVE OVER ANTIBIOTIC USE IN AGRICULTURE?

CDC recognizes the importance of collection of antibiotic use data in agriculture. Just as in human medicine, good data about antibiotic use and resistance can help us identify areas of concern or improvement. CDC strongly supports the important work of FDA, USDA, and others to improve antibiotic stewardship in veterinary medicine and agriculture. FDA's Guidance for Industry #209 and #213 are important steps, and CDC applauds the actions that veterinary pharmaceutical manufacturers and food producers are taking to effectively implement these changes that end labeling of antibiotics for growth promotion and bring the remaining uses of antibiotic under veterinary oversight. Recognizing that minimal data on antibiotic use in animal agriculture currently exist, CDC supports FDA's recently released funding opportunity to support antibiotic use data collection in animal agriculture (http://grants.nih.gov/Grants/Guide/rfa-files/RFA-FD–16–046.html).

In addition, CDC is participating in an interagency working group with FDA and USDA to evaluate approaches for measuring antibiotic use in food animals and how use relates to antibiotic resistance. Tracking the use of antibiotics is critical to know how we are doing with stewardship. Good information about where, why, and how antibiotics are used is the basic information needed to know when stewardship is going well and when it can be strengthened.

CDC has led antibiotic stewardship efforts in human health that could serve as a model for antibiotic stewardship in animal health. CDC has also shared information with FDA and USDA about CDC's core elements for antibiotic stewardship, antibiotic use and resistance data collection in human health, and partnerships to promote antibiotic stewardship. CDC partners with veterinary and agricultural associations, veterinary schools, and food safety experts, for example, working through the National Institute for Animal Agriculture to discuss shared interest in reducing an-

tibiotic use and shared CDC's efforts to reduce use in clinical settings and measure antibiotic use.

Ms. DELAURO. Okay. Thank you.

Mr. Chairman, if I could put this into the record, it is a Los Angeles Times article that talks about the Zika virus. It raises more questions and answers for pregnant women.

Mr. COLE. Without objection.

[The information follows:]

Motherhood in the time of Zika

By Alexandra Zavis and Katie Falkenberg

MARCH 22, 2016, 3:00 AM

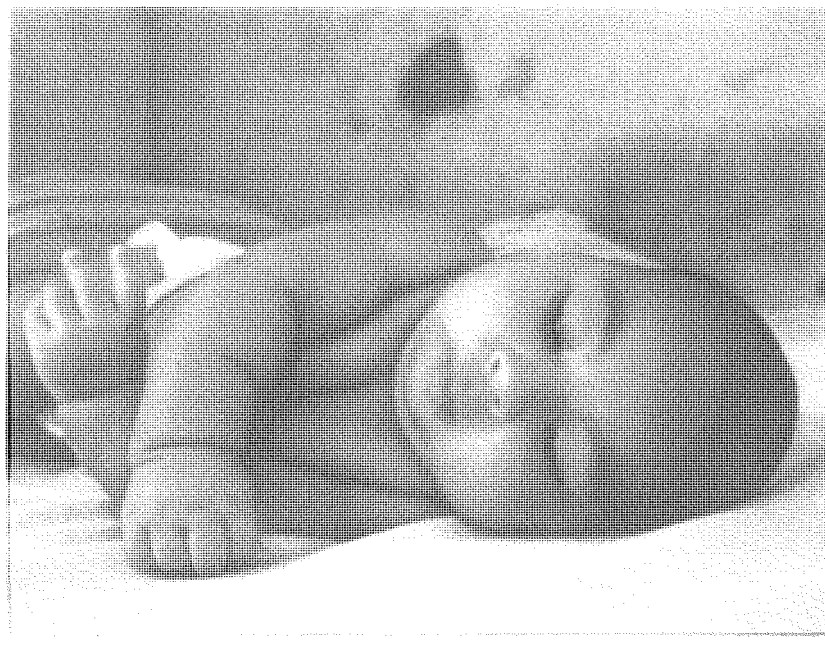
As the Zika virus has spread at an alarming rate across the Americas, new mothers there are grappling with the fear that their children could have a serious birth defect. The number of babies born with microcephaly -- an underdeveloped brain, leading to an -- has spiked since the virus came to Brazil. Though the condition hasn't been definitively proven to be caused by the Zika, pregnant women and mothers of newborn babies aren't taking any chances. Los Angeles Times correspondents Alexandra Zavis and Katie Falkenberg met several of them on assignment in Brazil. Here are some snapshots from their travels.

Maria and Kalissandra wait for their babies' physiotherapy appointments.

(Katie Falkenberg / Los Angeles Times)

Motherhood in the time of Zika - LA Times

Emanuel was born with microcephaly. His mother thinks she had Zika early in her pregnancy.

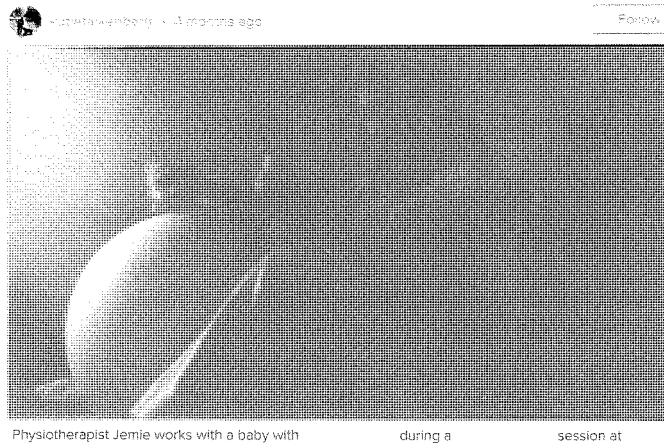


(Katie Falkenberg / Los Angeles Times)

Motherhood in the time of Zika - LA Times

Mothers line up to get therapy for babies with microcephaly at Dom Pedro I Hospital in Campina Grande.

Alexandre Davis / Los Angeles Times



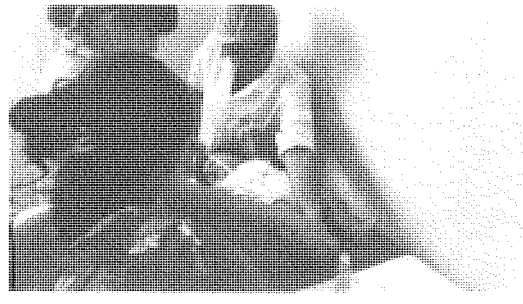
Physiotherapist Jemie works with a baby with during a session at Hospital Dom Pedro I in Campina Grande.

The CDC is helping Brazil study the link between Zika and microcephaly. This baby's measurements were normal.

(Alexandre Zavos / Los Angeles Times)

Motherhood in the time of Zika - LA Times

Evening in Campina Grande.



Katie Falkenberg
@KatieFalkenberg

This baby, who does not have microcephaly, is a control in CDC & Brazil study about link b/t Zika & the birth defect

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Ms. DELAURO. Thank you.

Mr. COLE. Thank you.

The gentlelady from California, is recognized for 3 minutes.

NEURAL-TUBE DEFECTS

Ms. ROYBAL-ALLARD. Dr. Frieden, for many years, the Congressional Hispanic Caucus has been working with the March of Dimes and the American Academy of Pediatrics to get corn masa fortified with folic acid to reduce the elevated incidence of neural-tube defects, especially among Hispanics.

It looks like the FDA will soon approve a petition to allow this fortification, and hopefully it will result in a significant decrease in spina bifida and anencephaly in our communities.

Concerns have been raised, however, that recent recommendations by the USDA to prioritize the consumption of whole grains in the American diet and mandate 100 percent whole grains in the school meal programs could result in lowering the intake of fortified grains and reverse the progress that we have made reducing neural-tube defects.

The CDC has been a leader in research, tracking, and prevention of neural-tube defects for over 2 decades, and your folic acid education program can take much credit for the progress that we have made in raising awareness of the importance of dietary folic acid for all childbearing women, and lowering the incidence of these birth defects.

How does the natural folic acid in whole grains compare with the levels found in enriched products? And for women of childbearing age, what are your recommendations about the consumption of whole grains versus enriched grain products?

Dr. FRIEDEN. Well, Congresswoman, on the issue of corn masa flour, this is something that we have been deeply engaged with the company, with the March of Dimes, and with the FDA for more than 7 years.

Ms. ROYBAL-ALLARD. I was going to say, we have been working on it for years.

Dr. FRIEDEN. Yes. And we have been trying hard to move forward, so we look forward to FDA action on that.

On the issue of whole grains, I will have to get back to you with a detailed answer of what our recommendations are and what the analysis is of both fortified and unfortified.

[The information follows:]

REP. ROYBAL ALLARD: COMPARISON OF NATURAL FOLATE IN WHOLE GRAIN TO FORTIFIED GRAINS

The CDC recommendation remains that women capable of becoming pregnant should take 400 micrograms of synthetic folic acid daily, from fortified foods or supplements or a combination of the two, in addition to consuming food with natural folate from a varied diet.

Studies have shown that there are many health benefits associated with consuming whole grains. Because of those health benefits, CDC supports the Dietary Guidelines for Americans' recommendation that at least half of grain consumption be whole grains and we support USDA's rule that 100% of grains in school lunches should be whole grain-rich (at least 51% whole grain). Because of those health benefits, CDC supports the recommendation by the USDA to prioritize the consumption of whole grains in the American diet. Commercially prepared whole wheat bread has about one-fourth the dietary folate equivalents (unit used to combine and compare natural food folate and folic acid in foods) of enriched white bread. If dietary

patterns shift from enriched products to whole grain products, we would anticipate a reduction in folic acid intake.

Women can consume folic acid through both fortified foods and supplements. CDC recommends that women who choose to consume no or limited amounts of folic acid-fortified foods should be sure to consume a supplement containing folic acid before and during early pregnancy. This is consistent with the CDC and the Food and Nutrition Board of the National Academy of Sciences Institute of Medicine recommendation that to reduce their risk for an NTD-affected pregnancy, women capable of becoming pregnant should take 400 micrograms of synthetic folic acid daily, from fortified foods or supplements or a combination of the two, in addition to consuming food with natural folate from a varied diet.

The recommendation specifies the dosage of folic acid intake from supplements, because there are no studies of the amount of natural food folate intake needed to decrease NTD risk. Therefore, the recommendations rely on studies that show that folic acid supplements or fortification of 400 micrograms per day before and during early pregnancy reduces NTD risk.

Ms. ROYBAL-ALLARD. Okay, I appreciate that. Thank you.

Mr. COLE. And for the last round of questions, my good friend from Pennsylvania is recognized for 3 minutes.

ZIKA

Mr. FATTAH. I will try not to consume all 3 minutes.

You said there were going to be 30 States participating in the conference on the Zika virus. The other States are not participating because?

Dr. FRIEDEN. They do not have the mosquito that spreads it.

Mr. FATTAH. Okay. And there is no fear? You said there were two types of mosquitoes?

Dr. FRIEDEN. Yes. They do not have either.

Mr. FATTAH. All right, we are good.

Thank you, Mr. Chairman.

Mr. COLE. Thank you very much. That was quick.

Dr. Frieden, again, I want to thank you very much for your testimony. Thank you again for your terrific public service. We look forward to working with you and your staff as we go forward this year.

Again, I appreciate all the good work on behalf of the American people.

Mr. FATTAH. We are going to remember the buildings.

Ms. DELAURO. We will not forget you. Thank you.

Mr. COLE. With that in the record, we are adjourned.

Department of Labor, Health and Human Services and Education and Related Agencies
FY 2017 Budget Hearing for the Centers for Disease Control and Prevention
with Dr. Thomas Frieden
March 23, 2016
Questions for the Record – Chairman Cole

(1) CDC's work in Indian Country

The U.S. Public Health system was largely developed in the mid-20th Century before we saw the resurgence of Tribal sovereignty and self-determination. As independent, sovereign nations, Tribal governments do not operate within the state regulatory structure, and often must compete with their own state governments for resources. Tribes are regularly left out of statewide public health plans and federal funding decisions for public health programs.

I appreciate the CDC proposal to dedicate a $15 million funding line for Indian Country to expand the already supported chronic disease activities on a population that bears a disproportionate burden of death, disease, disability, and injury compared to other racial and ethnic groups in the U.S. It would increases the total CDC level of support for Native Americans to $156 million or about 2% of the total CDC program level. I know we agree on the need to build the public health infrastructure at the Tribal level.

A) In your professional opinion, is this a large enough level of support for Indian Country to address this burden?

Response: CDC recognizes the disproportionate burden of disease, disability, injury and death that exists in Indian Country. The FY 2017 President's Budget Request for $15 million expands upon CDC's current Good Health and Wellness in Indian Country program. This is a scalable program model that can be expanded to support additional tribes and tribal organizations, and to increase capacity at the tribal epidemiology centers and work with Urban Indian Health Centers.

B) What are CDC's specific plans to strengthen the public health infrastructure of Tribes to ensure they have the ability to operate independently to meet the needs of this population?

Response: CDC plans to strengthen the public health infrastructure of the tribes under the FY 2017 budget proposal through a multi-pronged approach that will provide resources and support directly to tribes, as well as to tribal organizations and tribal epidemiology centers that will serve tribes.

- CDC will continue to support Tribal Epidemiology Centers (TECs) currently being funded through the Good Health and Wellness in Indian Country program, as well as two additional TECs. TECs are public health authorities, as designated by the reauthorization of the Indian Health Care Improvement Act (IHCIA) in 2010. CDC support will increase their capacity to provide technical assistance to obtain area-and Tribe-specific data on health and disease, health behaviors and health status, and environmental factors such as access to healthy foods and physical activity opportunities.

- Through the initiative, eleven Tribal Organizations will continue to be funded to provide leadership, technical assistance, training, and resources to American Indian tribes and Alaskan Native villages within their Indian Health Service (IHS) Administrative Areas to build capacity

among tribes not directly funded to implement effective strategies. An additional four tribal organizations will be funded through the Initiative.

- Some tribes will also be directly funded to build their capacity and implement sustainable initiatives, with an additional 12 tribes being funded through the Initiative. CDC has expertise in developing, implementing, and evaluating programs that are focused in preventing or delaying the progression of chronic diseases and their associated risk factors and can support tribes to do this.

C) What are CDC's priorities relative to public health conditions in Indian Country over the next five years?

Response: CDC's priorities in Indian Country for the next five years are to more comprehensively address the leading causes of death and their associated risk factors, and further incorporate the culturally driven wellness practices that build resilience and strengthen social and emotional wellbeing to more effectively address chronic diseases, depression and mental health, suicide, substance use, and alcohol-related motor vehicle injuries. Another priority is to begin collaborating with Urban Indian Health Centers (UIHCs). The majority of American Indians and Alaska Natives live off of reservations, and collaborating with the UIHCs will help to broaden the reach of interventions to address the disproportionate burden of death, disease, disability, and injury in American Indians and Alaska Natives. These priorities are embedded in the FY 2017 Budget Initiative.

D) CDC leadership has acknowledged a need to build the public health infrastructure at the Tribal level. Under FY 2017 budget proposal, what is the CDC's plan to strengthen the public health infrastructure of Tribes so that they can fully and independently function under the auspices of their sovereignty and inherent public health authority?

Response: As noted in item B, CDC plans to strengthen the public health infrastructure of the tribes under the FY 2017 budget proposal through a multi-pronged approach that will provide resources and support directly to tribes, and to the tribal organizations and TECs that serve tribes.

(2) **Hepatitis C Treatment in Indian Country** According to the CDC's most recent surveillance report on hepatitis C, in 2013, Americans Indians and Alaska Natives (AI/ANs) were the population with the highest hepatitis C-related mortality rate at 12.2 deaths per 100,000 people.

A) The Veterans Administration got a large supplement to fund HCV treatment last year. What is CDC doing to support links to treatment for AI/ANs?

B) What outreach and educational efforts is CDC planning for AI/ANs with the proposed $5 million for viral hepatitis?

Response: The prevalence of HCV infection for American Indian/Alaskan Native (AI/AN) in the United States varies; incidence rates of newly diagnosed HCV infection are typically higher relative to non-indigenous people. For example, health officials estimate 6% of Cherokee Nation adult citizens are infected with hepatitis C virus (HCV); this prevalence is six times that of other Americans. In response, in October 2015 the Cherokee Nation launched The Path Towards Elimination of HCV project with technical assistance from CDC. This project is optimizing care and treatment and moving

toward eliminating HCV among American Indians in the Cherokee Nation Health System. CDC conceptualized the project, participated in the launch of the program, and is providing technical experts to guide the HCV testing program for persons seeking care in the Cherokee Nation health system. Next steps for CDC include working with the Cherokee Nation to develop a comprehensive hepatitis elimination plan that includes an expansion of the HCV testing and linkage to care activities currently underway joined by the community-based interventions necessary to stop HCV transmission. To date, the Cherokee Nation project is the only one of its kind in the United States.

CDC has also been working with the Indian Health Service to evaluate the implementation of CDC's recommendation for one-time screening of hepatitis C for persons born between 1945-1965. The results of the evaluation indicate that the IHS efforts to prompt HCV testing through provider education and the implementation of clinical decision tools and electronic medical records has resulted in a large increase in the number of American Indians who have been tested and are now aware of their infection status. CDC expects to publish the results of this evaluation in the very near future.

CDC has worked on other fronts as well. CDC developed a multicenter study to monitor the quality of HCV testing and linkage to care and treatment for HCV infected persons. CDC recruited the Alaska Native Tribal Health Consortium to be a part of that study. In collaboration with experts of the consortium, CDC routinely analyzes data that can be used for quality improvement of testing, care, and treatment of HCV infected Alaska Natives. In addition, certain CDC-supported State Viral Hepatitis Prevention Coordinators work with Indian Country to implement HCV screening at tribal health facilities.

Finally, CDC recently awarded funds to the University of New Mexico through the Reduce Hepatitis Infections by Treatment and Integrated Prevention Services (Hepatitis-TIPS) among Non-urban Young Persons Who Inject Drugs (CDC-RFA-PS14-004) FOA. UNM is a is a Minority Serving Institution for AI/AN. The overarching goal of this cooperative agreement is to use epidemiologic data on risk behaviors, drug use patterns, and injection networks to support the development and implementation of an integrated approach to providing a complete cascade of screening, diagnosis, care, treatment, and prevention of hepatitis C to young, non-urban persons who inject drugs (PWID). In addition to providing hepatitis C virus testing, awardees will provide testing for the presence of infections with hepatitis B virus and HIV.

With the proposed $5 million increase, CDC will support the development of up to two model projects for the elimination of HCV transmission and disease and related mortality throughout an entire state, tribal area, or local community. The model programs will identify strategies that can be employed by CDC to help other communities reach elimination goals for HCV. Outreach and educational efforts will be a key component of the model projects given the need to increase awareness and understanding about the benefits of hepatitis C prevention, care, and treatment, with a particular goal of increasing the identification of persons who are currently unaware that they are living with hepatitis C.

(3) Zika

On Feb 22 the Administration submitted a request for supplemental funding to address the Zika virus. I notice that you have multiple lines within CDC already dedicated to things like combatting vector borne diseases and emerging infectious disease. I understand the same mosquitoes that transmit Zika also transmit Dengue and other similar diseases that we are already working on.

How much of your budget base is being or can be used to target Zika by building on these efforts and programs?

Response: Where available, CDC is using funds currently available for immediate Zika response needs. CDC is currently supporting the Zika response through a variety of budgetary accounts, including Emerging and Zoonotic Infectious Disease, Global Health, Birth Defect and Developmental Disabilities, and Public Health Preparedness and Response. However, current funding will not support all efforts needed to respond to Zika, and we have used transfer and reprogramming authority to redirect funding appropriated for other purposes.

Without supplemental funding, HHS has already been forced to reprogram funding from essential programs, such as our emergency public health grant and strategic national stockpile program, to fund our most immediate needs, such as critical lab supplies, surge staffing to Puerto Rico, vector control in the U.S., disease surveillance and health investigations to protect pregnant women.

The reduction of SNS by $5.75 million will result in decreased acquisition of 20,000 vials of anthrax vaccine which would be used to treat and/or prophylax 67,000 individuals exposed to anthrax. Reimbursement will allow for purchase later in the fiscal year. The reduction of PHEP by $44.25 million will result in reduced preparedness awards to states and cities.

Without supplemental funding, HHS will have no easy choices in terms of trying to identify additional resources to fund Zika response efforts. As we enter the spring and summer, mosquito activity will increase and we expect the adverse health outcomes associated with Zika virus will become more acute, and thus the funding needs will become more urgent. But we cannot wait until the weather gets warmer to make sure states with known mosquito populations that transmit Zika have preparedness measures in place.

(4) Zika Virus and Tribal Communities

A) How is the CDC planning to work with Tribes that have international boundaries within their lands to inhibit crossings of those people that may be infected with Zika?

