DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2019

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

TOM COLE, Oklahoma, *Chairman*

MICHAEL K. SIMPSON, Idaho
STEVE WOMACK, Arkansas
CHARLES J. FLEISCHMANN, Tennessee
ANDY HARRIS, Maryland
MARTHA ROBY, Alabama
JAIME HERRERA BEUTLER, Washington
JOHN R. MOOLENAAR, Michigan

ROSA L. DELAURO, Connecticut
LUCILLE ROYBAL-ALLARD, California
BARBARA LEE, California
MARK POCAN, Wisconsin
KATHERINE CLARK, Massachusetts

NOTE: Under committee rules, Mr. Frelinghuysen, as chairman of the full committee, and Mrs. Lowey, as ranking minority member of the full committee, are authorized to sit as members of all subcommittees.

SUSAN ROSS, JENNIFER CAMA, JUSTIN GIBBONS,
KATHRYN SALMON, KARYN RICHMAN, and LORI BIAS
Subcommittee Staff

PART 6

Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PUBLISHING OFFICE

30–871 WASHINGTON : 2018

COMMITTEE ON APPROPRIATIONS

RODNEY P. FRELINGHUYSEN, New Jersey, *Chairman*

HAROLD ROGERS, Kentucky[1]
ROBERT B. ADERHOLT, Alabama
KAY GRANGER, Texas
MICHAEL K. SIMPSON, Idaho
JOHN ABNEY CULBERSON, Texas
JOHN R. CARTER, Texas
KEN CALVERT, California
TOM COLE, Oklahoma
MARIO DIAZ-BALART, Florida
CHARLES W. DENT, Pennsylvania
TOM GRAVES, Georgia
KEVIN YODER, Kansas
STEVE WOMACK, Arkansas
JEFF FORTENBERRY, Nebraska
THOMAS J. ROONEY, Florida
CHARLES J. FLEISCHMANN, Tennessee
JAIME HERRERA BEUTLER, Washington
DAVID P. JOYCE, Ohio
DAVID G. VALADAO, California
ANDY HARRIS, Maryland
MARTHA ROBY, Alabama
MARK E. AMODEI, Nevada
CHRIS STEWART, Utah
DAVID YOUNG, Iowa
EVAN H. JENKINS, West Virginia
STEVEN M. PALAZZO, Mississippi
DAN NEWHOUSE, Washington
JOHN R. MOOLENAAR, Michigan
SCOTT TAYLOR, Virginia

NITA M. LOWEY, New York
MARCY KAPTUR, Ohio
PETER J. VISCLOSKY, Indiana
JOSÉ E. SERRANO, New York
ROSA L. DELAURO, Connecticut
DAVID E. PRICE, North Carolina
LUCILLE ROYBAL-ALLARD, California
SANFORD D. BISHOP, JR., Georgia
BARBARA LEE, California
BETTY MCCOLLUM, Minnesota
TIM RYAN, Ohio
C. A. DUTCH RUPPERSBERGER, Maryland
DEBBIE WASSERMAN SCHULTZ, Florida
HENRY CUELLAR, Texas
CHELLIE PINGREE, Maine
MIKE QUIGLEY, Illinois
DEREK KILMER, Washington
MATT CARTWRIGHT, Pennsylvania
GRACE MENG, New York
MARK POCAN, Wisconsin
KATHERINE M. CLARK, Massachusetts
PETE AGUILAR, California

[1] Chairman Emeritus

NANCY FOX, *Clerk and Staff Director*

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2019

WEDNESDAY, APRIL 11, 2018.

NATIONAL INSTITUTES OF HEALTH

WITNESS

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

INTRODUCTION BY CHAIRMAN TOM COLE

Mr. COLE. Good morning, and welcome to the Committee on Labor, Health and Human Services, and Education to discuss the fiscal year 2019 budget request for the National Institutes of Health. We are looking forward to hearing the testimony from NIH Director, from Dr. Collins, an old friend of all of us here.

I am very proud that Congress again provided a significant increase in funding for the NIH in the fiscal year 2018 Omnibus. The Omnibus increased in the NIH's funding by $3,000,000,000, which was the second-highest annual funding increase in NIH history. Funding—don't expect that again, by the way. Okay? [Laughter.]