Response: CDC is concerned about both imported and locally acquired cases of Zika virus infection in the United States. With the recent outbreaks, the number of Zika virus disease cases among travelers visiting or returning to the United States will likely increase. Potential locally acquired cases are of greater concern to CDC because this means that local mosquitoes are infected and could further spread the virus to people. CDC is not able to predict how much Zika virus would spread in the United States.

There are no restrictions for travelers entering the United States who have contracted Zika virus. CDC is not conducting enhanced entry screening of arriving travelers for Zika at this time.

- Because most people who have Zika do not have symptoms, entry screening will not work to prevent imported cases. CDC and Customs and Border Protection are working together to assess the situation and determine necessary measures.
- CDC has routine steps to detect sick travelers entering the United States, including requirements for ships and airplanes arriving in the United States to report certain illnesses to CDC. State and territorial health departments routinely notify CDC when cases of Zika are detected in the United States.

CDC is committed to keeping Tribal communities informed about this outbreak as it evolves. CDC is engaged with Tribes through these major tribal Zika activities. This engagement includes information and dialogue related to cross-border Zika risks and issues. Cross-border issues, for example the possibility of importation of the virus due to cross-border travel, is built into all of the communication/engagement activities listed below.

- **February 2016:** CDC sent a Dear Tribal Leader letter on Zika to all federally recognized tribes in the U.S.

- **February 2016**: Shared Clinician Outreach and Communication Activity (COCA) Updated Interim Zika Virus Clinical Guidance & Recommendation conference call invitation to tribal partners (IHS, NIHB and AAIP) to further share with their members/constituents, thereby connecting more broadly with tribes and tribal serving entities.

- **March 2016**: The National Indian Health Board (NIHB) was added as an attendee to the Emergency Operations Center's (EOC's) weekly Zika Partner Check-in Call to represent tribes. This call gives NIHB the opportunity to raise issues of concern, including cross-border issues.

- **March 22, 2016**: CDC/NIHB/Association of American Indian Physicians (AAIP) hosted a tribal Zika briefing for NIHB and AAIP membership, tribal leaders, and partners. CDC provided subject matter experts for the call. Topics included vector issues, epidemiology/surveillance, pregnancy and birth defects, laboratory science, traveler and border health, and blood safety. Transmission issues, including those related to cross-border travel, were discussed.

Ongoing activities:

- CDC is working with NIHB to effectively utilize NIHB's cooperative agreement with CDC to communicate Zika messaging to tribal leaders, tribal public health authorities and their membership.
- CDC is disseminating Zika guidance and public health prevention messaging to the Tribal Advisory Committee Members and Delegates for distribution to other tribal leaders.
- CDC is coordinating Zika speaking engagements for various partners and tribal nations upon request.

B) Will Tribes receive funds from the requested emergency supplemental and the base programs to support Zika related activity?

Response: CDC is encouraging Tribes to work with their state and local health departments regarding specific public health needs for Zika related activities. Also, CDC is urging state and local health departments to conduct active outreach to Tribes.

(5) Diabetes, Heart Disease, & Stroke

This Committee has significantly increased the funding within the CDC's Chronic Disease Center for Heart Disease, Stroke, and Diabetes. In FY 2016 we provided over $350 million towards diabetes, heart disease, and stroke--an increase of $70 million. This includes the $10 million increase that doubled the National Diabetes Prevention Program.

Please explain how the increased FY 2016 funds for Heart Disease, Stroke, and Diabetes are being competitively awarded this year in a manner that targets the increase to those communities with the highest burden of disease?

Please provide a table breaking down how much of the new funds were used to support new awards as described in the Omnibus report language.

Response: CDC is currently using the FY 2016 additional funding appropriated for Heart Disease, Stroke and Diabetes to support closeout activities for the third and final year of the Partnerships to Improve Community Health (PICH) cooperative agreement, as recommended by Congress in the FY 2016 Omnibus Report.

CDC is using the additional $10 million appropriated for the National Diabetes Prevention Program in FY 2016 to continue to expand and scale up the National DPP to reach those at greatest risk. Activities include:

- Extending our investment in the six national organizations participating in Preventing Type 2 Diabetes among People at High Risk for an additional year to further expand program delivery and work with employers and insurers toward sustainable funding/coverage for the program.
- Exploring messaging and partnership opportunities with state medical societies to increase physician screening, testing, and referral of people with prediabetes to CDC-recognized lifestyle change programs.
- Developing an initial suite of training and technical assistance materials (tools, training, and online resources) to support the needs of CDC-recognized program delivery organizations and grantees by enabling CDC to reach a larger audience than is currently possible through individualized technical assistance.
- Conducting market research to inform the development of a National DPP Customer Service Center and a marketing framework to provide strategic direction for National DPP outreach to audiences at high risk for developing diabetes.

(6) Intentional Injury Prevention – Suicide and Domestic Violence

1. AI/AN children and communities grapple with complex behavioral health issues at higher rates than any other population. Domestic and intimate partner violence also has a disproportionately large impact on AI/AN communities. According to the CDC, 45.9 percent of AI/AN woman have experienced intimate partner violence – the highest rate of any race or ethnicity in the U.S. Both suicide and domestic violence are key issues in Tribal communities.

   A) How much is CDC funding on intentional injury prevention programs for AI/ANs?

Response: CDC has a Cooperative Agreement for $30,000 working with the Association for American Indian Physicians to develop and tailor Adverse Childhood Experiences prevention messages for use in AI/AN communities.

CDC has released Funding Opportunity Announcements (FOA) for which tribal governments are eligible and could conduct violence prevention activities. Most recently, an FOA for the Core State Violence and Injury Prevention Program (Core VIPP) was released. The FOA closed on April 8, 2016.

   B) Specifically, what activities is CDC's doing with respect to suicide and domestic violence prevention in Indian Country?

Response: CDC funds state domestic violence coalitions through the DELTA FOCUS program. Some of the DELTA FOCUS grantees are working with AI/AN populations. For example, the Alaska DELTA FOCUS program has adapted several programs for an Alaska Native population to prevent intimate partner violence (e.g., Girls on the Run, Coaching Boys Into Men). Alaska DELTA FOCUS has also worked with school districts in Sitka to provide opportunities for youth to participate in educational opportunities that challenge them, honor the cultural heritage and the resilience of the Native people, and build protective factors to prevent intimate partner violence for Native Youth.

In the area of suicide prevention, CDC does not directly fund tribes but hosts quarterly calls with the Tribal Epidemiology Centers (TECs)to discuss suicide prevention and other injury related topics such as upcoming conferences, projects, research, and funding opportunities. In the FY 2017 President's budget, CDC proposed an expansion of its Good Health and Wellness in Indian Country Initiative that funds tribes, tribal organizations, and TECs to prevent diabetes, heart disease and stroke, and associated risk factors such as obesity and commercial tobacco use. The additional $15 million requested would support CDC to more comprehensively address not only the burden of chronic disease among this population, but depression and mental health, suicide, substance use, and alcohol-related motor vehicle injuries as well.

(7) Valley Fever Randomized Controlled Trial (RCT):

We appreciate the continued movement on the Valley Fever RCT. Please provide an update and timeline of the RCT with specific actions to be taken in the next six months on participant enrollment, and how CDC and NIH are coordinating on the research.

Response: CDC continues to closely partner with the National Institute of Allergy and Infectious Disease (NIAID) on Valley Fever. Staff continue to prepare for the expected initiation in FY 2016 of a randomized controlled trial (RCT) to address key unanswered questions regarding treatment of the

initial infection of Valley Fever. Updated information on CDC and NIAID's collaborative work on the Valley Fever RCT can be found in NIH's FY 2017
Significant Items.

During the formative phase of the Valley Fever Randomized Control Trial (RCT), CDC provided NIH with significant input on the study protocol. NIH holds monthly calls with CDC to provide updates on the current status of RCT.

As part of CDC's ongoing work with Valley Fever, CDC continues to work with partners in California, Arizona and many other states to increase healthcare provider and public awareness about Valley Fever and to track epidemiologic trends. In January 2016, CDC released a free Medscape Continuing Medical Education (CME) course for primary care doctors and nurses to help them be able to identify risk factors for Valley fever, recognize the signs and symptoms, and identify strategies for diagnosis, and management of Valley fever.

(8) Cancer Screenings in AI/AN Communities

The screening programs for Breast and Cervical Cancer as well as Colorectal Cancer were cut in this budget proposal since the Affordable Care Act (ACA) includes cancer screening coverage. However, Tribal communities do not access these ACA benefits in the same numbers as other populations because of the federal trust responsibility for healthcare to AI/ANs. In light of the proposed reduction – what is CDC's plan to support Tribal communities to ensure access to the appropriate cancer screenings?

Response: CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provides access to breast and cervical cancer screening services to underserved women in all 50 states, the District of Columbia, 5 U.S. territories, and 11 tribal organizations. Historically, the program was mandated to use the majority of its funding to pay for breast and cervical cancer screening services for low-income women who are uninsured or underinsured. The Affordable Care Act is increasing the availability of insurance coverage with no cost sharing for breast, cervical and colorectal cancer screenings. However, increased insurance coverage alone does not guarantee increased screening rates. Even with adequate health insurance, many people still face substantial barriers to obtaining cancer screenings such as geographic isolation, limited health literacy or self-efficacy, lack of provider recommendation, inconvenient times to access services, and language barriers. These barriers to screening exist for all groups (insured and uninsured), but are particularly prevalent among lower income or otherwise disparate populations who have had little or no access to the health care system previously.

In 2015, Congress provided greater flexibility to the NBCCEDP by allowing grantees to spend a greater percentage of funding on public health activities and evidence-based interventions to help people overcome barriers to screening. For example, both the NBCCEDP and the Colorectal Cancer Control Program (CRCCP) are putting greater emphasis on working with health systems to implement evidence-based interventions (EBIs) and strategies that can increase screening among both the newly insured and those who remain un- and under-insured.

With available resources, CDC will continue to work with all grantees to use evidence-based interventions that affect broad health systems change and improve cancer screening on a population

level. In addition, CDC will work with its tribal grantees to address special barriers to screening among this population in order to implement these systems changes and improve cancer screening within tribal communities.

(9) Underground Mining Research Facility

The Lake Lynn Laboratory and Experimental Mine provided a unique and critical resource for conducting large scale explosion tests and mine fire research which are essential components of preventing accidents and disasters in the mining industry. The safety of our Nation's underground miners relied on this resource for over 30 years.

The Committee has been reinforcing our expectations over the past several years to re-establish this resource. I appreciate that CDC is now starting to move forward on this effort but I am concerned that site identification is going to take until FY 2018.

Under CDC's current plan, a facility to test critical resources to keep miners safe will be years from being operational—and we really can't leave our miners' safety at risk for that long.

Please explain what CDC or HHS can do to help expedite the process to bring this facility back on-line faster?

Response: CDC is working in coordination with GSA to identify and purchase a replacement site for Underground Mining Research. The current timeline is as expeditious as possible given the necessary steps for acquisition. Pending the availability of funds for purchase and renovation, CDC will purchase the site in late summer 2017.

- CDC and GSA are jointly developing the site solicitation to be issued to the general public not to exceed $16.6 million for the purchase of a new site.
- The offers received in response to the site solicitation will be reviewed by both CDC and GSA for initial compatibility and suitability to meet the stated purpose. GSA and CDC will jointly develop a short-list of properties for additional investigation based on the selection criteria. CDC anticipates having potential site locations, site acquisition costs and associated site development costs in summer 2016.
- The short-listed properties will undergo further analysis, including program test fits, Phase I Environmental Site Audits, and a cost analysis. Once completed, the short list will be ranked. The availability of funds for purchase and renovation, as well as the analysis from the Phase I studies, will determine the ability to purchase a new site.
- The first ranked property will undergo a complete National Environmental Policy Act Environmental Assessment (EA) to determine suitability. If the first ranked property is determined suitable, negotiations will move forward for purchase; if the site is deemed unsuitable, the same EA process will begin for the second ranked property, and so forth.
- Once the property is purchased, CDC may occupy the site. The property purchase is anticipated to be completed in late summer 2017.

(10) Preventive Health and Health Services Block Grant

State health departments have the unique capacity to target resources to specific local needs. Key to this work is the Preventive Health and Health Services Block Grant. In fact, I have heard the funds from this program have supported mosquito control that is important for Zika prevention strategies and were used to support Ebola related activities.

I'm curious why, when Congress has repeatedly directed funding to this program, including the recent bi-partisan Omnibus, did your agency again recommend the elimination of this program?

Response: The President's Budget request has to consider a number of competing priorities. Activities funded by the Preventive Health and Health Services Block Grant (PHHSBG) program may be more effectively and efficiently implemented through categorical programs, such as the State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health program which provides resources to states to coordinate activities across categorical funding streams. Elimination of this program provides an opportunity to find savings, while enhancing functionality for core chronic diseases.

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. However, since 1981, categorical programs at CDC have grown the PHHSBG now represents a much smaller percentage of state budgets when compared to total available CDC funding.

(11) Strategic National Stockpile (SNS)

The CDC has stockpiled a certain level of antivirals to treat a percentage of the U.S. population, according to the recommendations outlined in the National Strategy for Pandemic Preparedness. Our understanding is while the shelf life for most of the stockpiled antivirals is 10 years, a large portion of the stockpile will soon begin to expire. The primary antiviral stockpiled will be losing its patent later this year.

A) Is CDC working with generic manufacturers to replenish the stockpile?

Response: CDC proactively coordinates with supply chain partners to understand and assess commercial market conditions, production capacity, and the changing antiviral drug landscape. CDC is aware that in February 2017 Tamiflu® (oseltamivir) will no longer have product exclusivity. CDC is evaluating expiring inventory, costs of replacement product, shelf life, and the changing antiviral drug landscape, including generic product equivalents that may enter the market in the future before awarding new federal contracts to replenish expiring SNS oseltamivir inventory.

B) Are there concerns with generic manufacturers' ability to meet the needs of the US federal government?

Response: The ability to meet the volume of orders required for the Strategic National Stockpile is one concern that will factor into CDC's evaluation of available generic alternatives.

C) I know generics are appealing. However, I understand that in some cases they have more limited shelf life and other manufacturing capability limitations. How will CDC factor the increased cost due to lower shelf life or more limited production capability in to the purchase decisions?

Response: CDC's evaluation of options for replenishment of expiring oseltamivir inventory will consider multiple factors including costs of commercially available replacement products, and the shelf life of those products. As with all other products in the SNS, CDC will evaluate its procurement strategy for antiviral drugs to ensure the best value for the government.

D) Please answer the following questions:

a. Is CDC completely funding their SNS medical countermeasure procurement contracts for FY2016 contract target levels? If not, please explain why.

Response: For products that cannot be purchased from an existing federal supply schedule or in situations where CDC may be able to negotiate a better price for a product, CDC attempts to negotiate "indefinite delivery indefinite quantity" requirements contracts for the SNS. Under these contracts, the agency is able to order the amount of product required to meet procurement requirements during the contract period at a specified price, without obligation to purchase any pre-determined amount of product. This contracting mechanism ensures that CDC retains the flexibility to meet prioritized requirements and support the government's MCM strategy as defined through the PHEMCE governance process, without paying for contracted deliveries that may no longer be required or supportable. Based on current projections, CDC will be able to purchase the required quantities of products to implement PHEMCE procurement recommendations for FY2016, as communicated in the 2013 SNS Annual Review Report.

b. What is the status of the Anthrax Material Threat assessment revision and to what degree is this revision expected to affect annual procurement of anthrax countermeasures by SNS in FY2016 and beyond?

Response: As called for in the 2014 Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategy and Implementation Plan, the Department of Homeland Security, with Health and Human Services, has now completed an update of the Anthrax Material Threat Assessment (MTA). The ASPR is currently leading a revision of the anthrax MCM requirements that will incorporate updated threat information, including a range of plausible scenarios identified in the new Anthrax MTA, revised public health and medical consequence assessments generated by ASPR, consideration of desired MCM product characteristics, and the national ability to effectively use anthrax MCMs in an emergency. These updated requirements will be incorporated into PHEMCE leadership's procurement processes, including the 2016 Strategic National Stockpile (SNS) Annual Review, informing sustainment and procurement decisions for the SNS as early as FY 2017.

c. HHS has invested in increasing anthrax vaccine manufacturing capacity - to what degree does SNS intend to utilize that capacity once the new manufacturing facility is licensed?

Response: CDC will continue to support procurement of anthrax vaccine at the levels directed by the PHEMCE governance process to meet a balanced procurement strategy across the participating enterprise agencies.

(12) World Health Org (WHO) Dairy Guidelines

We understand that on January 15, 2016 the World Health Organization (WHO) issued draft "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children." The guidance proposes to establish significant new restrictions and prohibitions on the promotion and marketing of milk products (including follow-up formulas, milk, cheese and yogurt) for young children up to three years of age without providing any evidence, scientific substantiation or an impact analysis to justify the measures.

I don't understand the logic of these recommendations, as we continue to hear that milk and milk products are good for our health. The HHS Dietary Guidelines notes a healthy eating pattern includes...fat-free or low free-free dairy, including milk, yogurt, cheese, and/or fortified soy beverages. The HHS guidelines apply to individuals age 2 and older. The WHO appears to contradict the nutritious food provided to children under three in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

A) Does CDC support these WHO draft guidelines? Why?

Response: CDC agrees with the importance ending inappropriate promotion of foods for infants and young children and avoiding practices that may undermine initiation and continuation of breastfeeding for mothers who are able to do so. However, we believe there are several issues which need to be addressed in the draft guidance. These include clarifying that natural milk or other products marketed to the whole family, and not specifically to children under 36 months, would not be affected by this guidance. Many milk products, when appropriately introduced in accordance with national dietary guidelines, are nutritious foods and may play an important role in optimal complementary feeding practices.

The Dietary Guidelines for Americans do encourage milk products as part of a healthy eating pattern for young children. However, they do not promote formula products or animal milks *over breast-milk* for children that are able to be breastfed. We believe WHO could further clarify that the guidance does not override national dietary guidance, nor undermine recommendations from health care providers, on an individual basis, to families.

B) What is your role in influencing WHO in this process?

Response: CDC has reviewed drafts and provided comments to WHO based on our technical expertise. Our comments and edits encouraged WHO to clarify some confusion in the original draft including a statement that the guidance does not override national dietary guidance.

C) How can we work together to ensure the WHO is developing science-based guidance to prevent unintended negative health consequences for young children and potentially violate World Trade Organization (WTO) trade rules, including imposing restrictions on the use of intellectual property by brand owners?

Response: We strongly support the development of science-based standards and guidance and will continue to provide technical input on the draft guidance to do what we can to ensure it is consistent with the latest rigorous science. The WHO Guidance is a set of voluntary, non-binding recommendations, not a regulation or standard. Ensuring consistency with WTO principles is an obligation of Member States, not the World Health Organization, which predates the WTO and does not have consideration of trade impacts within their mandate to advise their Member States on health and scientific matters.

(13) Global Health Security Agenda

A) What are the total funds available annually from all CDC sources (including Ebola balances) for Global Health Security Agenda activities? Please provide a table with FY source, availability, and obligations to date.

Response:

Obligations as of 3/30/2016	FY15-19 Ebola Emergency Appropriation	Total obligations to date	Emergency Appropriation Available
Global Health Security	$597.00	$99.25	$495.93
National Public Health Institutes		$1.82	
Total	**$597.00**	**$101.07**	**$495.93**

B) The priorities of the Global Health Security Agenda have been described by the administration as detection, prevention and response. Please describe the scope of each of these priorities?

Response: The United States government made a commitment to assist 30 countries over five years to achieve the targets of the Global Health Security Agenda (GHSA). In these countries, the host governments are partnering with the United States to establish a five-year country roadmap to achieve and sustain each of the 11 targets of the GHSA. These roadmaps identify the specific milestones, next steps, and gaps toward achieving capacity needed to prevent, detect, and respond to biological threats. Host country governments have been encouraged to make their roadmaps public as a way of encouraging coordinated, transparent investments from other donors and partners. To date, 10 countries have done so.

All countries participating in GHSA, including the countries supported by the United States, are encouraged to conduct GHSA assessments. The first stage is a self-assessment completed by the host country using self-reported data for the GHSA indicators. Half of the USG supported countries have finished this stage, and the rest will be complete it before the end of this calendar year.

In the second stage of the assessment process, this self-reported information is given to an external assessment team of subject matter experts from other GHSA countries. These subject matter experts visit the country for in-depth discussions of the self-reported data as well as site visits and meetings with relevant government stakeholders organized by the host country. After conducting the assessment visit, the team drafts a report that identifies the status levels for each action package indicator, and analyzes the country's capabilities, gaps, opportunities, and challenges. This information is shared with the host country and various other stakeholders in order to facilitate international support of country implementation efforts, share best practices and lessons learned, promote accountability, engage stakeholders, and inform and guide GHSA implementation both in the host country and internationally. Six of the US-supported countries have completed this stage, and four are either in progress or scheduled in the near future. The completed assessments are made available to the public on the GHSA website.