Ms. DELAURO. Why?

Mr. COLE. Why? Yeah. Well, I just want you to be surprised, if and when it happens.

The funding will accelerate the discovery of knowledge that will lead to new treatments and cures for diseases such as Alzheimer's, cancer, and heart disease. And while I realize your fiscal year 2019 budget request was submitted before Congress completed the fiscal year 2018 omnibus, I am still concerned that funding NIH at the requested level would prevent the United States biomedical research enterprise from achieving the progress we have begun to make with the past few years of funding increases.

I look forward to hearing about how the NIH is making use of the significant new investments in fiscal year 2018, as well as how the NIH will focus resources on its top priorities in the upcoming fiscal year. I hope to continue working with you to maintain the position of the United States as the world's leader in biomedical research.

I welcome, of course, Dr. Collins, the NIH Director, to the subcommittee. Dr. Collins is accompanied by five institute directors who can assist in answering specific Member requests. They are Dr. Anthony Fauci, the Director of the National Institute of Allergy

and Infectious Diseases; Dr. Ned Sharpless, the Director, new Director of the National Cancer Institute; Dr. Diana Bianchi, the Director of the National Institute of Child Health and Human Development; and Dr. Nora Volkow, the Director of the National Institute on Drug Abuse.

As a reminder to the subcommittee and our witnesses, we will abide by the 5-minute rule. And before I begin, I would like to yield to my good friend and my partner in this enterprise, the ranking member, the gentlelady from Connecticut, for any opening statement she cares to make.

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

And let me, too, welcome Dr. Collins, Director of the NIH; Dr. Fauci, Dr. Volkow, Dr. Sharpless, Dr. Bianchi. Thank you for being here this morning. It always is a glorious morning when the NIH comes before this committee with the great work that you do in saving lives. So—and we are going to talk this morning about funding for the NIH.

You know, the word "lifesaving" is thrown around a lot. But the work that you do at the NIH is absolutely lifesaving in a very, very profound way. One breakthrough at NIH can save potentially millions of lives over generations. That breakthrough can also heal the lives of many more loved ones, caretakers, and friends. That is what the NIH represents, and that is why your work is so critically important.

You all know that this is so personal to me as a survivor of ovarian cancer, and everyone on this subcommittee recognizes the importance of restoring NIH's budget.

I want to say a "thank you" to Chairman Cole, to all of the members of the Subcommittee for their great bipartisan work to boost NIH funding by $7,000,000,000 over the past 3 years. Last month, Congress showed once again that the NIH is a bipartisan priority by increasing its budget by $3,000,000,000 as a total of $37,100,000,000.

I am concerned about the Administration's 2019 budget, which would eliminate that entire amount. The proposal would take the NIH back to its fiscal year 2017 funding level, which is $3,000,000,000 below the level we just signed into law.

So, we cannot turn back the clock on lifesaving biomedical research. When we face a public health emergency, we often rely on NIH research to combat the tragic loss of life. For example, the flu has been particularly bad this season. According to the Centers for Disease Control, this year's flu has killed 142 children in the United States. In a given year, between 140,000 and 710,000 people are hospitalized due to the flu.

That is why we included a minimum of $100,000,000 in the Omnibus for research to develop a universal flu vaccine, and I am looking forward to hearing from Dr. Fauci about the National Institute of Allergy and Infectious Diseases and the plans to reach that important goal.

Now my grandfather died in 1918, died in 4 days with the Spanish flu, leaving a wife with 5 children and pregnant with a sixth child. So, it is completely unacceptable that over 100 years later, there are still thousands of people who are dying from the flu each year.

And under the current vaccine model, health officials are forced to predict what strains the annual flu should try to combat in any given flu season. We need to take the guesswork out of the equation by developing a universal flu vaccine, and we are relying on you to do that.

NIH has also been enlisted in a central role to help combat the opioid crisis. We provided an increase of $500,000,000 in the Omnibus bill for opioid-related research, including new advances in medication-assisted treatment, non-opioid pain relief. So pleased to hear that NIH is not wasting any time on this front and look forward to hearing from Dr. Volkow about the Helping to End Addiction Long-Term Initiative, otherwise known as the HEAL Initiative.