Regardless of whether the assessments have been completed or are in progress, all recipients of USG assistance are required to provide quarterly progress reports on their activities and indicators. This information is shared with the interagency GHSA leadership team, and allows for timely feedback and identification of any weaknesses that need to be addressed.

Within CDC specifically, monitoring of performance for recipients of CDC funding is even more frequent. CDC leadership has monthly performance reviews with the headquarters-based staff responsible for GHSA implementation, as well as regular calls with CDC's staff on the ground in the countries. All CDC funding is contingent upon performance, with no guarantees for continuation if progress is not demonstrated. Grants management specialists, project officers and subject matter experts evaluate performance through quarterly programmatic and financial reports, site visits, and day-to-day oversight of program activities.

Having technical staff on the ground to oversee program implementation is one of the core strengths of CDC's global health approach, but in the case of GHSA, there is also direct engagement from CDC leadership. Since funding for GHSA implementation was provided to CDC in November 2014, the CDC Director has personally visited 11 of the US-supported countries for face-to-face meetings with host country government officials and CDC staff. In addition, the Director uses other opportunities, such as the World Health Assembly and United Nations General Assembly, to engage with host country leaders to ensure they are aware of and committed to the achievement of the GHSA targets and compliance with the International Health Regulations. Similarly, the Director has engaged with US Chiefs of Mission in the GHSA countries through one-on-one meetings and visits by US Ambassadors to CDC in Atlanta. To date, seven Ambassadors from USG-supported GHS countries have visited Atlanta. This type of leadership engagement has shown to be effective in building host country commitment for other global health programs such as PEPFAR, and CDC believes a similar approach will ensure that host countries are prepared for and capable of sustaining global health security programs over the long term.

C) The WHO has identified WASH services as critical in health care facilities. What role is CDC playing within the GHSA relative to WASH services policies, guidance, and other potential activities? Further, how is CDC working with other countries and USAID to support enhancement and development of WASH services in GHSA countries?

Response: Global access to safe water, adequate sanitation, and proper hygiene education can reduce illness and death from disease, leading to improved health, poverty reduction, and socio-economic development. Through GHS, CDC is working to build capacities that will strengthen the public health system, and these could have an impact on WASH-related diseases. For example, better surveillance and laboratory networks will help identify when and where disease, including waterborne diseases, are occurring and enhanced emergency operations and management will improve response coordination. At this time, Kenya, Tanzania, and Cameroon are GHS countries addressing cholera as part of GHS implementation.

Many countries, including but not limited to GHS countries, are challenged to provide these basic necessities to their populations, leaving people at risk for WASH-related diseases. Recognizing this, CDC together with the Pan American Health Organization (PAHO) developed the Safe Water System (SWS), which protects communities from contaminated water by promoting behavior change and providing affordable and sustainable solutions. The SWS increases access to safe water by helping individuals treat and safely store water in homes, health facilities, and schools. The SWS encompasses three steps:

- Household water treatment
- Safe storage of the treated water
- Behavior change communication to improve hygiene, sanitation, and water and food handling practices

In terms of coordination with USAID, GHSA is an interagency effort. All planning and technical assistance is coordinated across the various implementing agencies at headquarters and by the Chef of Mission in-country.

D) Please describe the criteria, policies, procedures, and controls CDC is using to ensure the GHSA countries participate in the GHSA funding and have active programs in place to ensure the host countries supports these activities once the GHSA are completed? Finally, what is the evaluation trigger that would cause CDC from halting support to a country and how often are these triggers reviewed by CDC Leadership?

Response: CDC and US Government partners work with the government to develop comprehensive Roadmaps designed to achieve GHSA targets and reflect host country needs, priorities, and timelines. These Roadmaps serve as guides for implementation, are a country-owned, and reflect the needs and priorities of the host nation. Roadmaps include milestones for achieving the GHSA targets as well as an understanding of who will provide resources. The host country, the U.S. interagency team, and other stakeholders all play a role in developing, supporting, and implementing the Roadmaps. Host country governments have the option to make their Five-Year Roadmap public as a way of encouraging coordinated, transparent investments from other donors and partners.

Throughout the process of GHSA implementation, the country will provide updates on their progress, including completion of internal and external assessments to gauge their capacity to respond to public health events.

(14) Gun Control

CDC is again proposing a new program to conduct $10 million of gun research. In addition, the National Violent Death Reporting System (NVDRS) program includes an increase to collect information from multiple data sources on firearms for future research.

a. Please explain what research questions are proposed to be addressed and how the information from each effort is planned to be used.

Response: On January 16, 2013 the President released his plan to reduce firearm violence, *Now is the Time*. Part of this plan directed CDC and other scientific agencies to conduct research into the causes and prevention of firearm violence.

In FY 2017, CDC proposes $10 million to pursue research activities that align with the priorities identified in the IOM/NRC report, Priorities for Research to Reduce the Threat of Firearm-Rated Violence. This includes understanding the characteristics of firearm violence (e.g., patterns of access and use among children and youth, and among high-risk racial/ethnic minority populations; rural/urban differences in firearm-related violence); the risk and protective factors for interpersonal and self-directed firearm violence (e.g., alcohol, other situational or environmental factors; the factors influencing non-fatal firearm violence); and the effectiveness of interventions to prevent firearm violence (e.g., safe storage practices; whether existing evidence-based approaches and policies for preventing interpersonal violence are effective in reducing firearm-related deaths and injuries).

Understanding the patterns, characteristics, and impact of firearm violence is an important step toward preventing firearm injuries and deaths in the US. The information garnered from firearm violence research can inform public health programs that could reduce violence.

The National Violent Death Reporting System (NVDRS) provides states and communities with a clearer understanding of violent deaths to guide local decisions about efforts to prevent violence and track progress over time. NVDRS is the only state-based surveillance (reporting) system that pools data on violent deaths from multiple sources into a usable, anonymous database. These sources include state and local medical examiner, coroner, law enforcement, crime lab, and vital statistics records. NVDRS covers all types of violent deaths—including homicides and suicides—in all settings and for all age groups. NVDRS may include data on mental health problems; recent problems with a job, finances, or relationships; physical health problems; and information about circumstances of death.

b. Please describe any limitations or safeguards on the information to prevent it from being used to develop or support policies, guidelines, or recommendations which may limit Second Amendment rights or create a list of gun owners.

Response: CDC understands and appreciates the rights granted to citizens by the Second Amendment. The guiding principle behind CDC's gun violence prevention work is to prevent firearm injuries and deaths while protecting the rights of lawful gun owners. CDC collects data from already existing sources and pools information into an anonymous database. CDC has not and will not use these data to develop policy, guidelines, or recommendations to limit lawful access to guns, ammunition, or create a list of gun owners. Whereas law enforcement/criminal justice focuses on public safety, prosecution, and criminal penalties related to violent acts, CDC focuses on preventing violence in the first place.

An understanding of the full extent of all firearm-related injuries and deaths helps state and local communities to design and implement effective prevention strategies to reduce future incidents.

(15) Laboratory Challenges

A) Please provide an update on the status of your corrective action plan. Specifically, how the funds provided in FY 2016 and what level of base funding is being used to address the various laboratory challenges CDC has faced over the past several years?

Response: Following the laboratory-related safety incidents in 2014, CDC obtained rigorous internal and external reviews of its laboratory safety practices, which were exhaustive in their scope and depth. The recommendations spanned a broad range of structures and practices that impact laboratory safety. CDC continues to implement and track progress on each recommendation it received during this process. While more work remains to be done, the progress made to date has been significant, particularly in CDC's laboratory oversight structure and approach.

In 2015, CDC created the position of the Associate Director for Laboratory Science and Safety—a single, agency-wide point of accountability for CDC laboratory science and safety who reports directly to the CDC Director. This new role and its associated office directs two key functions: oversight of CDC laboratory science, quality, and training; and direct oversight of all aspects of safety in laboratories across all CDC campuses.

In FY 2016, CDC was appropriated additional funding to stand up this office and implement the laboratory safety and quality initiatives called for by the internal and external reviews. This critical investment is in addition to funding that CDC realigned from elsewhere within the agency to advance vital laboratory safety initiatives. Signature achievements include:

- **Standing up rigorous oversight of laboratory safety:** With the 2015 investment, CDC consolidated all laboratory safety oversight functions (including biological, chemical, and radiological safety) into a single office directly accountable to the CDC Director to standardize safety across the agency and ensure laboratories adhere to safety policies.
- **Ensuring exacting scrutiny of critical safety policies:** CDC created the Laboratory Safety Review Board, a new body made up of CDC laboratory experts to provide exacting and independent review and scrutiny of every single protocol for the transfer of biological materials out of high-containment laboratories. This is a critical reform that addresses a key issue in the 2014 incidents.
- **Training tomorrow's laboratory leaders:** CDC launched the Laboratory Leadership Service, a new program to prepare the most promising early career laboratory scientists to become a future elite corps of laboratory leaders.
- **Cutting edge training for a modern laboratory workforce**: CDC has started critical overhaul of its laboratory training curriculum to ensure CDC scientists have access to impactful training and keep in step with new developments in laboratory science and safety.
- **Investing in the science of safety:** CDC is working to apply the same rigorous scientific methods it uses to protect the public's health to advance the safety of its laboratories. The agency launched the *Laboratory Safety Science and Innovation Intramural Research Fund* to provide one-time awards to laboratories across CDC to advance innovative solutions to

laboratory safety challenges. This year, CDC will fund 13 projects that enhance the science of laboratory safety in diverse ways, from developing a 3D lab risk-assessment training tool to improving virus inactivation techniques and evaluating the efficacy of disinfectants.

The President's Budget for FY17 includes a request of $5.0 million to further advance this critical work. This increased investment would allow CDC to acquire:

- **Data analysis to make laboratories smarter and safer:** With this new investment CDC would make key upgrades to laboratory information technology systems to streamline reporting, tracking, and analysis of potential safety issues.
- **Continued advances in laboratory training**: With the FY17 investment CDC could continue its major modernization and reimagining of its laboratory training curriculum. The investment would facilitate the creation of new, high-quality and interactive courses that would strengthen key safety competencies among CDC's broad and diverse laboratory workforce.
- **Advanced calibration of laboratory technology:** CDC would also use this investment to enhance calibration of laboratory equipment to sharpen the quality of laboratory results and reduce costs by increasing efficiency of critical laboratory procedures.

B) Please describe the process CDC has implemented to monitor the corrective action procedures and ensure processes are being followed?

Response: CDC's guiding principles for laboratory work are to ensure the safety of all staff and the community and be as transparent as possible about our work as we conduct high-quality scientific research to protect people in this country and around the world. CDC created the Office of the Associate Director for Laboratory Science and Safety as a single point of accountability for laboratory science and safety. The Office provides high-level oversight and coordination of critical laboratory policies and operations, particularly those associated with laboratory safety and quality management programs. To continually ensure that procedures and policies are followed CDC:

1. Requires that only validated methods be used to inactivate dangerous pathogens
    a. Established the Laboratory Safety and Review Board (LSRB) to approve new and amended protocols for the inactivation and transfer of biological materials from biosafety (BSL)-3 and BSL-4 laboratories to those of lower containment.
2. Requires verification of sterility of any materials sent out of CDC
    a. All materials sent out of CDC's high-containment laboratories must be accompanied by a material transfer certificate (MTC), documenting the transferred materials were inactivated.
3. Requires secondary verification of essential steps in inactivation protocols of all materials sent out of high containment laboratories
    a. Several methods of secondary verification were approved for use at CDC, including second person, camera system, dose indicator labels, filtration devices, programmable robotics and automatic equipment.
4. Requires all laboratory scientists and other staff to report any possible problem with laboratory safety
    a. Guidance is posted on the laboratory safety internet site
5. Provides guidance ensuring any incident or potential incident is promptly reported to all relevant regulatory authorities

a. The Laboratory Infectious Agent Exposure Risk Assessment: Response and Notification Flow Chart was created to help guide laboratory staff and their supervisors on how to initiate the notification process regarding the potential exposure to a laboratory infectious agent.

(16) Interstitial Cystitis

For over a decade, Congress has supported CDC's interstitial cystitis (IC) program, and has consistently recommended a programmatic focus on patient and professional awareness as it relates to this debilitating condition. Without consulting the Committee, we have learned that CDC changed the focus of this program to support an epidemiology study, and ended program activity supporting professional and public awareness. We are aware the that NIH's Multidisciplinary Approach to Pelvic Pain (MAPP) Study supports significant epidemiology activity and that there was interstitial cystitis epidemiology collected in a privately funded study by the Rand Corporation.

A) Please explain how the CDC study dovetails with already on-going work with NIH? What coordination occurred with NIH prior to contemplating or beginning this study?

Response: To ensure that CDC's supported work fills gaps in the current research, its new IC funding opportunity announcement (FOA), "Interstitial Cystitis Epidemiologic Study, Translation and Education," (DP15-010) was developed after a comprehensive review of the major epidemiological cohorts that have been established or analyzed to better characterize the morbidity of interstitial cystitis in the United States. Research gaps continue to be identified by the grantee, Cedar-Sinai, in collaboration with an advisory or multidisciplinary workgroup of expert IC partners, collaborators, and stakeholders. To date there have been some limited epidemiologic studies on IC, including research funded by the National Institute of Diabetes and Kidney Diseases (NIDDK). Most of those studies have been clinic based rather than population based as the new CDC FOA requires. The studies have focused primarily on estimating the prevalence of IC or examined correlates. Very few have estimated the incidence rate of interstitial cystitis or considered differences by race/ethnicity, socioeconomic status, or geographic region, as required in the CDC epidemiologic study. Although at least 4 million people in the United States are estimated to have IC based on small clinical patient studies and registries, IC has not been extensively measured in the general population. As a result, it is unknown whether this number accurately reflects the actual IC burden. In addition, estimates of healthcare utilization, diagnosis, and treatment in the US population are also unknown.

Moreover, very few studies have considered factors such as work productivity, impairment/disability, or outcomes related to specific therapies for IC. In addition to obtaining estimates of IC in different subpopulations, the CDC supported study will define the demographic and clinical patterns of IC, including practice variations in the management of IC, and will document the impact of various clinical practices on the outcome of the disease. The study will describe a multitude of factors affected by variations in clinical practice; this will be an outstanding contribution to understanding the epidemiology of IC in the United States and will facilitate a data driven public health response to IC.

B) Please explain why the Center Director did not conduct advance communication with the committee and how this study supports the long-term Congressional intent for these funds.

Response: CDC issued a new, competitive FOA for the IC cooperative agreement on December 19, 2014. Congressional staff inquired about the FOA, and CDC amended the FOA to respond to Congressional input on February 22, 2015. The revised FOA clarified that work on education and awareness would continue to be supported in the new project period.

C) Please describe how the funds are being used to support education, outreach, and public awareness activities?

Response: Public health surveillance and epidemiological research is essential for informing public health practice and ensuring educational activities are based on the latest data. DP15-010 enhances CDC-supported IC education and awareness activities by adding an epidemiologic study that will provide the public health data necessary for a better understanding of the epidemiology and treatment of IC—data essential to continue effective provider and public education. These data will inform clinical best practices and contribute to the development of targeted interventions for groups at high risk.

The FOA requires a detailed dissemination plan to describe how the collected data will serve as a resource to key public health practitioners, academic researchers, governmental agencies, private organizations, and the public. As a result, these activities will make a stronger impact on the millions of patients who live with IC, as well as on those who treat and study it. The FOA is modeled on similar successful work to identify and close research gaps for Crohn's disease and Lupus, resulting in improved education and awareness for people affected by those diseases.

(17) **<u>CDC Win-able Battles</u>**

A) Please provide an overview on how we are making progress to reduce childhood and adolescent obesity

Response: Some progress has been made in reducing childhood obesity. Obesity among low-income preschoolers declined, from 2008 through 2011, in 19 of 43 states and territories studied. CDC programs continue to further drive this decline, through funding, training, and technical assistance to a variety of state and community agencies and other organizations for childhood obesity prevention efforts. For example, the Early Care and Education (ECE) Learning Collaboratives Project, a 5-year cooperative agreement launched October 2012, funds the Nemours Foundation to establish and implement learning collaboratives in states to support ECE programs to make improvements in nutrition, breastfeeding support, physical activity, and screen time. Most recently, CDC is supporting obesity prevention programs working with land grant universities and cooperative extension offices in 8 rural counties with greater than 40 percent obesity. Finally, we are continuing progress to ensure children with obesity and overweight are identified early in physician offices and get the community weight management services needed through our Childhood Obesity Research Demonstration (CORD) Project. The U.S. Preventative Services Task Force recommends that clinicians screen children aged 6

years and older for obesity and offer them or refer them to comprehensive, intensive behavioral intervention to promote improvement in weight status. We funded this 4 year project through September 2015 to four grantees to and will publish results in the end of 2016 A new funding opportunity for the next phase of CORD is currently in process. Awards should be announced in Summer 2016. Lessons learned from these projects will inform future CDC efforts.

B) Describe in detail how burden of disease is being used and planned for in competitively and non-competitively awarded funds?

Response: CDC recognizes that the burden of chronic diseases, including cancer, heart disease and stroke, diabetes, and arthritis is significant and pervasive. CDC considers burden as one factor in determining funding levels for state chronic disease prevention programs. NCCDPHP's major program funding opportunity announcements (FOA) include a base funding amount to ensure adequate support of state chronic disease prevention efforts, which is then modified based on burden of disease, typically defined by disease or risk factor rates or by poverty level as a proxy for burden. In some cases, supplemental funds are awarded on a competitive basis in order to further enhance work, extend activities, and implement innovative approaches. NCCDPHP also includes language in its FOAs that directs grantees to focus their efforts on addressing health disparities by serving populations that experience high burden of disease.

C) Provide a breakdown of how much of all CDC obesity funds are spent in rural vs urban population centers?

Response: Most extramural funds go to states who then distribute based on need. Our high obesity program funds primarily rural counties with obesity rates of 40% or greater.

D) Provide a table of the top 50 communities in the country with the highest obesity rates (population adjusted) and how much of all CDC obesity funds were spent in each community for FY 2014, FY 2015, and FY 2016 est.

Response: All counties funded through High Obesity (1416) have an adult obesity burden of 40% or higher (based on 2012 Behavioral Risk Factor Surveillance System (BRFSS) data). Below is a summary of the number of counties covered in each state. Other counties may he receiving funds to address obesity through other grants, but we do not have that level of detail since the funds are distributed by the state.

- Alabama received $791,222 in 2014 and $1,185,080 in 2015 to work in 14 counties, 6 of those counties are in the top 50.
- South Dakota received $588,456/year in 2014 and 2015 to work in 6 counties, 2 of those counties are in the top 50.
- Texas received $783,000 in 2014 and $933,000 in 2015 to work in one county which is in the top 50.
- Kentucky received $629,004 in 2014 and $786,056 in 2015 to work in 6 counties, 3 of those counties are in the top 50.
- Tennessee received $987,774 in 2014 and $998,000 in 2015 to work in 4 counties, none of these counties are in the top 50.

- West Virginia received $467,816 to work in 3 counties, none of these counties are in the top 50.
- Louisiana received $624,977 in 2015 to work in 3 parishes, none of which are in the top 50.
- Arkansas received $624,978 in 2015 to work in 4 counties, 1 county is in the top 50.

E) Describe how the FY 2017 requested increase focuses on the areas of the country with the highest proportion of obese children and adolescents and what is the expected reduction in children and adolescent obesity based on the requested increase?

Response: The FY 2017 President's Budget did not include an increase for nutrition, physical activity and obesity. With the additional funds for High Obesity Rate Counties in FY 2016, CDC will soon publish a Funding Opportunity Announcement (FOA) titled "Programs to Reduce Obesity in High Obesity Areas to Boost Prevention." Approximately $1.7 million per year is available to fund up to three Land Grant Colleges and Universities located in states with counties with an adult obesity prevalence of over 40 percent.

F) Provide an update on each of the other seven battles areas.

a. Describe how CDC is measuring winning from FY 2014 through FY 2016 for each battle?

Response: A comprehensive set of indicators establishes baselines and targets for all Winnable Battle areas. These indicators help us measure the impact of programs and policies on our nation's health, and support the Department of Health and Human Services' strategic plan and other priorities. Derived from Healthy People 2020 and other established measures, the related targets are ambitious yet achievable, evidence-based, and specific to the priorities and opportunities within each of these health areas. CDC's recent Winnable Battles Progress report provides a dashboard, which provides a snapshot of each indicator by comparing recent data trends to the 2015 Winnable Battle.

b. How CDC uses burden of disease to determine where to focus resources for each of the battle areas?

Response: CDC uses risk factors and health indicators to identify the extent to which each state contributes to the national public health burden. In many cases, a small number of states account for a large proportion of the burden (this is commonly known as the Pareto principle or the 80-20 rule). The data also serve as a model for analyses that could be conducted by states at the county level. These types of analyses can be helpful in understanding disease burden as a critical element in targeting resources effectively.

Chronic Diseases

Chronic diseases such as diabetes, cancer and heart disease are the leading cause of poor health, disability and death, and among the most costly to treat. But they also are the most preventable.

a. Please describe how CDC programs and resources being targeting to areas of the country with the highest demonstrated burden of disease on an age adjusted basis?

Response: Currently, CDC's major heart disease, diabetes and cancer program funding opportunity announcements (FOAs) fund all fifty states and the Distriet of Columbia, include a base funding amount to ensure adequate support of state chronie disease prevention efforts, which is then augmented based on burden of disease typically defined by disease or risk factor rates or by poverty level as a proxy for burden. Award decisions are made by an objective review process where applications are judged based on their technical merit and quality of the application.

Base funding supports the skills and competencies needed for a statewide public health approach to chronic disease prevention and health promotion including:

- gathering and analyzing data to track disease and risk factor trends over time
- informing the general public and partners about chronic disease burden, risks, and prevention
- implementing evidence-based programs
- evaluating the effectiveness of chronic disease prevention strategies

In some cases, supplemental funds are awarded on a competitive basis in order to further enhance work, extend activities, and implement innovative approaches. CDC also includes language in the major FOAs that directs grantees to focus their efforts on addressing health disparities by serving populations that experience high burden of disease. Sample language includes:

- *State Public Health Actions (1305): Applicants must describe the specific target population(s) to be addressed in their jurisdiction to allocate limited resources, target those at greatest health risk, and achieve the greatest health impact. Applicants should use data, including social determinants data, to identify communities within their jurisdictions or community served that are disproportionately affected by the public health problem, and plan activities to reduce or eliminate these disparities.*
- *State and Local Public Health Actions (1422): recipients will describe the population selected, including relevant health disparities, and how the selected interventions will improve health and reduce or eliminate one or more identified health disparities.*
- *Tobacco: Applicants must address how they will include target populations who can benefit from the program. Applicants should describe how they will be inclusive of populations disproportionately affected by tobacco use, secondhand smoke exposure, and associated disease, death, and disability through (1) representation on state and local coalitions, (2) fostering specific partnerships, (3) inclusion of evidence-based interventions and strategies addressing tobacco-related disparities and health equity in long-range plans as well as annual work plans, and (4) other relevant work plan activities and actions.*
- *Comprehensive cancer: Ensure the plan focuses efforts on the highest burden cancers, and those with available evidence or practice-based public health interventions, and show links with relevant existing chronic disease plans. Clearly describe populations experiencing health disparities and appropriate strategies to reduce disparities.*

Grantees strive to achieve population-wide improvements in health, with greater gains in population subgroups that experience a disproportionate burden of disease. Grantees are required to track the impact of program investments on the disease or risk factor overall and in the target populations.

b. Please provide a table with the top 50 counties that have the highest level of burden (age adjusted rate) and the funding CDC has provided in each of the past 3 years for each of the following: obesity, diabetes, stroke, heart attack, and cancer. Plus, a list of the top 50 counties that received CDC funds for each of the preceding identified disease areas.

Response: CDC is currently collating data on the top 50 counties that have the highest level of burden for heart, diabetes and cancer. CDC will provide the data requested under separate cover. The majority of these funds are awarded to states; county-level funding data are not available.

c. Please explain how CDC is using established metrics that capture prevalence of disease when awarding grants and using projected impact on the measure when considering which grantee to award for chronic disease programs funded through CDC?

Response: CDC recognizes that the burden of chronic diseases, including cancer, heart disease and stroke, diabetes, and arthritis, is significant and pervasive. Thus, CDC considers burden as one factor in determining funding levels for state chronic disease prevention programs. CDC understands and shares the view of Congress that burden should serve as a significant criterion for chronic disease funding decisions. CDC is currently reexamining the way it supports state chronic disease programs to more consistently factor disease burden in funding decisions across all 50 states and D.C. The following principles will guide the development of major new FOAs:

- Maintain core funding for every state: every state should have a base level of funding that supports chronic disease prevention efforts (based on available funds).
- Take into account burden of disease: incorporate disease rates and number of people affected into state funding levels. Assure technical merit and applicant capacity to address burden effectively through an objective review.
- Factor in population size: accounts for population size to reflect the magnitude of the work in each state.

CDC will also maintain its efforts in performance-based monitoring to ensure that grantees meet the goals and objectives of each program and efficiently expend Federal funds over the course of the FOA award period.

Centers FTEs

For each CDC Center and CDC Office of Director Function, please provide a table with the total number of full time equivalent civilian employees and full time equivalent contracts supported for each Center of function within the CDC Office of the Director for each of the past five actual years, FY 2016 estimate, and budget request level.

Response: CDC Civilian Full Time Equivalent (both direct and reimbursable) for FY 2011-2017 are included below:

Civilian Full Time Equivalent - Direct and Reimbursable	2011	2012	2013	2014	2015	2016	2017
Immunization and Respiratory Diseases	568	599	564	565	592	592	592
HIV/AIDS, Viral Hepatitis, STI and TB Prevention	985	1086	1093	1094	1053	1053	1053
Emerging and Zoonotic Infectious Diseases	1079	1000	991	930	962	975	975
Chronic Disease Prevention and Health Promotion	926	900	836	844	844	844	844
Birth Defects, Developmental Disabilities, Disability and Health	223	229	221	216	193	193	193
Environmental Health	409	394	414	401	407	407	407
Injury Prevention and Control	205	208	204	215	219	228	228
Public Health Scientific Services	1033	994	979	876	885	885	885
Occupational Safety and Health	1121	1073	1043	1046	1025	1025	1025
Global Health	622	768	864	943	925	925	925
Public Health Preparedness and Response	475	499	516	548	545	545	545
Cross-Cutting Activities and Program Support	1868	1952	2216	2243	2289	2290	2290
Total	9514	9702	9941	9921	9939	9962	9962

These amounts are sourced from FY 2013-2017 Congressional Justifications (CJs).

FY2016 Contractors

The total number of contractors as of March 7, 2016 is 8,324. This includes Contractors (not Vendors) but excludes Fellows, Guest Researchers, Intergovernmental Personnel Act (IPA) contractors, Committee Board Members and Personal Services Contractors. The included contractors may or may not work in a "full time" status. The data was downloaded from OCIO Enterprise Reporting System (ERS) as of March 7, 2016 and does not provide an analysis of full time versus part time employees.

Antimicrobial Resistance

Please describe how the significant increase for this program is to support evidence based approaches to stop the spread of drug resistant bacteria and preserve existing antibiotics. Specifically, the criteria being used and how it was developed in coordination with BARDA, NIAID, and others as directed in the FY 2016 Omnibus.

Response: The FY 2016 funding increase provided by Congress for CDC's Antibiotic Resistance Solutions Initiative (AR) initiative is a substantial opportunity for state and local public health to expand capacity to detect and respond to AR threats in healthcare and communities, protect patients, and save lives. CDC plans to distribute the largest extramural portion of the FY 2016 funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement. The ELC AR funding will support comprehensive and coordinated public health action against antibiotic resistance across states, counties, and cities. These activities align with the National Strategy

and Action Plan for Combating Antibiotic-Resistant Bacteria. CDC is committed to implementing its components of the National Action Plan, which outlines aggressive action to move the nation towards major reductions in the incidence of urgent and serious AR threats.

One critical FY 2016 ELC AR component is scaling State Healthcare-Associated Infections (HAI)/AR Prevention Programs in up to 25 states to support evidence-based interventions and implement best practices for reducing inappropriate inpatient antibiotic use and preventing the spread of AR threats most commonly transmitted in healthcare. CDC's August 2015 Vital Signs outlined how a coordinated approach for action could significantly prevent AR infections and *C. difficile*. The proposed FY 2017 increase will expand the FY 2016 HAI/AR prevention efforts from 25 states to up to 50 states, six large cities, and Puerto Rico.

With the FY 2016 funding increase, CDC is also expanding nationwide laboratory capacity to detect emerging HAI/AR threats by supporting a lab network of up to seven AR regional laboratories to serve as a national resource for cutting-edge lab support to states. Through the FY 2016 increase, CDC is increasing state public health laboratory capacity in all 50 states, six large cities, and Puerto Rico to confirm resistance and detect known resistance mechanisms for CRE and carbapenem-resistant Pseudomonas aeruginosa using CDC recommended methods. CDC is also implementing antibiotic stewardship programs that align with CDC's Core Elements for Antibiotic Stewardship in inpatient, outpatient, and long-term care settings.

The primary outcome of these activities will be demonstrated reductions in reported HAI and AR infections or pathogens moving towards national targets established in the National Strategy for Combating Antibiotic-Resistant Bacteria.

Always seeking to expand the evidence base and develop new interventions, CDC supports collaboration with academic medical centers, veterinary schools, schools of public health, state public health departments, and other academic institutions. CDC also coordinates with other federal agencies, including BARDA and NIH, to implement activities aligned with the National Strategy for Combating Antibiotic-Resistant Bacteria. CDC's work with states and other partners helps provide information to inform the research priorities and needs for AR therapeutic and diagnostic development for NIH and BARDA. In addition, CDC is partnering with NIH and FDA to sequence high priority reference strains identified through outbreaks and other activities to populate NIH's sequence database of resistant pathogens with strain information. The AR Regional Laboratory Network supported with FY 2016 AR funds will provide isolates to support the CDC/NIH/FDA collaboration. CDC is also working closely with NIH and BARDA in preparations for the prize to develop a rapid diagnostic test to be used by health care providers to identify highly resistant bacterial infections at the point of patient care.

Partnerships to Improve Community Health (PICH)

The 2016 Omnibus did not provide the requested $60 million for a separate PICH program but did allow CDC to shift certain FY 2016 costs to close out the program. Please provide a table that shows PICH close out costs and the specific chronic budget activity CDC is using to support that activity in FY 2016.

Response: CDC is currently finalizing estimates for PICH close-out costs. CDC will provide the table requested under separate cover.

Opioid Prescription Drug Overdose (PDO) Prevention Activity

A) The 2016 Omnibus provided a significant increase to combat opioid and prescription drug overdose activity based on a competitive population-adjusted burden of disease model. Please provide the criteria CDC is using to competitively awards these new funds.

Response: Congress made a major investment in expanding CDC's prescription drug overdose prevention activities. CDC plans to utilize a 4-pronged approach to award the additional funding for states to combat opioid and prescription drug overdose, focusing on providing the most funding to states with the highest burden coupled with the readiness to implement activities.

- Add states to the PDO Prevention for States (PfS) program, by funding states based on the score received during the competitive application review process. Thirteen additional states have been added to the program as of March 15, 2016 for a total of 29 states. The average award to states is $870,000.
- Competitvely supplement the PfS states to expand prevention support, especially for high burden states, who experienced high drug overdose death rates in 2014. All 29 awarded states will be eligible to compete.As part of the application review process, applicants will receive points according to the age-adjusted drug overdose death rate in their state. CDC will calculate the points assigned to applicants under this section using 2014 National Vital Statistics System drug overdose mortality by state. States will be able to compete for an additional $1 millionin funding to be added to their current PfS award. In addition to burden, they will be scored on capacity, and proposed work plans submitted as part of their application. The supplement will be comprised of 4 components, similar to PfS strategies:
    - Enhance and maximize PDMPs;
    - Implement community or insurer mechanisms or health systems interventions;
    - Conduct policy evaluations; and,
    - Develop and implement Rapid Response Projeets (giving states flexibility in quickly responding to changing eircumstances in communities.

- Expand the PDO prevention program nationally with a new FOA, *PDO: Data Driven Prevention Initiative (DDPI)* for which any state not already funded under the PfS program (and also Washington, DC) is eligible to apply. Of the 21 eligible states, 5 are in the top 20 for burden and an additional 9 are in the top 40. CDC will heavily weigh burden to prioritize investments in the hardest hit states. The new FOA will have two components with total possible funding for a state up to $750,000:
    - Component 1: up to $300,000 to improve state data capacity and planning for an impactful data-driven prevention program.

- Component 2: Up to an additional $450,000, focusing on implementing effective prevention (i.e., PDMPs enhancements, health system/insurer, community prevention).

- Enhanced surveillance of opioid morbidity and mortality through a new three-year FOA that will fund approximately 10 states. All 50 states and Washington, D.C. are eligible to apply for this funding. The goal of the FOA is to assist states with high or rapidly increasing drug overdose death rates to improve the timeliness of fatal and nonfatal opioid overdose surveillance. Total possible funding per state will be $800,000 per year. Applicants will be funded to:
  - Increase the timeliness of aggregate nonfatal opioid overdose reporting.
  - Increase the timeliness of fatal opioid overdose and associated risk factor reporting.
  - Disseminate surveillance findings to key stakeholders working to prevent or respond to opioid overdoses.

As part of the application review process, applicants will receive points according to the age-adjusted drug overdose death rate in their state as well as the absolute change (from year 2012 to year 2014) in age-adjusted drug overdose death rate in their state:

- 2014 Drug Overdose Burden: CDC will calculate the points assigned to applicants under this section using 2014 National Vital Statistics System drug overdose mortality by state. Applicants among the states with the 10 highest age-adjusted drug overdose death rates will receive 10 points. Applicants among the states with the 11th—19th highest age-adjusted drug overdose death rates will receive one less point per incremental decrease in ranking beginning with 9 points (i.e., 11th will receive 9 points, 12th will receive 8 points, ..., 20th or lower will receive 0 points).
- Change in Drug Overdose Burden 2012-2014: CDC will calculate the points assigned to applicants under this section using 2012 and 2014 National Vital Statistics System drug overdose mortality by state. Applicants among the states with the 10 largest changes in age-adjusted drug overdose death rates will receive 5 points.

B) Please include a breakout of the top 50 counties with the highest burden of disease and the dollar amount of the new funds they are expected to receive?

Response: CDC does not have reliable county-level data specific to opioid overdose. Although states can work closely with counties to address specific issues, the eligibility for the FOA is limited to states. With the currently funded PfS states, 16 of the top 20 highest burden states are funded. States not already funded under PfS are eligible to apply for DDPI and all 50 states and Washington, DC are eligible to apply for the FOA to enhance surveillance of opioid morbidity and mortality.

Laboratory Safety

In the past year how many reportable laboratory safety events have occurred within CDC and how many near misses have been reported. Please explain how CDC tracks reportable laboratory safety events and near-misses.

Response: CDC is committed to building a culture of safety in its laboratories. Transparency and reporting of all incidents and near misses—no matter how small—is a foundational feature of such a culture and is instrumental to ensuring safety issue does not become a safety incident.

To ensure CDC's Associate Director for Laboratory Science and Safety can identify and address any potential safety issues, CDC requires that all laboratory incidents and near misses are reported. CDC works continually to ensure all workers, including laboratory scientists, managers, and support staff, are aware of this requirement and how to report incidents. As the single point of accountability for laboratory safety issues, the Associate Director for Laboratory Science and Safety receives, tracks, and follows up on all reports of incidents and near misses.

CDC tracks incidents, near misses, and "other" occurrences in all its laboratories. An "incident" is defined as a potential exposure, injury, or illness in a laboratory or involving a pathogenic organism. Examples of incidents include sharps incidents, animal bites, equipment-related injuries, and potential exposures. A "near miss" is an unplanned event that did not result in injury, illness, or damage but had the potential to do so. Examples of near misses include equipment malfunctions and sharps injuries with no chance of potential exposure. The "Other" category includes occurrences that do not fit in these earlier categories but are potentially useful information to report, like an abnormal TB skin test in a laboratory worker that is not related to a laboratory exposure or incident.

Since the creation of the Office of the Associate Director for Laboratory Science and Safety (OADLSS) in June 2015, laboratory incidents and near misses have been reported to OADLSS in a timely way that has allowed OADLSS to follow up on each event and conduct investigations as needed to identify any potential systemic or ongoing issues that needed to be addressed.

Public Health Leadership and Supporting Details

The last several congressional reports have directed CDC to provide additional details on the CDC Public Health and Leadership funded activity, to include the CDC Office of Director Function details. Please provide the specific information and details requested in the FY 2015 and FY 2016 Omnibus reports for these activities.

Response:

FY 2015 Public Health Leadership and Support: Summary by Object Class

OC	Description	Total
11	Compensation Summary	$31,938,011
12	Personnel Benefits	$9,981,231
21	Travel and Transportation of Persons	$1,180,825
22	Transportation of Things	$52,800
23	Rent, Telecommunication, Other Comm. & Utilities	$4,933,892
24	Printing and Reproduction	$279,718
25	Consulting & Other Services	$37,876,942
26	Supplies & Materials	$401,586
31	Equipment	$3,407,766
41	Grants	$7,798,910
42	Insurance Claims	$61,500
	Working Capital Fund	$15,656,819
Grand Total		**$113,570,000**

Department of Labor, Health and Human Services and Education and Related Agencies
Budget Hearing: CDC Dr. Thomas Frieden
Questions from Rep. Mike Simpson
Tuesday, March 22, 2016

Opioid Guidelines

1. CDC released guidelines last week about the prescribing of opioids for chronic pain for primary care providers, but did not mention dentists, who prescribe such drugs. Why didn't the guidelines include dentists?

Response: This guideline is intended for primary care providers who are treating adult patients for chronic pain in outpatient settings. Primary care providers are the target audience for the guideline because they account for a large proportion of all dispensed opioid prescriptions and their prescribing rates have increased at high rates compared to other specialties. Primary care providers have expressed concern about opioid pain medication misuse, are worried about patient addiction, and have expressed their desire for more training in prescribing opioids (see attached article). Dentists represented a much smaller proportion of all dispensed opioid prescriptions.

2. Can you go back and include the Division of Oral Health and dentistry to address this oversight?

Response: Given that data show that primary care specialists accounted for nearly half of all dispensed opioids in 2012, the target audience for the Guideline and complementary tools and resources is primary care providers. Many of the tools already released and those under development, however, may be tailored and adapted to inform dentists with regard to the benefits and risks associated with opioid prescribing for chronic pain. CDC's National Center for Injury Prevention and Control already has reached out to the Division of Oral Health to discuss further effective means for sharing these tools and resources with dentists and national dentistry organizations to maximize the reach of dissemination and educational efforts.

3. Would CDC be willing to train dentists on the new guidelines as they apply to the distinct prescribing patterns in dentistry?

Response: CDC currently is working to develop tools and resources to facilitate training and education of providers with regard to appropriate prescribing of opioids for chronic pain. Such tools will include, for example, development of a series of webinars containing information from the Guideline in which clinician participation can be used to fulfill continuing education criteria. The primary audience for this training is primary care providers, but the information contained will have relevance for other clinical professions, including pharmacists and dentists as well. In soliciting participation among providers for this series of webinars and also other training and educational opportunities, CDC will ensure sharing through various channels to reach a broad audience, inclusive of dentists.

4. Does CDC have plans to issue separate guidelines for primary care prescribers of opioid medications to manage short-term pain, as is more commonly done in dental offices?

Response: The guideline leverages the most recent scientific evidence informing the benefits and harms of long-term opioid therapy, and allows for updated guidance that is consistent with technological advances, such as availability of Prescription Drug Monitoring Programs. As evidence related to short term/acute pain becomes available, CDC will reevaluate and continue coordination with partners to determine the next steps.

5. What can CDC do to enhance the opioid prescriber training the ADA is already making freely available to member and non-member dentists? (ADA.org/opioids)

Response: The series of webinars that CDC will be creating will be archived and made publicly available free of charge on CDC's website. CDC wants to ensure broad reach and use and will be sharing with partners, including provider organizations like the ADA, of their availability to encourage their respective constituencies to take advantage of these training opportunities.

Tamiflu Stockpile

The CDC has stockpiled a certain level of antivirals to treat a percentage of the U.S. population, according to the recommendations outlined in the National Strategy for Pandemic Preparedness. Our understanding is while the shelf life for most of the stockpiled antivirals is 10 years, a large portion of the stockpile will soon begin to expire. The primary antiviral stockpiled will be losing its patent later this year.

a. Is CDC working with generic manufacturers to replenish the stockpile?

Response: CDC proactively coordinates with supply chain partners to understand and assess commercial market conditions, production capacity, and the changing antiviral drug landscape. CDC is aware that in February 2017 Tamiflu® (oseltamivir) will no longer have product exclusivity. CDC is evaluating expiring inventory, costs of replacement product, shelf life, and the changing antiviral drug landscape, including generic product equivalents that may enter the market in the future before awarding new federal contracts to replenish expiring SNS oseltamivir inventory.

b. Are there concerns with generic manufacturers' ability to meet the needs of the US federal government?

Response: The ability to meet the volume of orders required for the Strategic National Stockpile is one concern that will factor into CDC's evaluation of available generic alternatives.

c. I know generics are appealing. However, I understand that in some cases they have more limited shelf life and other manufacturing capability limitations. I am assuming CDC has a process to look at the full cost, including impact on future replacement for these types of purchases, to ensure the tax payer gets the best long-term value. For example, since the current shelf life for pandemic Tamiflu is 10 years if a generic has a shelf life of only 2 years. How will CDC's factor the increased cost due to lower shelf life or more limited production capability in to the purchase decisions?