But I have to say that I am deeply, deeply concerned and that the President and Leader McCarthy are talking about reneging on last month's spending bill. If there is this view that we can rescind funding from the NIH or, for that matter, anywhere else in the Labor-H bill, I believe, collectively, we will fight to preserve those funds.

I think that to be driven by an extreme right wing of the party that we would break our word on last month's bipartisan bill is wrong. But I sometimes—and I don't know what other people's view on this is, you know, we and the administration fought to enact $2,000,000,000,000 in tax cuts for the wealthiest in the Nation and corporations and now trying to cut the programs that help middle-class families, low-income families, just families in the United States and work to save lives.

Under the omnibus we passed 2 weeks ago, the NIH would be able to fund an additional 2,000 to 2,500 grants this year. That is the direction that we need to be moving in. But a cut of $3,000,000,000, like the administration's proposal, reverses those additional grants, and a rescission would eliminate them immediately.

NIH is now funded at a nominal high of $37,100,000,000. That is thanks to the increase of $7,000,000,000 over the last 3 years. But funding is still below its historical peak. After accounting for 2018, NIH's budget is still nearly $5,000,000,000 below the 2003 level when adjusted for inflation. We need to go forward and not backward.

So we ought to be discussing how to fully restore NIH to the peak established in 2003, which is why I just reintroduced the Accelerating Biomedical Research Act, which would ensure stable, predictable growth for years to come. This sets us on a path of doubling the NIH budget, as we did in the late 1990s.

Finally, Dr. Collins, let me raise three quickly specific points. I strongly oppose the administration's proposal to transfer AHRQ, NIOSH, and I quite frankly don't know how to pronounce EEOICPA, and the National Institute on Disability, Independent Living, and Rehabilitation Research to become part of the NIH. These entities have independent missions that are different from NIH's mission.

AHRQ should remain in its own operating division, as the others, NIOSH and EEOICPA should remain at CDC and the Department of Labor, respectively. And the National Institute on Disability,

Independent Living, and Rehabilitation Research should stay at the Administration for Community Living, where it has a much better fit.

Second, I am concerned that the salary caps will force investigators to divert time from lifesaving research and instead will have to be spending money raising funds outside for their research. I am concerned that reducing investigators' salaries will further disadvantage academic research in comparison to what the private sector is offering in terms of salary. So I think the proposal needs further discussion.

Finally, I want to urge you in the strongest terms to renew the NIH's research initiative for gun violence prevention. Following the tragedy in Newtown, Connecticut—20 children, 6 adults were killed—the NIH launched a 3-year initiative to encourage research related to gun violence prevention. Unfortunately, the initiative was not renewed in 2017, and recent mass murders make abundantly clear that we need to continue this research.

Gun violence in the United States is an epidemic that kills more than 30,000 Americans every year. It is a crisis. Since Congress stopped funding research for gun violence in the 1990s, more than 600,000 Americans have been killed by firearms. We need to use every tool at our disposal to reduce the number of gun deaths.

And I want to provide all of my thoughts and all of my prayers, but that just is not enough. Secretary Azar has acknowledged that the Department of Health and Human Services has the authority to do the research. I would go further and say that HHS has the responsibility to do this research. So I urge you to act immediately and to renew gun violence prevention research as a top priority.

To all of the panelists, let me just conclude by saying you and the work that you do at the National Institutes of Health represents the power, the power, to do more good for people than anything else that is in the purview of the Federal Government. So I thank you for what you do, look forward to your testimony and to our opportunity to have a conversation.

Thanks very, very much. Thank you, Mr. Chairman.

DR. FRANCIS S. COLLINS OPENING REMARKS

Mr. COLE. You bet. Thank the gentlelady.

Just to advise the panel and the Members, I would expect that Chairman Frelinghuysen and I am sure Mrs. Lowey will probably be here as well. So, whenever they arrive, we will interrupt whatever we are doing for any statement that they care to make.

With that, Dr. Collins, the floor is yours for whatever opening statement you care to make.

Dr. COLLINS. Well, thank you, Chairman Cole, Ranking Member DeLauro, all the friends of NIH here today.

Once again, you have gone above and beyond in your support of NIH research and the patients for whom it brings healing and hope. On behalf of all of them, I am immensely grateful for your consistent support.

I spend a lot of time with early-stage researchers. Wherever I go, I set aside time to hear directly from them about their dreams, their ideas, and yes, their concerns. I know you, too, have met with many of them, both in your home districts—here I am with Con-

gressman Womack just last week—and also, Committee, on your much-appreciated visits to NIH, an example here where you were hearing from early-stage investigators about their hopes and dreams.

As we begin the process of implementing fiscal year 2018 budget and you begin considering the fiscal year 2019 request, it is a good time to think about those early-stage researchers and to ask what are we doing to foster this next generation of discovery, and what could we do to help our Nation remain the world leader in biomedical innovation? I believe the answers could be said to lie in certain key areas that we could call the five keys to success in science today.

They are, first and foremost, a stable trajectory of support, followed by a vibrant workforce, computational power—you might not have seen that one a few years ago, but you do now—new technologies and facilities, and perhaps most important of all, scientific inspiration.

The good news is that, thanks to you, early-stage researchers are now beginning to see and are totally energized by the concept of a stable trajectory of support. Your work over the last 3 years is helping us to begin to reverse a distressing decade-long decline in NIH's purchasing power for research and, of course, that research carried out in every State of the Nation. You have turned that around.

Strong, stable public support lies at the heart of NIH science and is absolutely vital to our second key to success, which is a vibrant workforce. Clearly, success cannot lie in simply boosting the number of grants made. It must also include increasing the number of creative minds, scientists, that are receiving those grants.

So look at this new metric that we are now using to evaluate success. This shows the trend in the number of individual principal investigators supported by NIH over the past 15 years. As you can see, that number is once again growing nicely. Note the surge that occurs around 2016, a surge that reflects when you began to change the trajectory of NIH support and shows how that investment in NIH science is starting to pay off.

[The information follows:]

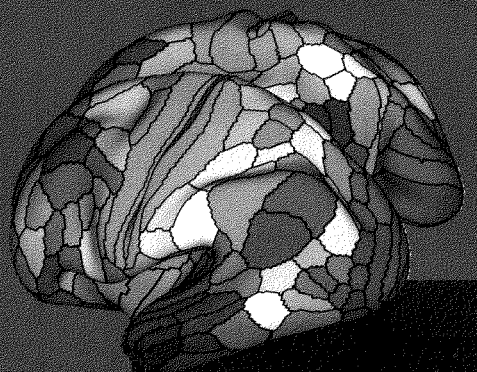
Vibrant Workforce
NIH Grant Awardees Over Time
Thousands of PIs
30
29
28
27
26
25
24
23
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
Fiscal Year

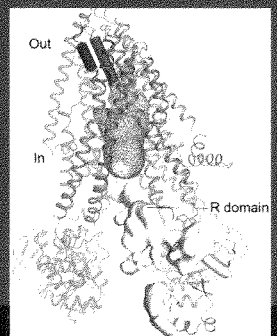
Dr. COLLINS. The third key to success is computational power. Like so much else, biomedical research has been transformed by the recent explosion in computing power and all of the big data that we are generating. For example, the BRAIN Initiative, which you have supported for the past 5 years, has created new imaging tools that are churning out troves of amazing data.

And there is also data generated by structural biology and microbiome research, not to mention at the bottom of the slide, the All of Us Research Program supported by your Precision Medicine appropriation. Very soon, All of Us will start enrolling 1 million Americans, or maybe more, producing an unprecedented amount of data on how individual differences in lifestyle, environment, and biological makeup can influence health.

[The information follows:]

Computational Power





All of Us RESEARCH PROGRAM

The Future of Health Begins With You

Enroll & Consent

Surveys

Baseline Measurements

Electronic Health Records

Apps, Phones & Wearables

Bio-Samples (Blood/Urine)

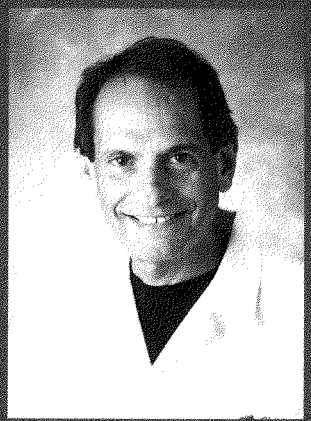
Dr. COLLINS. To realize the full potential of these and other resources, it is also necessary for us to develop new technologies and facilities. Now quite often, it is the technology itself driving the need for equally innovative facilities. Take the case of the new cell-based treatments, immunotherapy and gene therapy. Many involve removing cells from a patient's body, using technology to re-engineer those cells, and then returning them to the patient. The challenge is that many of our labs aren't set up to handle these highly individualized processes. So, it is critical we make upgrades to keep pace. The President's fiscal year 2019 proposal includes a much-needed increase in buildings and facilities to assist with that.