Response: CDC carefully prioritizes procurement decisions for all countermeasures, including antiviral drugs based on PHEMCE recommendations and will continue to utilize existing analytics and projection models. CDC uses the lifecycle cost of the product in decision-making – this takes into account cost of the product, projected shelf life of product, and ability to procure the necessary amount.

Centers for Disease Control and Prevention
Budget Hearing: CDC Director Thomas Frieden, MD, MPH
Questions from Rep. Harris
Wednesday, March 23, 2016

1. Opioid guidelines
    a. How will the CDC continue to advocate for patient access to non-opioid, multi-modal therapies such as interventional procedures?

Response: CDC, in collaboration with other HHS agencies, is working with public and private insurers to examine current coverage of non-pharmacological treatments for chronic pain as well as explore opportunities to expand coverage to include these therapies. In addition, CDC has created resources to help improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. Additional details, including effective approaches to treating chronic pain are available here - http://www.cdc.gov/drugoverdose/pdf/alternative_treatments-a.pdf

    b. Will the CDC encourage coverage for said therapies that will prevent patients from starting opioids and prevent opioid dose escalation?

Response: CDC is working closely with federal and non-federal partners to identify and offer strategies and tools for private and public insurers and their pharmacy benefit plan managers to foster implementation of the guideline through proactive use of claims information and improvement in coverage and service delivery payment models, with specific attention to non-opioid therapies for chronic pain. In addition to the tools and resources for providers, CDC is creating educational materials for patients which promote safer and more effective pain management. An example of such a resource is available here - http://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-patients-a.pdf

2. Zika

a) The Administration claims we will $250 million to address the increased FMAP (55 to 65%) to Puerto Rico and territories. Would you anticipate similar financial needs to other states in a comparable outbreak situation?

Response: Unlike states, Medicaid funding in territories is capped, which has limited their capacity to respond to emerging health needs such as Zika. In addition, territories receive less federal matching funds from Medicaid than they would if treated like states. The proposal to increase the FMAP in territories by 10 percentage points to address Zika would not be counted toward current Medicaid allotments, which is the reason for the estimated $246 million cost. CMS does not need similar funding for states since their existing Medicaid programs are uncapped, and they can draw additional funds as appropriate if their costs increase related to the Zika outbreak. For both territories and states, the available federal matching percentage is a statutory determination and, as such, CMS does not have the flexibility to alter it.

b) Could you define what would be considered "other vector-borne diseases, or other infectious diseases and related health outcomes" as referenced in the FY16 Zika Supplemental?

Response: Zika is the latest in a series of unpredicted, and unpredictable, health threats. What is predictable is our need to prepare by strengthening the ability of countries around the world to find, stop, and prevent health threats when they first emerge. CDC is still discovering more, literally every day, about Zika and its health effects, including microcephaly, and Guillain-Barrè Syndrome. We are working around the clock to find out as much as we can, quickly inform the public, and do everything we can to reduce the risk to pregnant women.

c) Could any of this funding be used to pay for Title X Clinics?

Response: The Administration's request for $1.9 billion for Zika response as emergency spending in FY 2016 does not include funding for direct payments to Title X clinics.

d) Could any of this funding be used for the President's Emergency AIDS Relief or related HIV/AIDS spending?

Response: The proposal requests funding "to prevent, prepare for, and respond to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes, domestically and internationally." It would not be used to supplant existing funding, such as the funding provided for international or domestic HIV/AIDS through PEPFAR or CDC's annual appropriation.

3. Community Preventive Services Task Force and Community Guide
    a. As you know, support and funding for the Community Preventive Services Task Force and the Community Guide has been eliminated by Congress. The FY 16 House Report stated quite clearly that "the Committee does not provide support for the Community Guide or the operations of the Community Prevention Services Task Force." Can you affirm that since no funds were provided through the Prevention & Public Health Fund that the Task Force will not be funded in 2016? If, for some reason, the Guide or Task Force were funded, could you elaborate why it was funded, under what authority, and from where the funds were drawn?

Response: Prior to FY 2014, PPHF funding was allocated by the Secretary of Health and Human Services, with some funds being allocated to the Community Guide activity. Starting in FY 2014, Congress directed the transfer of PPHF for specific activities, and no longer included the Community Guide in those transfers. CDC continues to support Congressionally mandated activities related to the Task Force on Community Preventive Services through our Public Health and Scientific Services budget authority.

Community Guide Funding History: Fiscal Years 2009-2015				
Fiscal Year	PHSS Budget Authority (BA)	Prevention and Public Health Fund (PPHF)*	Funds received from other CDC programs and Federal Agencies for specific activities	Total Funding
FY 2015	$4,144,000	$0	$1,558,000	$5,702,000
FY 2014	$4,030,000	$0	$1,095,000	$5,125,000
FY 2013	$1,465,000	$7,400,000	$68,800	$8,933,800
FY 2012	$800,000	$10,000,000	$200,000	$11,000,000
FY 2011	$1,400,000	$7,000,000	$0	$8,400,000
FY 2010	$1,754,000	$5,000,000	$660,000	$7,414,000
FY 2009	$1,773,000	N/A	$860,000	$2,633,000
* Starting in FY 2014, PPHF Funds were directed by Congress, and no PPHF fund were directed to the Community Guide.				

b. Is CDC part of any Inter-Agency Agreements related to the Community Guide, Community Preventive Services Task Force, or their funding? If so, could you please provide the text of these agreements?

Response: CDC has an Inter-Agency Agreement (IAA) with the Oak Ridge Institute for Science and Education (ORISE) to secure scientific expertise to assist in conducting a wide range of systematic effectiveness reviews, systematic economic reviews, and dissemination and evaluation activities. CDC also has current IAAs with three federal agencies that provided funding in past fiscal years for work in areas of programmatic interest to them. Descriptions of all IAAs are provided below.

HHS Office on Women's Health (OWH) IAA – CDC received funds in FY15 and work is in progress.
This Interagency Agreement between OWH and CDC aims to create a women's health focus area in the Guide to Community Preventive Services (referred to as the "The Community Guide"); to increase the knowledge of public health practitioners of how to improve women's health using community based interventions. This will entail creating communication materials which are a compilation of existing women's health focused prevention recommendations in The Community Guide; and, identifying a women's health issue, which will be the topic of a systematic review led by CDC scientists under the oversight of the Community Preventive Services Task Force (Task Force).

NIH IAA – CDC received funds in FY15 and work is in progress.
The proposed project is an expansion of efforts to update existing Community Guide obesity reviews and to expand the portfolio of reviews to provide a more comprehensive representation of interventions, with a focus on interventions to reduce childhood obesity.

NHTSA IAA – CDC received funds in FY13 and funded activities completed in FY 14 (October 2013); No active projects since October 2013.

This funding supported the preparation of additional systematic reviews of motor vehicle injury prevention programs for inclusion in the Guide to Community Preventive Services.

4. How has the CDC interacted with the FDA in relation to the proposed guidance on laboratory-developed tests? Does CDC feel public health laboratories will be able to meet the diagnostic needs of the patient population in relation to the Zika virus?

Response: Recently, 77 laboratories (65 domestic public health labs covering all 50 states and DC, and 12 Department of Defense labs) received Trioplex Real-time RT-PCR Assays (Trioplex rRT-PCR), which is appropriate for use in the identification of Zika virus RNA in acute serum, cerebrospinal fluid (CSF), urine, or amniotic fluid. CDC Zika IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA), can be used to detect recent Zika exposure within 2 to 12 weeks. Zika MAC-ELISA reagents have been distributed to 39 public health and Department of Defense laboratories in 30 States, DC, and the USVI. Ten of the 39 laboratories verified their capability to test for Zika using MAC-ELISA. Numbers of tests that can be performed per laboratory per week vary based on number of staff, available instrumentation, and resources.

CDC is facilitating testing for Zika virus and working to distribute test kits to qualified laboratories in the Laboratory Response Network (LRN). The LRN is an integrated network of domestic and international laboratories that can respond to biological and chemical terrorism and other public health emergencies and are able to perform testing to detect and report cases. On the biological side of the LRN, there are currently more than 150 member laboratories, representing all 50 states, Australia, Canada, the United Kingdom, Mexico and South Korea.

Now that the CDC has two diagnostic assays that were reviewed by the FDA under the Emergency Use Authorization (EUA) process, other manufacturers may also seek EUAs for their tests for Zika virus. Commercial product manufacturers are working with the FDA to develop and submit applications for emergency use of diagnostic tests for the Zika virus. FDA is actively engaged with CDC, the National Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority (BARDA) to advance the development of diagnostic tests, vaccines, therapies, and donor screening and pathogen reduction technologies for blood products to help mitigate the Zika virus outbreak.

At this time, CDC's testing capacity is keeping pace with demand. In preparation for a possible increase in demand, a CDC laboratory based in Atlanta has been trained and equipped to accept specimens for MAC-ELISA testing. If CDC detects a further increase in demand, it can expand capacity through training of additional staff at CDC and within state and local health departments. CDC also partners closely with the Association or Public Health Laboratories, (APHL), which can also assist with expansion of laboratory capacity. Finally, availability of a commercial manufacturer would also assist with capacity.

5. MCMs and SNS
   a. I appreciate your responses regarding coordination among BARDA and CDC. I worry about potential gaps in preparedness by conflicting stockpiling authorities within BARDA and CDC. Can you please describe the process CDC uses to coordinate with BARDA the

ongoing stockpiling of medical countermeasures? What could be done to improve this process to ensure critical investments made by BARDA do not go to waste?

Response: BARDA and CDC currently participate in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to achieve a coordinated vision and action on medical countermeasures intended for the SNS. The current PHEMCE governance process provides clear directives for stockpiling goals, including products developed by BARDA, some of which will be added to the SNS when there is enough data available to use the product under an Emergency Use Authorization (EUA) or Investigational New Drug (IND), or if the product is FDA-approved. For each fiscal year, CDC receives clear guidance from PHEMCE on the prioritization of capabilities and requirements for the SNS in the SNS Annual Review. The recommendations in this report provide the foundation for CDC procurement decisions and strategy for the SNS, and includes guidance on the BARDA-developed countermeasures held in the SNS. Through the interagency work on the PHEMCE Multiyear Budget, and more recently, the Multiyear Budget Report to Congress, CDC and BARDA work closely to identify the products added to the SNS under BARDA contracts that will be transitioning to CDC responsibility and then establish financial projections for CDC requirements to support such products.

b. Could you comment on the expanding role of the SNS in preparedness?

Response: In 1998, Congress appropriated funds for CDC to acquire a pharmaceutical and vaccine stockpile to counter potential biological and chemical threats that could affect large numbers of persons in the civilian population. The program was originally called the National Pharmaceutical Stockpile program, but on March 1, 2003, became the Strategic National Stockpile (SNS) program and now includes not just drugs but medical supplies and medical equipment required to protect America's public health and safety from multiple hazards (terrorist attack, earthquake, emerging infectious disease threats such as flu, Ebola, Zika). As defined in 42 U.S. Code § 247d–6b, the Secretary is "directed to maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency."

c. The program was designed for bioweapons and expanded to all hazards, emerging infectious disease, and pandemic influenza. During Katrina, H1N1, and Ebola, the SNS played an important role in providing personal protective equipment, vaccines and antivirals. Due in large part to BARDA's successful advanced development efforts we now have next generation products which need to be stockpiled in the event of a deliberate chemical or biological attack. Given the SNS' very broad role in preparedness but its somewhat limited resources, how are you ensuring that the critical investments made by BARDA do not go to waste?

Response: CDC constantly strives to make the most efficient use of limited resources, thereby maximizing the government's investments in SNS. Through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) governance process, of which CDC is a core HHS member,

CDC collaborates with PHEMCE to develop future procurement strategies and priorities, and informs the establishment or adjustment of MCM requirements across the enterprise. Two goals of enterprise participation are to ensure that no MCM development or procurement investments are wasted, and to maintain the MCM capabilities developed to meet established and validated requirements for the SNS.

While CDC ensures that the SNS is prepared to respond in support of state and local partners whenever needed, this does not mean that CDC needs to hold every MCM in the SNS. CDC is also leveraging public-private collaborations to reach more efficient solutions to stockpiling. CDC staff are actively engaged with the commercial medical supply chain to identify and implement new solutions to meet MCM needs in an emergency with the resources available, whether in stockpiles such as the SNS or in commercial supplies across the nation.

6. 317 immunization program proposed reductions—Does CDC have evidence of decreased demand? If so, could you elaborate on this evidence?

Response: The FY 2017 Budget request includes a decrease of $50.339 million for the Immunization Program. This decrease will be targeted to vaccine purchases. Health insurance expansion increases access to immunizations and is expected to decrease the number of uninsured and underinsured individuals in need of discretionary Immunization Program vaccine for routine immunizations.

Prior to the ACA, CDC's discretionary vaccine purchase was primarily targeted towards meeting the needs of underinsured children not able to access vaccines through the Vaccines for Children Program. At that time, approximately 11 percent of young children and 20 percent of adolescents were underinsured with respect to vaccines. The ACA requirement that private insurance plans cover vaccines without any cost to the beneficiary when provided by an in-network provider has significantly decreased the size of this population; our current estimates are that 5 percent of young children and 11 percent of teens are underinsured. As a result, CDC now prioritizes the use of discretionary vaccine purchase for vaccinating underinsured adults and for use in outbreak response.

Department of Labor, Health and Human Services and Education and Related Agencies
Budget Hearing: CDC Director Frieden
Questions from Rep. Roby
Wednesday, March 23, 2016

The past couple years have been challenge for CDC as far as laboratory safety is concerned. It was unprecedented, based on our knowledge, to have three laboratory events related to potential exposure of anthrax, Ebola, and the Bird Flu virus. Much work has been done to correct these safety hazards, but I hope we can both agree that much work is yet to be done.

An observation from the Report of the Advisory Committee to the Director of the CDC, a review by a group of independent biosafety experts, from 2014, stated:

"The results of the Culture of Laboratory Safety survey indicate that a significant percentage of CDC staff have concerns about experiencing negative repercussions . . . as a result of reporting incidents involving exposures to pathogenic organisms or other hazardous materials."

A follow-up observation from October 2015, a year later, suggests that these deficiencies still persist:

"There is still some apprehension about the possibility of retribution if staff, especially contractors, report accidents or safety concerns. Consequently, there is a need to work on building trust in the reporting processes and resultant management response. There is also the sense from some staff that a significant portion of the CDC reaction to the accidents has been in the form of increased paperwork and that signing a form does not necessarily lead to a fundamental improvement in safety culture."

Questions:

- Will you commit to totally ending any remnants of a culture of fear around reporting accidents at the CDC? What steps will you take to build trust among your staff?

Response: Open, immediate reporting of incidents and near misses is integral to the culture of safety CDC is building in its laboratories. The agency is absolutely committed to ensuring that staff are encouraged to report and they have no fear of reprisal for doing so.

Laboratory staff are required by CDC policy to report all incidents and ensuring this requirement is fully and easily met by staff is a CDC priority. CDC continues to reinforce the message that reporting incidents is a part of everyone's job and there will be no adverse action for reporting unsafe conditions or incidents. Incident reporting is the subject of an upcoming internal communication campaign aimed at ensuring that all CDC staff are aware of this requirement, know there is no disciplinary consequences for reporting, and understand the importance of reporting to protect their colleagues and the public. Since the establishment of OADLSS, incidents and near misses have been reported to OADLSS in a timely way, indicating that staff feel able to report as required.

- Is there any information that you could share from the report this committee directed you to produce by this April that could clarify any new standard operating procedures you have developed to address laboratory safety?

Response: The upcoming Report to Congress highlights the number of standard operating procedures and protocols reviewed by the Laboratory Safety Review Board, or LSRB. The LSRB is a key laboratory safety reform and addresses one of the major issues identified in the safety reviews following the 2014 incidents.

The LSRB is composed of laboratory experts and leaders from across the agency and is charged with reviewing every single protocol for the transfer of biological materials out of high-containment laboratories. The board reviews every transfer protocol from across the agency every year. The board also provides a rigorous review of any new or amended protocols for the transfer of biological materials out of high containment laboratories. Virtually every aspect of these protocols is scrupulously examined to ensure that best practices are followed and ensure the policies address any potential risks posed by the inactivation and transfer of the materials. The Report to Congress will highlight that in its first year of operation, the LSRB reviewed 82 transfer protocols; 43 existing protocols and 39 new or amended protocols.

- Also, please feel free to elaborate on any planned steps that would enhance and support laboratory safety and training in your 2017 budget request.

Response: The President's Budget for FY17 includes a request of $5.0 million to further advance CDC's efforts to improve safety across all of its laboratories and build a modern, well-trained laboratory workforce prepared to meet the scientific and safety challenges of today. This increased investment would allow CDC to acquire:

- Data analysis to make laboratories smarter and safer: With this new investment CDC would make key upgrades to laboratory information technology systems to streamline reporting, tracking, and analysis of potential safety issues.
- Continued advances in laboratory training: With the FY17 investment CDC could continue its major modernization and reimagining of its laboratory training curriculum. The investment would facilitate the creation of new, high-quality and interactive courses that would strengthen key safety competencies among CDC's broad and diverse laboratory workforce.
- Advanced calibration of laboratory technology: CDC would also use this investment to enhance calibration of laboratory equipment to sharpen the quality of laboratory results and reduce costs by increasing efficiency of critical laboratory procedures.

CDC Hearing: Director Frieden
Questions from Rep. Dent
Wednesday, March 23, 2016

Hepatitis:

- Please tell the subcommittee about CDC's implementation of hepatitis C screening activities. The committee has made recommendations in the past about the role of rapid, point-of-care testing. How are grantees able to utilize this technology that provides a result in about 20 minutes to intervene effectively and start the process of referral to care and treatment? Would the additional funding recommended in the budget proposal help CDC carry out more hepatitis C screening activities?

Response: CDC estimates that of the approximately 3.5 million people living with hepatitis C, at least 50 percent do not know they are infected. Therefore, many hepatitis C-infected persons have not even received the most basic care, including assessments of infection, liver health, and potential benefit from treatment. The availability of a rapid test for hepatitis C virus (HCV) antibody and other strategies enables wider access to testing in settings such as physician offices, hospital emergency departments, health department clinics, and substance use disorder settings; however, follow-up testing is needed to determine whether someone is currently infected with hepatitis C. To improve the HCV testing, care, treatment, and cure of affected persons (also known as the care cascade), CDC is supporting community-based programs, known as Test and Cure Hepatitis C, which strengthen primary care provider capacity to diagnose and cure hepatitis C infection among populations most impacted. A priority of these activities is building testing, care, and treatment capacity in settings that serve low income communities and persons who would have otherwise limited access to health care. Because of advances in treatment, with a modest increase in capacity to improve hepatitis testing, linkage to care, and treatment, implementation of CDC and U.S. Preventive Services Task Force (USPSTF) recommendations for HCV testing will save an estimated 321,000 lives.

Zika:

- We all want to know more about how public health officials are responding to the threat of the Zika virus. Certainly diagnostics are an important part of this discussion. How would the development of a rapid, point-of-care screening tool fit into this emerging challenge?

Response: CDC recognizes the expertise and authorities that exist across the federal government and is collaborating with many agencies in order to effectively detect, prevent, and respond to Zika virus. We are working around the clock to provide test kits and reagents to designated public health laboratories nationwide and to ensure these laboratories achieve the proficiency required to test for Zika virus.

In response to a request from the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Trioplex Real-time RT-PCR (Trioplex RT-PCR) assay on March 17, 2016. The Trioplex RT-PCR assay is a diagnostic tool for Zika virus that allows doctors to tell if an individual is currently infected with chikungunya, dengue, or Zika using one test, instead of having to perform three separate tests to determine which infection one might have. CDC will begin distributing the test during the next two weeks to qualified laboratories in the Laboratory Response Network, an integrated network of

domestic and international laboratories that respond to public health emergencies. The test will not be available in U.S. hospitals or other primary care settings.

There are currently 28 laboratories in 21 states, DC and Puerto Rico that have validated the RT-PCR assays for Zika virus, meaning they have the capacity to test for Zika virus.

These laboratories are located in the following states/territories: Arkansas; California; Conneeticut; District of Columbia; Florida; Hawaii; Kentucky; Louisiana; Maryland; Massachusetts; Maine; Minnesota; Nebraska; New Hampshire; New York; New Mexico; Nevada; Ohio; Oklahoma; Puerto Rico; South Carolina; Tennessee; Texas

Colon Cancer:

- The committee supports a robust national program at CDC for colon cancer prevention and education. Please tell the subcommittee about the status of this program and progress made to reduce colon cancer and improve screening rates.

Response: Colorectal cancer (CRC) is the second leading cause of death from cancer in the United States. There is substantial evidence that screening for CRC reduces incidence of and death from the disease. Screening for CRC can both detect disease early when treatment is more effective and prevent cancer by finding and removing precancerous polyps. Of individuals diagnosed with early stage CRC, more than 90% live five or more years. The U.S. Preventive Services Task Force recommends screening average risk adults aged 50-75 years for colorectal cancer with either: 1) fecal occult blood test (FOBT) or fecal immunochemical test (FIT) annually, 2) colonoscopy every 10 years, or 3) flexible sigmoidoscopy every 5 years with FOBT or FIT every 3 years. Despite strong evidence to support CRC screening, currently, only 65% of adults report being up-to-date with CRC screening, with more than 22 million age eligible adults estimated to be untested. Individuals who don't live in a city, Hispanics, adults aged 50-64, men, American Indians/Alaska Natives, and people with lower education and income are less likely to be screened. Lower rates of screening directly contribute to disparities in CRC morbidity and mortality. To reduce CRC morbidity, mortality, and associated costs, use of CRC screening tests must be increased among age-eligible adults with the lowest CRC screening rates.

In 2015, CDC funded a new five-year cooperative agreement titled, "Colorectal Cancer Control Program (CRCCP): Organized Approaches to Increase Colorectal Cancer Screening." The purpose of the CRCCP is to increase colorectal cancer (CRC) screening rates among an applicant-defined target population. The priority population for the CRCCP are populations with an age range of 50-75 years with CRC screening rates lower than the state or national overall screening rate. The program has two components:

Component 1: Funding for this component is used to implement priority evidence-based interventions (EBIs) and other supporting strategies in partnership with health system clinics to support organized approaches to CRC screening.

Component 2: Funding for this component is used to provide direct screening and follow-up services for a limited number of individuals aged 50-64 in the program's priority population who are

asymptomatic, at average risk for CRC, have inadequate or no health insurance for CRC screening, and are low income.

Thirty grantees received CRCCP awards including 22 states, 1 tribal organization, and 7 universities. All 30 grantees received component 1 funding while six of these also received funding for Component 2. During their first program year, grantees have been conducting start-up activities to establish agreements with partner health systems, develop implementation plans with these partners, and assess CRC screening rates and other data for baseline measurement.

To date, approximately two thirds of CRCCP grantees have shared baseline data from partner health systems clinics. Overall, 226 clinics from a total of 78 health systems have been recruited for participation in the CRCCP (Component 1). These clinics represent nearly 441,000 patients aged 50-75 and nearly 2,000 primary care providers. Approximately 71% of the clinics are federally qualified health centers (FQHCs). The primary screening test used at this clinics is the fecal immunochemical test (FIT, 40%) and colonoscopy referral (34%). The average baseline CRC screening rate for clinics is approximately 35%. Recruitment of partner health systems and their clinics will continue for the duration of the 5-year grant period. Therefore, we anticipate that program reach will expand considerably over time. CDC is providing extensive technical assistance to grantees to support program start-up and early implementation. A comprehensive evaluation, led by CDC, has been planned and is underway. The evaluation will include annual collection of CRC screening rates for every participating clinic so that we can closely monitor our primary outcome which is to increase screening. Component 2 grantees will submit patient level data for all persons screened with program resources. These data will be analyzed to assess the extent and quality of screening through the CRCCP.

In addition to the Colorectal Cancer Control Program (CRCCP), CDC has implemented a national media campaign, Screen for Life: National Colorectal Cancer Action Campaign, for more than 15 years, to educate the public about the importance of CRC screening for people aged 50 to 75 years. To extend its reach at the local level, CDC partners with all 50 state health departments, two tribal organizations, and the District of Columbia in providing Screen for Life campaign messages and materials that can be locally branded and tailored to specific populations.

Our program of applied research has identified problems in the quality of some CRC screening services. To address this issue, CDC created a comprehensive continuing education program for primary care providers and endoscopists to improve quality of CRC screening among our programs and beyond. The "Screening for Colorectal Cancer: Optimizing Quality," Continuing Medical Education course was released in March 2015. Providers across the country are using this program to learn about the optimal ways to implement CRC screening.

Working with funded investigators through CDC's Prevention Research Center program, CDC also continues to investigate barriers to the use of CRC screening tests among specific populations and evaluate the effectiveness of innovative approaches to increasing CRC test use. For example, two grantees currently are testing a mailed stool test program aimed at increasing CRC screening among low-income and underserved populations.

Tamiflu:

- The initial efforts in 2005-2008 to prepare for and fund the National Strategy for Pandemic Influenza cost billions of dollars. As part of this plan, the NSPI recommends to have enough influenza antivirals stockpiled to treat 25% of the U.S. population. Tamiflu, one of the primary antivirals stockpiled, has a shelf life of 10 years. With this stockpile beginning to expire, is the CDC planning to replenish it? If so, what is the estimated cost?

Response: The following table shows current antiviral products expiring between FY 2016 and 2022 as well as the projected replacement costs for each fiscal year.

		Projected Replacement Costs (millions of dollars)						
Medical Countermeasure Treatment	**Product in inventory Expiring 2016-2022 *(treatment courses)***	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Oseltamivir (Tamiflu) 75 mg capsules	38.0M	.00	.00	.10	20.14	33.98	251.83	184.03
Oseltamivir (Tamiflu) 45 mg capsules	3.2M	.00	.00	.65	1.33	.77	1.26	1.31
Oseltamivir (Tamiflu) 30 mg capsules	11.8M	.00	.00	1.27	1.76	3.29	1.67	4.27
Oseltamivir (Tamiflu) Oral Suspension 12 mg/ml, 25ml bottle	0.99M	.00	7.73	.00	.48	.00	.56	1.55
Zanamivir (Relenza) 5 mg blisters	16.4M	90.64	72.95	31.81	.00	.00	37.19	122.37
Total		**90.64**	**80.68**	**33.83**	**23.71**	**38.04**	**292.51**	**313.53**

Projected product replacement costs for every product held in the SNS will vary from year to year based on the amount of product expiring, product purchase costs, eligibility of product extension through the Shelf Life Extension Program, and changes in product requirements or procurement recommendations from PHEMCE. The projections for oseltamivir replacement in FY 2017 and beyond are based on the most recent purchase price for the product, and will be adjusted as pricing information becomes available for the commercially available oseltamivir products. CDC will continue to evaluate expiring inventory, costs of replacement product, shelf life, and the changing antiviral drug landscape, including generic product equivalents that may enter the market in the future before awarding new federal contracts to replenish expiring SNS oseltamivir inventory. As the procurement strategy to meet requirements for oseltamivir are refined, CDC will continue to update the projected requirements for antiviral products.

- Tamiflu, which makes up 80-85% of the stockpile, is losing its patent exclusivity this summer. Is SNS planning using generics to replenish the stockpile. If so, is the agency considering other factors, such as a dedicated domestic supply chain, or product shelf life?

Response: No decisions have been made on replenishment of oseltamivir inventory. As part of pandemic planning efforts CDC is assessing future replenishment options for stockpiled oseltamivir. Evaluation of replenishment for expiring oseltamivir inventory will consider multiple factors including costs of replacement product, shelf life, and understanding the changing antiviral drug landscape, including generic product equivalents that enter the market in the future and ability to meet demands.

CDC relies on the acquisition of goods and services to fulfill its mission. Therefore, proactively coordinating with supply chain partners to understand and assess commercial market conditions and production capacity is an important part of our ongoing work. Procurement of new product and replenishment of expiring SNS product requires balancing budgetary limitations with market availability and production.

Since 2004, HHS has maintained open communication with both Genentech and GSK manufacturers of oseltamivir and zanamivir in the United States to understand the products' seasonal and pandemic availability and manufacturer surge capacity. This information is proprietary in nature, but factored into HHS' planning and response for pandemic influenza antiviral needs. In addition, understanding the changing antiviral drug landscape is part of pandemic planning efforts.

Department of Labor, Health and Human Services and Education and Related Agencies
Budget Hearing: CDC Director Dr. Thomas Frieden
Questions from Rep. Roybal-Allard
Wednesday, March 23, 2016

Cancer Prevention

While the proposed Moonshot to Cure Cancer is a laudable goal, the American Cancer Society estimates that half of all cancer deaths could actually be prevented. By simply eating well, being physically active and maintaining a healthy weight, and avoiding tobacco and too much sun exposure, Americans could prevent a third or more of all cancer cases each year. Additionally, early detection of cancer through screening is well documented to reduce mortality from cancers of the colon and rectum, breast, cervix, and lung; and there is strong support for prostate screening in successful treatment of early prostate cancer.

For these reasons I was very disappointed to see that your FY17 budget actually proposes significant cuts to cancer prevention programs, including a $40.8 million reduction for Breast and Cervical Cancer activities, a $3.8 million decrease in Colorectal Cancer screening activities, and the elimination of all funding for prostate cancer screening.

Questions:

1. What role do you believe that the CDC, as our nation's chief public health and prevention agency, should play in the Cancer Moonshot proposal?

Response: CDC is committed to being a leader in nationwide efforts to ease the burden of cancer. Through its Division of Cancer Prevention and Control (DCPC), CDC works with national cancer organizations, state health agencies, health care systems and providers, and other key groups to develop, implement, and promote effective strategies for preventing and controlling cancer. Areas where CDC can play a critical role in supporting the Cancer Moonshot include the following:

- Strengthening Cancer Registries: The National Program of Cancer Registries (NPCR) is one of CDC's most complete and sophisticated disease surveillance systems, efficiently and cost-effectively collecting information on the vast majority (96%) of cancer cases diagnosed in the US. When combined with data from the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER), reporting of cancer incidence and mortality is available for the entire U.S. population. Cancer is the only notifiable chronic condition, and the cancer registry data serve as a census of all cancer cases used to define and monitor burden at the local, state and national levels; to investigate patterns of cancer treatment; and to evaluate the effectiveness of public health prevention efforts. This data system will be invaluable in monitoring and evaluating the impact of nearly all prevention or treatment initiatives funded through the Moonshot to Cure Cancer initiative.

- Coordinating Public Health Action: The cancer burden is not equally distributed, with some groups experiencing disproportionate incidence, later stage diagnosis, and lower rates of survival. For example, survival for white women with breast cancer is longer than for black

women. Coordination across health and public health sectors is needed to address disparities in cancer, including improving health literacy, increasing screening, ensuring adequate follow-up and quality care, coordination of care for multiple chronic conditions and supporting the needs of cancer survivors. CDC's state programs have demonstrated ability to reach some underserved and underrepresented populations through well-established partnerships, outreach efforts, and other innovative means. These programs provide education on cancer risk and symptoms using culturally-appropriate means, and initiate systems-level changes, such as the use of patient navigation, to assist with early diagnosis and timely treatment of cancer.

- Supporting Evidence-Based Public Health Action: A significant proportion of cancers can be attributed to behavioral factors such as tobacco use, obesity and weight gain, alcohol use, UV exposure, , and lack of physical activity. CDC supports state and local public health agencies in creating healthy environments, empowering people to make healthy choices, and improving preventive health services to prevent new cancer cases and improve survival among cancer patients and cancer survivors.

- Connecting Health Care and Public Health: CDC's work in cancer prevention and control enhances the effectiveness of preventive health services and treatment. Over the past 25 years, CDC cancer programs have built strong capacity within the clinical care system and developed partnerships with key stakeholders at the national, state and local level. In particular, we work closely with other chronic disease programs to coordinate efforts to reduce common risk factors such as tobacco use and build the evidence base for effective public health efforts. This capacity can be leveraged to educate the public, providers and partners about new research as well as translate research and community-based interventions into practice to improve cancer prevention and control on a population level.

2. If we were not able to meet the 2010 Healthy People cancer screening goals with your more robust budgets in Fiscal Years 15 and 16, how will your significantly reduced FY17 budget be adequate to address cancer prevention, especially in minority communities?

Response: As more Americans become insured, CDC is embracing new roles and expanding existing roles to increase cancer screening on a population level. CDC's screening programs, The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the Colorectal Cancer Control Program (CRCCP), are working to ensure the most vulnerable continue to have access to screening, while increasing focus on broader public health activities that can help all adults (insured and uninsured) overcome barriers to screening. This goal can be achieved by expanding key public health roles such as public education and outreach; provision of screening services and care coordination; quality assurance, surveillance and monitoring; and strategies to enable more organized systems of care.

In particular, both the NBCCEDP and the CRCCP program are focused on working with health systems to implement evidence-based interventions (EBIs) initiatives that increase screening among both the newly insured and those who remain un- and under-insured. Evidence-based interventions proven to be effective in increasing cancer screening include provider-oriented EBIs such as reminder systems that send messages to providers to remind them to make a screening recommendation, and assessment and feedback to providers about their performance in meeting

specific benchmarks (e.g. assessing cancer screening rates among their client population). The EBIs also include patient-oriented strategies such as small media to increase awareness about screening, written or telephone reminders to clients due for screening, and efforts to reduce structural barriers that impede screening (e.g., expanding clinic hours). Additionally, CDC is enhancing targeted outreach to disadvantaged populations with low screening rates; supporting cancer screening, follow-up and treatment through patient navigation; and tracking screening and follow-up to assure quality standards are met.

Cancer disparities continue to be a challenge in the US. The largest disparities today are between the insured and uninsured. One of the overarching goals of HP 2020 is to achieve health equity, eliminate disparities, and improve the health of all groups. With available resources CDC will continue its efforts to meet these goals.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Folic Acid Fortification of Grains and Corn Masa

For many years the Congressional Hispanic Caucus has been working with the March of Dimes and the American Academy of Pediatrics to get Corn Masa fortified with Folic Acid in order to reduce the elevated incidence of neural tube defects among Hispanics. It looks like the FDA will soon approve a petition to allow this fortification, and hopefully that will result in a significant decrease in spina bifida and anencephaly in our communities.

Concerns have been raised by some groups, however, that recent recommendations by the USDA to prioritize the consumption of whole grains in the American diet, and mandate 100% whole grains in the school meal programs, could result in lowering the intake of fortified grains and reverse the progress we have made in reducing neural tube defects.

The CDC has been a leader in research, tracking and prevention of neural tube defects for over two decades. Your folic acid education program can take much of the credit for progress we have made in raising awareness of the importance of dietary folic acid for all childbearing women, and lowering the incidence of these birth defects. So your insight on these issues is critical for us to hear.

Questions:

1. How does the natural folate in whole grains compare with the levels found in enriched products, and for women of childbearing age, what are your recommendations about the consumption of whole grains vs. enriched grain products?

Response: Studies have shown that there are many health benefits associated with consuming whole grains. Because of those health benefits, CDC supports the Dietary Guidelines for Americans' recommendation that at least half of grain consumption be whole grains and we support USDA's rule that 100% of grains in school lunches should be whole grain-rich (at least 51% whole grain). Because of those health benefits, CDC supports the recommendation by the USDA to prioritize the consumption of whole grains in the American diet. Commercially prepared whole wheat bread has about one-fourth the dietary folate equivalents (unit used to combine and compare natural food folate and folic acid in foods) of enriched white bread. If dietary patterns shift from enriched products to whole grain products, we would anticipate a reduction in folic acid intake. Consideration should be given to using the FDA rule used to add folic acid to breakfast cereals and corn masa flour to add folic acid to whole grains if dietary patterns shift away from enriched cereal grains toward whole grain products. The CDC recommendation follows the 1998 IOM recommendation that women capable of becoming pregnant should take 400 micrograms of synthetic folic acid daily, from fortified foods or supplements or a combination of the two, in addition to consuming food with natural folate from a varied diet.

2. What outreach docs CDC have planncd for Hispanic communities once the FDA approves corn masa fortification?

Response: CDC will continue to collaborate with partners in industry and advocacy to increase awareness of the importance of folic acid intake for the prevention of birth defects. In addition, we will continue monitoring neural tube defects and blood folate concentrations among women to assess the impact of corn masa flour fortification.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Maternal Mortality

Despite really significant progress reducing infant mortality and teen pregnancy rates - for which the CDC deserves a lot of credit, we haven't seen the same rate of progress in reducing maternal mortality rates and other critical indicators of women's health.

Questions:

1. What is CDC doing to expand efforts around safe motherhood?

Response: A critical role for CDC reducing maternal mortality rates and improving other indicators of maternal health is conducting surveillance to better understand chronic disease risk factors and conditions that put women and infants at risk for health problems. These surveillance efforts are conducted through a number of different systems.

Pregnancy Risk Assessment Monitoring System (PRAMS)
In FY 2017, CDC will continue to fund a cooperative agreement that supports PRAMS surveillance at 50 sites—representing approximately 90% of all U.S. live births. PRAMS is a joint surveillance project between CDC and state health departments that collects state-specific, population-based data on maternal attitudes and experiences before, during, and shortly after pregnancy, including chronic disease risk factors and conditions. The PRAMS program helps to:

- Identify factors that put women and infants at risk for health problems
- Monitor access to care and services
- Identify trends in in behavior and health status
- Measure progress in improving the health of mothers and infants

Data from PRAMS have been used to monitor and research a variety of chronic disease risk factors and conditions, including trends in smoking before, during, and after pregnancy; estimates of postpartum depression; pre-pregnancy obesity; gestational weight gain; and gestational diabetes.

National Assisted Reproductive Technology (ART) Surveillance System (NASS)
Under Congressional mandate, CDC collects data from all fertility clinics in the United States and calculates standardized success rates for each clinic. This gives a potential ART user an idea of their average chances of success. While ART relieves the burden of infertility for many couples, it presents significant public health challenges due to the substantial risk for multiple birth delivery, which is associated with poor maternal and infant health outcomes. For this reason, CDC considers it vital to monitor the safety and effectiveness of ART procedures in the United States. Based on preliminary 2014 data from CDC's National ART Surveillance System, there were 173,362 ART cycles performed at 460 reporting clinics in the United States during 2014 for which we would expect a resulting preganacy or birth, resulting in 57,332 live births (deliveries of one or more living infants) and 70,352 live born infants. http://www.cdc.gov/art/nass/index.html

2. What do you see as the best opportunities for progress in reducing maternal mortality in this country?

Response: Each year, more than 600 women die as a result of pregnancy or delivery complications in the United States. The number of reported pregnancy-related deaths steadily increased from 7.2 deaths per 10,000 live births in 1987 to a high of 17.8 deaths per 10,000 live births in 2011. The most severe complications of pregnancy, generally referred to as severe maternal morbidity (SMM), affect more than 50,000 women every year. Like pregnancy-related mortality, the burden of SMM has been steadily increasing. There was a 26.1 percent increase in SMM rate between 2008 and 2011. Rises in pregnancy related-death and SMM are likely driven by a combination of factors, including improved identification, increases in maternal age, increases in cesarean delivery, pre-pregnancy obesity, and pre-existing chronic medical conditions. The consequences of increasing SMM prevalence are wide-ranging and include higher health service use, higher direct medical costs, extended hospitalization stays, and long-term rehabilitation. Variability in the risk of death by race, ethnicity, and age indicates that more can be done to understand and reduce these tragic events.

CDC is working to:

- Increase our knowledge of the leading causes of maternal death and morbidity and their risk factors.
- Build capacity of states to collect and use information on maternal mortality and pregnancy complications.
- Reduce maternal mortality and high risk complications of pregnancy stemming from chronic conditions.

Pregnancy Mortality Surveillance System (PMSS)
The PMSS collects data on women who died while pregnant or within 1 year of the end of pregnancy from all 50 states, the District of Columbia, and New York City. These data are used to describe conditions that lead to death, identify risk factors for pregnancy-related deaths, and identify disparities in death rates. These national surveillance data drive interventions to improve maternity care. For example, PMSS data show three causes—maternal hemorrhage, hypertension in pregnancy and pulmonary embolism (blood clots in lung)—comprise approximately 30% of pregnancy-related deaths. These data inform ongoing quality of care improvement initiatives. Our partners (American Congress of Obstetricians (ACOG), Society for Maternal Fetal Medicine (SMFM), and Council on Patient Safety in Women's Health) have used these data to inform initiatives to prevent maternal mortality.

Surveillance of Severe Maternal Morbidity (SMM)
In a joint effort to reduce mortality and the burden of complications, CDC has begun surveillance on severe maternal morbidity. By studying these more common severe events, we hope to gain better insight into processes of maternity care that can be improved and monitor the effectiveness of such interventions.
http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/SevereMaternalMorbidity.html

Improving Maternal Mortality Review
The Maternal Mortality Review Data System (MMRDS) is a recent collaboration between CDC, the CDC Foundation, the Association of Maternal and Child Health Programs, and Merck for Mothers to produce stronger, standardized data on maternal mortality and to foster collaboration that can lead to effective interventions. For nearly 100 years, many states and jurisdictions have funded local groups of experts—known as maternal mortality review committees—to meet periodically to assess available data on maternal mortality and use those data to identify opportunities for preventing deaths among mothers. To date, the groups have worked largely independently, resulting in non-standard data collection and restricting information-sharing between committees. The new project will address both of these challenges. This collaboration will give us three critical outcomes: 1) A standard data-collection and analysis tool, called the Maternal Mortality Review Data System (MMRDS); 2) A web-based resource portal that will assist all states and jurisdictions in establishing or improving a maternal mortality review; and 3) A data report, expected in 2017, with information from all jurisdictions reporting data through MMRDS.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Prematurity

The United States has made tremendous strides in recent years to drive down the rates of preterm birth and infant mortality. In fact, the infant mortality rate decreased 2.3 percent to a historic low in 2014 and the preterm birth rate continues to decline from its peak of 12.8 percent in 2006. This promising progress is the result of strategic federal investments coupled with private sector commitments, such as the March of Dimes' Prematurity Campaign.

The CDC has played an important role in reducing prematurity with its Safe Motherhood Initiative. However, despite promising trends, there continues to be significant, persistent, and very troubling racial, ethnic, and socioeconomic disparities in the rates of preterm birth and infant mortality. Without addressing these disparities, the United States will be unable to build on recent gains.

Question:

1. Can you outline the actions CDC will take to reduce these disparities and improve birth outcomes for all Americans?

Response: CDC is working with partners to reduce health disparities associated with preterm birth and infant mortality by improving the quality of maternity care and health outcomes for women and newborns. We also work with states to monitor risk factors associated with infant deaths at less than one year of age which helps states develop targeted prevention and intervention strategies. CDC also assigns epidemiologists to state, local, and tribal levels to support epidemiologic research and provides scientific information to improve maternal and child health programs and policies. Some examples of these activities include:

Perinatal Quality Collaboratives (PQCs)
In FY 2017, CDC will continue studying preterm birth to better understand its impact and advance new strategies for prevention by funding six state-based Perinatal Quality Collaboratives (PQCs) in California, New York, Ohio, Illinois, Massachusetts, and North Carolina. PQCs include hospitals, pediatricians and neonatologists, obstetricians and perinatologists, midwives, nurses, and state health department staff. Since the initiation of the PQCs in FY 2011, grantees have accomplished the following:

- The California PQC has shown a 57% decrease in the percentage of elective deliveries (37-38 weeks gestation). This PQC has also seen a 12% reduction in severe complications among women with severe preeclampsia/eclampsia.
- The New York State PQC has shown a 92% decrease in elective deliveries (36-38 weeks gestation) including an 86% decrease in labor inductions and a 94% decrease in scheduled C-sections without a medical indication.
- The Ohio PQC saw an estimated cost savings of over $27.789 million associated with a shift (from 37-39 weeks) of 48,400 births to 39 weeks gestation or greater and a 68% decline in the rate of deliveries less than 39 weeks without a medical indication.

Recognizing the value that PQCs can bring to improving perinatal health, CDC recently worked with experts to develop a resource guide to help develop and advance the work of state PQCs: *Developing*

and Sustaining Perinatal Quality Collaboratives: A Resource Guide for States. The guide includes information about starting a state-wide collaborative, launching initiatives, data and measurement, sustainability, and links to other useful resources for perinatal quality improvement work.

Sudden Unexpected Infant Death (SUID) Case Registry
The SUID case registry monitors risk factors associated with infant deaths at less than one year of age and provides comprehensive information about the circumstances associated with these deaths to develop targeted prevention and intervention strategies and improve medical and legal practices. In FY 2017, CDC will fund 12 states to implement the SUID Case Registry: Arizona, Colorado, Louisiana, Michigan, Minnesota, New Jersey, New Mexico, New Hampshire, Wisconsin, Alaska, Kentucky, and Pennsylvania, to improve data collection on infant deaths and promote consistent reporting of SUID cases.

The Maternal and Child Health Epidemiology Program (MCHEP)
The MCHEP program assigns epidemiologists to state, local, and tribal levels to support epidemiologic research and provides scientific information to improve maternal and child health programs and policies. In 2016, 13 senior MCH epidemiologist assignees and 11 fellows from the Council of State and Territorial Epidemiologists were working in 15 public health agencies or institutions.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard
Hepatitis

There are over 5 million people with hepatitis B or C in the United States and well over half of that number are not aware of their infection. Clearly we don't do enough testing, our surveillance system is weak, and there is very little public education about Hepatitis in our country.

The CDC budget is just $34 million for the entire nation, which translates into a very small amount of money for each state to actually carry out all the necessary work to combat such a serious and sometime fatal infectious disease. Sadly, we are witnessing a dramatic increase in cases of acute hepatitis C across the country. And, the number of annual deaths from hepatitis C now surpasses all 60 other nationally notifiable infections conditions combined.

Question:

1. The Administration has requested to increase hepatitis prevention at the CDC by $5 million in FY2017. Will that be enough funding to deal with the current situation we have in the U.S?

Response: The FY 2017 President's Budget proposes a $5 million increase to help stop disease transmission and reduce hepatitis B and hepatitis C related disability, mortality, and healthcare costs, for a total request of $39 million. With this increased investment, CDC will:

- Strengthen detection, investigation and response to new HBV and HCV infections
- Establish a regional health training and technical assistance center
- Accelerate adoption of HBV and HCV testing and treatment of persons living with viral hepatitis
- Support the development of up to two model projects for the elimination of HCV transmission and related mortality throughout an entire state, tribal area, or local community.

Aligned with the priorities of the *HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, the goals of the proposal are to:

- Enhance viral hepatitis prevention efforts that will prevent viral hepatitis deaths and stop the hepatitis C epidemic among young people in highly affected states
- Reduce mother-to-child transmission of hepatitis B and hepatitis C

To achieve these goals, CDC will:

- Ensure viral hepatitis prevention core capacity exists in each state to strengthen coordination of policy and program development, and use data to improve programs, the quality of care provided to patients, and to track progress toward achieving prevention goals
- Strengthen professional education to expand the number of providers prepared to test and treat persons living with hepatitis B or hepatitis C
- Enhance targeted programs in states reporting the largest increases in new HBV and HCV cases to prevent disease transmission
- Improve access to recommended hepatitis B testing in states with large numbers of persons born in Asia or Africa, and hepatitis C testing, care, and treatment services in states with large numbers of residents born from 1945-1965 and young persons at risk
- Improve policies and programs to eliminate mother-to-child transmission of hepatitis B

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

National Diabetes Prevention Program

The National Diabetes Prevention Program works to reduce the rising epidemic of type 2 diabetes by ensuring the availability of low-cost, highly successful diabetes prevention programs in local communities across the country, including two sites in my district – the Downey Family YMCA and the Lindora Weight Loss and Wellness Center, also in Downey. While I am pleased there are now over 1,000 National Diabetes Prevention Program sites nationwide, I am eager to see the National Diabetes Prevention Program implemented in even more communities in California and others across the country, which have been hard-hit by the diabetes epidemic.

Questions:

1. Given its incredible promise, what are the agency's plans to expand the number of National Diabetes Prevention program sites and individuals, particularly in underserved areas highly impacted by diabetes, participating in the National Diabetes Prevention Program in FY 2017?

Response: The National Diabetes Prevention Program (National DPP) works to make it easier for people with prediabetes to participate in affordable, high-quality lifestyle change programs to reduce their risk of type 2 diabetes and improve their overall health. To date, the National DPP has reached almost 50,000 eligible participants across 48 states and D.C. Sixty commercial health plans are covering the lifestyle change program, and state employees are covered in nine states. Over 8,000 lay and professional coaches are using a CDC approved curriculum to deliver the program. Average weight loss for participants attending at least four sessions was 4.9%.

In the FY17 President's Budget request, CDC proposes to use $20 million for National DPP to continue to expand and scale up the National DPP to reach those at greatest risk. Selected activities include:

- Extending our investment in the six national organizations funded under the Preventing Type 2 Diabetes among People at High Risk cooperative agreement for an additional year to further expand program delivery and work with employers and insurers toward sustainable funding/coverage for the program.
- Exploring messaging and partnership opportunities with state medical societies to increase physician screening, testing, and referring of people with prediabetes to CDC-recognized lifestyle change programs.
- Developing an initial suite of training and technical assistance materials (e.g., tools, training, online resources) to support CDC-recognized program delivery organizations and grantees by enabling CDC to reach a larger audience than is currently possible through individual technical assistance.
- Conducting market research to inform the development of a National DPP Customer Service Center and a marketing framework to provide strategic direction for National DPP communication and messaging to priority audiences.

2. Given that there are currently 86 million people with prediabetes, do you have an estimate of the resources needed for the National Diabetes Prevention Program to confront the human and economic pain diabetes exacts on our country beyond FY 2017?

Response: The FY 2017 President's Budget request of $20 million for the National DPP is level with the FY 2016 appropriation. This proposed funding level is in conjunction with the recent HHS announcement that a DPP model tested in Medicare meets the criteria for expansion under the Social Security Act, meaning that the Centers for Medicare & Medicaid Services can implement DPP nationwide as a service available to Medicare beneficiaries. The Medicare expansion, if fully implemented, would result in a significant increase in the population eligible to participate in CDC-recognized lifestyle programs and a commensurate need to further build out the National DPP infrastructure to handle the growth and meet any new requirements imposed by CMS under the expansion

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard
Tuberculosis

CDC recently released data showing the first increase in tuberculosis (TB) cases in the US in over 20 years. As you know, we are seeing more multi-drug resistant cases of tuberculosis, and the December 2015 release of the National Action Plan for Combating Multidrug-Resistant Tuberculosis (MDRTB) will be critical to addressing this crisis.

Questions:

1. Can you explain the causes for this increase in TB cases?
2. Do state TB control programs have the resources needed to reverse this trend and put us back on track to eliminating TB in the US?
3. What is the status of the implementation of the National Action Plan to Combat Multi-Drug Resistant MDRTB? Why does the budget proposal feature the action plan, yet fail to provide the funding to implement the plan?

Response: CDC's most recent TB surveillance data show that, following 20 years of progress toward TB elimination, the rate TB incidence has leveled off in the United States at approximately 3.0 new cases per 100,000 people. From 2014 to 2015, the number of U.S. TB cases increased from 9406 to 9563. This represents 157 excess cases, or a 1.7 percent increase in case count. Twenty-nine states and the District of Columbia had an increase in cases between 2014 and 2015. Of those states, some contributed more significantly to the overall U.S. case count increase of 157 cases; for example, Texas had 65 more cases in 2014 than it did in 2015.

Although further evaluation is needed, modeling suggests that even if the previously observed annual declines in the United States had been sustained, TB elimination would not occur by the end of this century. Approximately one percent of the annual number of cases of TB are multi-drug resistant. This percentage has remained constant since 2009.

Resuming declines in TB incidence in the United States will require enhancing our current comprehensive public health approach toward TB Elimination. More emphasis should be placed on strengthening U.S. systems for detecting and treating latent TB infection and interrupting TB transmission, as well as accelerating reductions in TB globally. Finally, more emphasis should be placed on interrupting the relatively limited, but persistent, ongoing TB transmission (e.g., among persons experiencing homelessness) in the United States, as well.

State and local health departments have critical responsibilities in the control and elimination of TB in the United States. CDC provides funding via cooperative agreements to support TB elimination in 50 states, 8 major U.S. cities (New York City, Houston, Baltimore, San Francisco, San Diego, Philadelphia, Chicago, Los Angeles), the District of Columbia, and 8 territories. To make the most of federal resources for TB elimination, CDC allocates funds to states or jurisdictions via a formula based on a rolling, 3-year average number of TB cases by state, which are weighted to account for complexity of completing therapy for those cases, for example, among persons experiencing homelessness, substance abuse, or incarceration, or are HIV-infected.

The National Action Plan is intended to promote greater investment and coordination of U.S. Government resources to reduce the domestic and global risk of MDR-TB and to encourage other bilateral and multilateral donors, the private sector, and affected countries to invest additional resources in these important actions.
CDC's Division of TB Elimination will lead activities for achieving the goals of the Domestic section (Goal 1):

- Lay groundwork to upgrade TB surveillance, nationwide, to ensure complete and accurate detection of drug-resistant TB
- Explore ways to strengthen state and local capacity to prevent transmission of drug-resistant TB and create surge capacity for drug-resistant TB contact investigations
- Explore ways to ensure that patients with drug-resistant TB receive treatment until cured; potential options include creation of a small national TB stockpile of drugs, providing treatment options for those individuals with no medical home, and strengthening management of transnational cases

In addition, CDC will carry out activities in support of the Plan's research goals (Goal 3):

- Evaluate treatment regimens to treat drug-resistant TB
- Build evidence base for developing strategies to assure completion of therapy
- Study correlates of progression from TB infection to active disease
- Assess shorter MDR-TB regimens using existing TB drugs

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

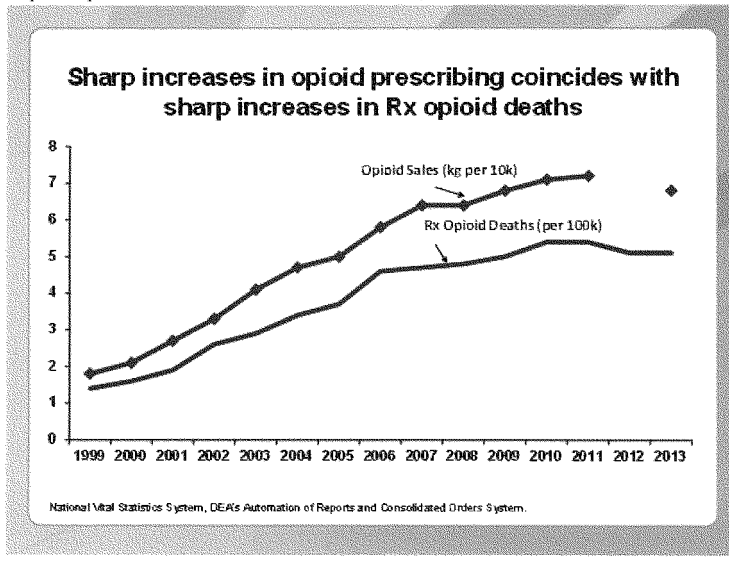
Opioids

The CDC recently released the guideline for prescribing opioids for chronic pain, which discussed the effectiveness of non-pharmacologic, behavioral and psychosocial interventions for chronic pain.

Questions:

1. What is the state of the science on opioid prescribing practices?

Response: Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2013 but there has not been an overall change in the amount of pain Americans report[2, 3]. During this time period, prescription opioid overdose deaths increased similarly.



- Health care providers wrote 259 million prescriptions for opioids in 2012, enough for every American adult to have a bottle of pills[4].
- The supply of prescription opioid pain relievers remains high in the U.S[5]. An estimated 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings[3].
- From 2007 – 2012, the rate of opioid prescribing has steadily increased among specialists more likely to manage acute and chronic pain. Prescribing rates are highest among pain medicine (49%), surgery (37%), and physical medicine/rehabilitation (36%). However, primary care providers account for about half of opioid pain relievers dispensed[3].

2. What is CDC doing to make sure information on evidence-based non-pharmacologic treatments, administered alone or in combination with pharmacological intervention, are effectively disseminated to those who could make use of the information?

Response: CDC is working with public and private insurers to examine current coverage of non-pharmacologieal treatment for chronic pain as well as explore opportunities to expand coverage to include these therapies. In addition, CDC has created resources to help improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. Additional details, including effective approaches to treating chronic pain are available here - http://www.cdc.gov/drugoverdose/pdf/alternative_treatments-a.pdf.
CDC is working with partners to disseminate these tools and resources, including public and private insurers, health systems, and professional organizations.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

National Early Child Care Collaboratives

The National Early Child Care Collaboratives Program provides funding to 10 states to promote healthy eating and physical activity in Early Care and Education (ECE) settings. This program has a strong footprint in my district, and we have seen firsthand the impact the Collaboratives are having for our constituents. Analyses across three cohorts have shown statistically significant increases in adoption of best practices among participating centers.

Questions:

1. What are some of the most effective strategies for promoting best practices for healthy eating and physical activity that this program has helped to reveal?

Response: CDC's ECE program is based on a 'Spectrum of Opportunities' framework that helps states consider how best to embed obesity prevention standards and support for implementing these standards into components of their ECE system. Several components of a state's ECE system can be used to support ECE facilities in their jurisdictions to achieve recommended standards and best practices for obesity prevention. Strategies include:

- Finance: States can set standards for federal funding and require or incentivize ECE providers that receive subsidies to implement obesity prevention policies and programs as a condition for participation.
- Licensing and Administrative Regulations: Regulations and enforcement standards vary considerably by state. States can change licensing and regulations to require or encourage the inclusion of key components of CDC's ECE program.
- Quality Rating and Improvement Systems (QRIS): Through QRIS, states define what constitutes a higher quality of care based on designated criteria. QRIS is often linked to child care subsidy reimbursement rates, licensing and administrative regulations as a baseline to define what constitutes improved quality, and enhanced training, professional development, qualifications, and program accreditation.
- Child and Adult Care Food Program (CACFP): CACFP can work by enhancing state CACFP standards to align with other national nutrition guidelines such as the U.S. Dietary Guidelines for Americans.
- Pre-service and Professional Development: States can set standards for credentialing and continuing education credits for professionals which will prepare and maintain professionals for the field.
- Early Learning Standards: As state agencies create new or revise existing early learning standards, opportunities exist to emphasize nutrition, physical activity, and screen time.

2. What strategies have specifically targeted changes in ECE centers that serve high numbers of racial and ethnic minorities? Have linguistic or cultural adaptations been made to the curriculum or model?

Response: The National Early Child Care Collaboratives Program worked with states to follow recruitment procedures that targeted ECE Centers serving low-income children (e.g. centers serving subsidized children; Head Start programs; and programs participating in the state's Child and Adult Care Food Program). Most materials are translated into Spanish.

3. What do you see as the future for the next phase of this program to continue to build upon its success and reach more children?

Response: Because of direct program support of over 1,400 child care institutions, the quality of care for over 145,000 children in 9 states' (Arizona, Florida, Indiana, Kansas, Kentucky, California, Missouri, New Jersey, and Virginia) has improved, and children in childcare have access to healthier food, increased time for physical activity, and reduced screen time. The current cooperative agreement will end in 2017. In 2018, CDC plans to enhance and improve the model based on what we've learned from the first round of funding.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Public Health Preparedness Grants

CDC recently informed states that the FY2016 Public Health Emergency Preparedness grants would be reduced and reallocated for the Zika response. LA County's Public Health Laboratory is part of the CDC's Laboratory Response Network. With cuts to PHEP funding, DPH will not be able to purchase needed chemical laboratory equipment, procure testing supplies, or hire bench scientists needed to perform chemical testing. This will lead to DPH's inability to perform chemical specimens locally, and sending chemical specimens to the state laboratory which could hamper timely analyses of chemical agents.

Questions:

1. Can you explain the CDC plan for this money, and how it will be allocated?

Response: The Administration requested $1.9 billion for Zika response as emergency spending in FY2016, including $1.5 billion for HHS, of which $743 million is for CDC. CDC activities for Zika include domestic vector control, surveillance and laboratory work, vaccine and diagnostic development and clinical trials, international support, and targeted support for states and territories.

CDC is continuing to pursue supplemental resources to support the US response to Zika. We hope Congress acts quickly to respond to this public health crisis. In the meantime, CDC had no choice but to use existing resources from our public health preparedness funding to support our most critical needs. These resources are critical to support short-term activities while we continue to work with the Congress to fund our Zika efforts and replenish resources directed from other sources.

Amongst other reallocations, this includes $44.25 million in FY 2016 funding from the Public Health Emergency Preparedness (PHEP) program. This is approximately 7% of the $612 million PHEP funding in FY 2016. The redirected funds will temporarily allow CDC to continue to work aggressively to combat the Zika virus outbreak in Puerto Rico and the U.S. territories.

In the meantime, CDC Zika response activities currently underway directly support state, local, tribal, and territorial health department response activities. These activities include such things as

- Improving surge laboratory testing capacity and laboratory training
- Deploying CDC staff to affected areas
- Providing vector control guidance and services
- Conducting maternal health surveillance and outreach, including implementation of a U.S. pregnancy registry
- Providing risk communications guidance and materials

2. Assuming cuts to PHEP (between 1 and 10%), what are you likely to do away with to absorb that cut?

Response: To support Zika activities, CDC had to reduce the PHEP awards by $44.25 million. Each awardee will have to determine how best to manage the cut based on their program and unique circumstances. In general, it will result in significant reductions in state and local public health emergency management and response capabilities, including staff layoffs at the state and local level. This includes well-trained, public health emergency managers, highly skilled laboratorians, epidemiologists, public health nurses, and risk/health communicators.

These public health first responders play key roles in responding to public health emergencies ranging from routine food-borne disease outbreaks to more catastrophic events such as influenza pandemics or other highly infectious disease outbreaks. Any lapses in PHEP funding affect state and local personnel and contracts, potentially resulting in staff layoffs. Rehiring staff can be difficult despite subsequent reimbursement of funds. CDC has requested reimbursement authority in the Zika supplemental request.

3. If a supplemental does not get approved, what are the implications for state and local all-hazards preparedness? If a supplemental is approved, will the FY16 PHEP be made whole?

Response: If the request for supplemental appropriations to fight Zika is not approved, then we are likely to see significant reductions in state and local public health emergency management and response capabilities, including the reduction of on-the-ground, first responder staff. The request for supplemental appropriations includes a request for reimbursement authority.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Environmental Health

The ongoing crisis in Flint, Michigan and the Exide Battery Plant contamination in Vernon, California have underscored the need to ensure that our communities are environments that support – not endanger – our health. Unfortunately the President's budget for FY17 proposes significant cuts to the National Environmental Public Health Tracking Network – the closest thing we have to an environmental public health surveillance system – which currently only funds half of our states. Additionally, the CDC Healthy Homes and Lead Poisoning Prevention program, which provides critical surveillance and monitoring of elevated blood lead levels, was level funded despite the fact that its current funding only allows for 35 state grants.

Question:

1. Can you tell me why the budget has proposed cutting the Tracking program?

   Response: The President's Budget request must balance a number of competing priorities. We recognize that the environmental health tracking network is critical to surveilling environmental health hazards such as lead poisoning. Although CDC is unable to support all states for environmental health tracking, we will continue to leverage program resources in order to protect citizens from public health threats.

2. How many states will receive funding for surveillance and monitoring of lead and other environmental hazards under your proposed FY2017 budget?

   Response: In FY 2017, CDC will begin a new 3-year, competitive cooperative agreement for 38 state and local health departments. These awards will emphasize primary prevention of lead poisoning through the elimination and control of lead hazards before children are exposed. Based on CDC-funded data collection, state and local health departments implement primary prevention interventions, including housing rehabilitation, housing and health code enforcement, early childhood programs, and engagement with clinical care. These interventions protect children who live in the highest risk housing in buildings, blocks, and neighborhoods.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Community Health Prevention – Program Evaluations

As a longstanding supporter of community health prevention and improvement programs at the Centers for Disease Control and Prevention (CDC), I was disappointed that the FY16 omnibus agreement removed the budget line for the Partnerships to Improve Community Health (PICH) program. Over the last decade there have heen a series of short term CDC investments in community health programs which begin with a lot of hype and then end without any true justification for their elimination. This has included three new community programs: Communities Putting Prevention to Work (CPPW), Community Transformation Grant (CTG), and Partnerships to Improve Community Health (PICH) programs, as well as seven iterations of the Racial and Ethnic Approaches to Community Health (REACH) Program. Of all these programs, REACH alone has been formally evaluated, with more than 150 journal articles documenting the achievements of REACH in reducing health disparities.

As we consider funding for FY17 and beyond, I believe this is an important time to consider these CDC investments in community health and what lessons we have learned that could help us design and fund evidence-based programs in the years to come.

Questions:

1. Does the Department, and CDC specifically, have immediate plans to release the CPPW and CTG data and any related taxpayer-funded evaluations or studies in the near future, and provide those findings to Congress and the public?

Response: CPPW Program Findings: CDC has been generating findings from the Communities Putting Prevention to Work (CPPW, 2010-2012) program.

- CPPW Publications: There are over 100 CPPW peer-reviewed publications that describe community-level interventions, key partnerships, and community impact. One recent study concluded that CPPW provided 45.2 million Americans with increased access to opportunities to be physically active; 40.9 million Americans with increased access to places with healthy food and beverage options; and 27.4 million Americans protection from secondhand smoke exposure. According to the study, if CPPW interventions are sustained through 2020 three core long-term results are expected: 14,000 chronic disease related deaths will be averted; $2.4 billion in health care costs would be averted; and $5.44 is the estimated savings for each dollar invested in the program.
- Community Based Interventions: Executive Summary. This report summarizes activities conducted as part of the CPPW program, technical assistance provided to awardees, local and national evaluation activities, major accomplishments, and lessons learned.
- Community Health Short- and Long- Term Findings and Benefits. This report summarizes short-term findings, projected long-term benefits of CPPW, and examples of published local evaluation findings from CPPW communities.
- Community Health Key Findings. This report includes background, success stories, and short- and long-term benefits of the program.

CTG Program Findings: Evaluation studies for the Community Transformation Grant program are currently being analyzed.

- Final CTG program data will be available September 2016. These data will show the impact of the investments in CTG funded communities, during the first three years of the five year program, in increasing access to healthy eating and physical activity opportunities, smoke-free environments, and access to cholesterol and blood pressure monitoring opportunities. Years four and five of the program were not funded.
- CDC expects to release a final report for CTG describing short-term and long-term benefits of the three year CTG investment by February 2017.

2. Are there specific plans in place to evaluate PICH grantees and release related data and studies in a timely fashion after they've completed FY16-funded activities?

Response: CDC will produce a final report of the impact of PICH interventions, specifically increased access to healthy eating and physical activity opportunities, smoke-free environments, and community-clinical resources. We expect completion of data collection for this study by September 2017. A final report will be available by Spring of 2018.

3. Given that the REACH program is the one community prevention program with strong documentation of its effectiveness, why does your budget propose a 40% reduction to the program, and how will the program adequately address health disparities with its reduced investment?

Response: The REACH program, first established in 1999, is CDC's flagship program to reduce racial and ethnic disparities, affecting change in areas of the country and among populations that experience the highest rates of chronic disease in the United States. REACH is one of only two CDC programs focused specifically on the needs, assets, and opportunities of racial and ethnic minorities and seeks to narrow the gaps in racial and ethnic disparities in chronic diseases and risk behaviors.

At the requested funding amount, REACH will continue to build upon its legacy of successfully reducing health disparities. REACH 2017 will use a collaborative model to bring community and anchor organizations together to implement evidence-based interventions to address upstream factors to reduce disparities and improve the health outcomes of racial and ethnic minorities, low income and rural populations.

The evidence base developed through the REACH program also informs investments in other CDC programs such as State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health that include a focus on addressing health disparities.

4. What do you hope to learn from yet another national evaluation of the REACH program, and how much of its proposed reduced investment will be directed towards this evaluation?

Response: CDC will conduct a national evaluation of REACH 2017 to measure community-level impact based on established health performance indicators. Components of this evaluation could include economic analyses, clinical data extraction from electronic medical records, and community data collection to understand the community context and program implementation factors. Awardees will conduct separate local evaluations in partnership with academic or research institutions to document the health impacts and cost savings resulting from program implementation. These findings will inform future investments in REACH as well as guide investments in other CDC programs. CDC will dedicate approximately 10% of REACH budget to evaluation.

Questions for the Record for Dr. Thomas Frieden from Rep. Roybal-Allard

Novovirus

In December the California Department of Public Health reported an increase in the reported cases of novovirus, and we have heard anecdotal reports from physicians that the virus appears to be causing significantly more severe symptoms this season.

Questions:

1. Since CDC launched CaliciNet in 2009 to collect information on norovirus strains, how many different strains of the virus have been identified? Has CaliciNet identified a new strain of the novovirus this year?

Response: Of the more than 30 different norovirus strains (genotypes), between 2009 and 2015 the majority (>50%) of outbreaks in the Unites States have been caused by a single type GII.4. In the current (2015-2016) winter this trend has been broken and several different strains have caused outbreaks with no single virus causing a majority of outbreaks. Overall, there is little evidence that certain strains cause more severe clinical symptoms than others.

2. Has there been an increase in novovirus-associated emergency department visits and /or hospitalizations this year?

Response: The New Vaccine Surveillance Network (NVSN) monitors year-to-year trends in pediatric norovirus-associated hospitalizations and emergency department visits. However, there are significant time lags in laboratory testing and data analysis. As such, NVSN data for the current year are not yet available. To assess norovirus activity in more real-time, CDC coordinates the Norovirus Sentinel Testing and Tracking Network (NoroSTAT). States participating in NoroSTAT provide reports of norovirus outbreaks to CDC within 7 business days of their initial notification. Based on outbreak data reported through NoroSTAT, the current year has exhibited below average norovirus activity relative to the past few years. During August 1, 2015 – April 23, 2016, 626 norovirus outbreaks were reported by NoroSTAT participants compared with an average of 799 (range: 755–855) norovirus outbreaks reported during the same time period in the 3 preceding years.

3. Your budget justification states that CDC exceeded the target of 28 states reporting to CaliciNet in FY 2015, representing an increase of 11 states reporting since FY 2014. Which states are currently not participating in this surveillance, and what needs to be done to reach 100% participation in the program?

Response: Currently all states and the District of Columbia have the ability to do their own norovirus testing and strain typing or are covered by any of 5 state-based CaliciNet Outbreak Support Centers or CDC.

While participation in CalciNet is at the discretion of the states, CDC worked with all 50 states to assure that each state can participate in CaliciNet, with about 40 states report norovirus outbreaks to CaliciNet annually. The remaining states that do not report are often states that are less densely populated and often have resource issues at the state level, or have no norovirus outbreaks reported.

4. How does the Norovirus Sentinel Testing and Tracking network that was established in 2012 interact with or enhance the CaliciNet surveillance efforts? Why are only 5 state health departments involved in this effort?

Response: The NoroSTAT network is made up of seven health departments that serve as sentinel sites for norovirus outbreak reporting to CDC's National Outbreak Reporting System (NORS) for epidemiologic data on outbreaks and Calicinet. These seven health departments report preliminary outbreak data to NORS and CaliciNet within seven business days of notification at the state health department, thus providing a near real-time assessment of norovirus outbreak activity among these sentinel states. The seven participating states are selected based on reporting performance and availability of funds. Other states still report outbreaks in NORS and CaliciNet but do not have to adbere to the same stringent reporting requirements as NoroSTAT participants. The current NoroSTAT states provide CDC with representative data when compared to the national level.

Department of Labor, Health and Human Services and Education and Related Agencies
Budget Hearing: CDC Director Tom Frieden
Questions from Rep. Barbara Lee
Wednesday, March 23, 2016

Viral Hepatitis

Question: Hepatitis infection rates are on the rise now, largely due to a spike in injection drug use fueled by an opioid abuse epidemic.. Thirty percent of people living with HIV are co-infected with Hepatitis C. This number jumps to 80% for injection drug users. Given this disturbing trend and emerging outbreaks of HIV and Hepatitis in places like Indiana more recently, I am seriously concerned about our overall response to hepatitis in the U.S.
The CDC hepatitis budget to address Viral Hepatitis in FY2017 is $39 million, which translates into a very small amount of money for each state to actually carry out all the necessary work to combat such a serious and sometimes fatal infectious disease.

How does the CDC plan to address the rising rates of viral hepatitis? Does this current level of funding give you what you need to accomplish the goals lined out for the CDC for combatting HIV/HCV co-infection that is included in the updated National HIV/AIDS Strategy?

Response: An estimated 3.5 million people in the U.S. are living with hepatitis C, and as many as 2.2 million people are living with hepatitis B. Adding to the large number of people living with hepatitis C and hepatitis B, approximately 53,000 new viral hepatitis infections occur each year. From 2010 to 2013, new HCV infections increased by more than 150% nationwide. Therapies are available that cure HCV infection in more than 90% of persons who complete treatment (8-12 weeks). However, up to 60% of people infected with HCV are unaware of their infection and even fewer are receiving appropriate care and treatment.

The FY 2017 President's Budget proposes a $5 million increase to help stop disease transmission and reduce hepatitis B and hepatitis C related disability, mortality, and healthcare costs, for a total request of $39 million. With this increased investment, CDC will:

- Strengthen detection, investigation and response to new HBV and HCV infections
- Establish a regional health training and technical assistance center
- Accelerate adoption of HBV and HCV testing and treatment of persons living with viral hepatitis
- Support the development of up to two model projects for the elimination of HCV transmission and related mortality throughout an entire state, tribal area, or local community.

Aligned with the priorities of the *HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, the goals for the proposal are to:

- Enhance viral hepatitis prevention efforts that will prevent viral hepatitis deaths and stop the hepatitis C epidemic among young people in highly affected states
- Reduce mother-to-child transmission of hepatitis B and hepatitis C

In addition, CDC is working on several fronts to address HIV and HCV coinfection. CDC has worked with HHS to develop guidance for syringe services programs (SSPs) to improve HIV and HCV

prevention for persons who inject drugs (PWID). More specific program guidance for CDC grantees is under development. CDC also conducted a national assessment to identify, based on available national indicators, counties in the United States that might be particularly vulnerable to outbreaks of HIV and hepatitis C virus (HCV) if those viruses are introduced into networks of people who inject drugs (PWIDs). The identification of vulnerability does not mean that an HIV or HCV outbreak is inevitable or that there is a current problem among PWID. Actual vulnerability will be better assessed by examining more detailed data that is available locally and may not be reported nationally. CDC shared information from this analysis with state health departments and encouraged them to assess evidence of risk in their jurisdiction, to ensure that venues likely to encounter persons who inject drugs offer HIV and HCV testing and to prepare an outbreak response plan if their assessment indicates a need to do so. Finally, CDC will working closely with HRSA's HIV/AIDS Bureau to implement the FY 2017 budget request to address HIV and HCV coinfection among persons served by HRSA's Ryan White program.

Chronic obstructive pulmonary disease (COPD)

Question: Chronic obstructive pulmonary disease (or COPD) is this nation's third leading cause of death, and a disease with which I am intimately familiar. CDC and NIH have embarked on the development of a Federal Action Plan for Chronic Obstructive Pulmonary Disease (COPD).

Can you tell us more about CDC's involvement in the establishment of a COPD Action Plan and how this budget request reflects that work?

Response: CDC has partnered with the National institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) in the past to support the dissemination of surveillance data, public health research findings, and messages about COPD. NIH and CDC are committed to raising awareness of COPD, and agree that a coordinated national approach is the best way to affect the course of COPD. In response to the Federal appropriations language of the 111th Congress, the NHLBI and the CDC laid the groundwork for such a plan. In 2011, the CDC released the Public Health Strategic Framework for COPD Prevention, which included NHLBI participation. In 2013, CDC released state-by-state fact sheets on COPD prevalence, a result of interagency collaboration between NHLBI and CDC on the Behavioral Risk Factor Surveillance System. In May 2013, the NHLBI hosted a forum on COPD in which participants from a number of federal agencies and the NIH Institutes shared information about their current COPD-related activities and discussed opportunities for further cooperation, collaboration, and enhanced effectiveness. A summary report of this meeting has been published on the NHLBI public website (http://www.nhlbi.nih.gov/research/reports/2013-copd-workshop.htm).

To further advance these efforts, the NHLBI and the CDC again assembled federal representatives of these agencies and Institutes in November 2014 with the additional participation of the National Institute of Nursing Research and the Agency for Healthcare Research and Quality to discuss progress in COPD-related activities and collaborations and to chart the next steps towards developing a National Action Plan. A consensus was reached that Healthy People 2020 (HP2020) respiratory objectives RD-11 (reduce hospitalizations for COPD) and RD-12 (reduce emergency department visits for COPD) were specific goals that warrant coordinated federal action. In late 2015, the NHLBI convened a meeting involving federal and non-federal stakeholders, including patients, to develop a

National Action Plan to coordinate activities targeting this disease, particularly those addressing these HP2020 objectives.

In 2016, NHLBI convened the COPD Action Plan Town Hall to discuss effective and efficient implementation of the National Action Plan for COPD, a complex, multifaceted disease with a high burden and cost. At this event, a number of critical issues were identified, including the importance of early detection and treatment of COPD to reduce preventable hospitalizations and improve quality of life and the important but under-used COPD case management strategies of pulmonary rehabilitation, smoking cessation, and physical activity.

CDC does not currently receive appropriations for COPD, including surveillance or implementation of the National Action Plan. Previous work on COPD was funded by the Community Health Promotion subline, which was eliminated in the FY 2016 Omnibus Appropriations Act.

Sickle Cell

Question: Dr. Frieden, according to the CDC, a study of 3,000 people with hemophilia showed that those who used a Hemophilia Treatment Center (HTC) were 40% less likely to die of a hemophilia-related complication. Surely, this model for comprehensive care should be applauded as a public health success. Unfortunately, those who suffer from another rare blood disorder, sickle cell disease, continue to struggle with community-based linkages to care and significant issues of morbidity and mortality. The President's FY17 budget requests $4.5 million in level funding for Public Health Approach to Blood Disorders.

Do you believe an effective parallel program for sickle cell disease could be established that mirrors (and possibly supplements) the hemophilia treatment center model facilitated through CDC?

How would such a sickle cell treatment centers program be structured from CDC's perspective, what other areas of HHS would such a program coordinate with, and what resources would CDC require to appropriately fund this new activity within the blood disorders program?

Response: An effective program could be established based on the basic Hemophilia Treatment Center (HTC) model. It should be noted that any such program must be tailored to the specific needs of the sickle cell population.

While some HTCs can easily integrate the appropriate provider expertise to incorporate SCD care, this would not apply to all HTCs across the nation. Stand-alone SCD care models should be part of the consideration.

If a comprehensive care model for SCD were to be implemented, CDC would work alongside other federal agencies, specifically HRSA. Significant investments to CDC for both financial resources and human capital would be required.

Tuberculosis

Question: Dr. Frieden, you have long been a champion of the fight against tuberculosis, both here at home – during your days as Health Commissioner in New York City – and abroad, while working in India with the World Health Organization. As the co-chair of the Bipartisan HIV/AIDS Caucus, I am well aware that the leading cause of death for people living with HIV worldwide is TB. Worldwide, and even here in the U.S., cases of multidrug resistant TB are increasing. The WHO has declared MDR TB a public health crisis, and the CDC itself has pointed out that states and localities often find themselves struggling to cope with shortages of TB medications and overwhelmed by just one case of MDR TB.

I applaud the Administration for releasing the long-awaited National Action Plan for Combating Multidrug-Resistant TB last December. Yet the FY2017 Budget Request for the CDC's Division of TB Elimination is for $142 million – the same as FY2016 enacted levels.

Given the release of the National Action Plan, is this level of funding adequate to tackle the challenge that TB poses to this country and the global community? And how is the CDC using the currently available funds to implement the new Action Plan?

Response: To effectively and fully address tuberculosis (TB) in the United States, we must address TB on both fronts: at home and around the globe. While the majority of cases of drug-resistant TB occur outside the U.S., TB is an airborne infectious disease. TB respects no national borders – TB anywhere is TB everywhere. The entire global community must move quickly to both improve the quality and effectiveness of proven (existing) tools and expand our current toolkit.

CDC's Division of TB Elimination will lead activities for achieving the goals of the Domestic section (Goal 1):

- Lay groundwork to upgrade TB surveillance, nationwide, to ensure complete and accurate detection of drug-resistant TB
- Explore ways to strengthen state and local capacity to prevent transmission of drug-resistant TB and create surge capacity for drug-resistant TB contact investigations
- Explore ways to ensure that patients with drug-resistant TB receive treatment until cured; potential options include creation of a small national TB stockpile of drugs, providing treatment options for those individuals with no medical home, and strengthening management of transnational cases

In addition, CDC will carry out activities in support of the Plan's research goals (Goal 3):

- Evaluate treatment regimens to treat drug-resistant TB
- Build evidence base for developing strategies to assure completion of therapy
- Study correlates of progression from TB infection to active disease
- Assess shorter MDR-TB regimens using existing TB drugs

Poorly functioning TB programs create drug-resistant TB faster than we can diagnose and treat it, which is a reason that CDC works closely with Ministries of Health and other key partners to strengthen the basics of effective TB prevention and treatment. We must do better with what we have, but we must also innovate. CDC has one of the largest contingents of TB experts in the world

developing innovative, data-driven approaches to find, cure, and prevent the disease globally. We are implementing new strategies to make existing tools more effective by developing:

- A gold standard for diagnosis of TB among children
- New drug regimens that are less toxic and less costly
- New and improved treatment approaches for pediatric TB

As a key implementer of National Action Plan, CDC is accelerating its global efforts to prevent, find, and cure drug-resistant TB on a number of fronts including:

- Strengthening the capacity of laboratories to diagnose MDR TB
- Establishing best practices to end MDR TB transmission in health facilities
- Intensifying collaboration with developers to speed up the discovery of an effective vaccine
- Continuing efforts to prevent MDR TB among those co-infected with TB and HIV—through PEPFAR

We also work closely with our public and private partners to make sure new tools and technologies are effective by:

- Developing real-world guidance on their use
- Training the public health workforce
- Evaluating impact of new tools and technologies on patients and programs

The need for global support remains, and the National Action Plan is intended to promote greater investment and coordination of U.S. Government resources and encourage greater investment from our private sector and public sector partners around the world. Bilateral and multilateral donors, the private sector, and affected countries should be encouraged to invest additional resources in these important actions.

WITNESSES

	Page
Collins, F. S	1
Fauci, A. S	1
Frieden, Thomas	215
Hodes, R. J	1
King, Hon. John	167
Lowy, Douglas	1
Skelly, Thomas	167
Volkow, N. D	1