But now on to my favorite, scientific inspiration. I can assure you that NIH-funded researchers come to work every day full of innovative ideas and the wherewithal to see those ideas through. I could talk about this all day, but mindful of the clock, let me just share one example.

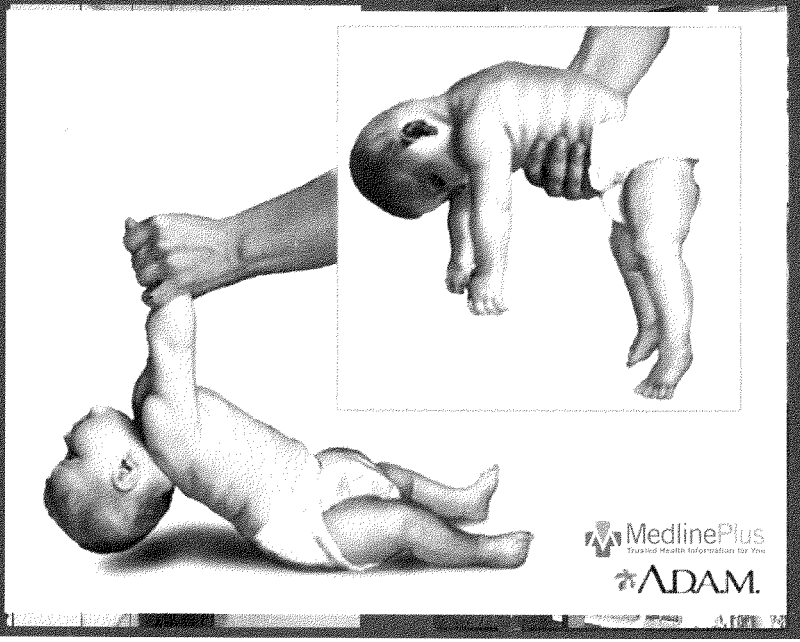
More than a decade ago, NIH launched a special project on spinal muscular atrophy, SMA, a rare and uniformly fatal inherited disease. In its most severe form, as you see here, it leaves babies floppy, unable to hold their heads up, to feed well, and eventually even to breathe. Death by 15 months is the tragic and universal result.

[The information follows:]

Scientific Inspiration: Gene Therapy for Spinal Muscular Atrophy



Jerry Mendell/Nationwide Children's Hospital, Columbus, OH



Dr. COLLINS. Now, 10 years ago, there was no treatment for SMA, but researchers had just discovered the DNA mutations that cause it. So NIH supported more research, working closely with patient advocates and industry to move promising leads into therapeutic development. One of the most exciting comes from Jerry Mendell's team at Nationwide Children's Hospital in Columbus, Ohio, which recently tested gene therapy in 15 infants with severe SMA. They infused a viral vector designed to deliver the normal gene to the spinal cord and held their breath.

And over the next few months, something truly dramatic happened. Like little Mateo Almeda, whom you see in this video, 100 percent of the infants who got the highest dose of Mendell's gene therapy were alive at 20 months. Nearly all could talk and eat on their own. And some, like Mateo, shown here at age 2, were able to walk and—this is truly astounding—even play on the monkey bars with his dad.

As a direct result of an NIH-inspired effort, we are seeing the emergence of a lifesaving gene therapy for spinal muscular atrophy.

In closing, I am proud to lead NIH at this time of unprecedented scientific opportunity and strong congressional support. The resources you have entrusted to us will be used to bring hope to untold numbers of patients and their families.

In that spirit, I would like to leave you with a favorite quote from the poet, Peter Levi, "Hope in every sphere of life is a privilege that attaches to action. No action, no hope."

At NIH, our idea of action is to support the best investigators to apply the best science to find answers for the millions waiting for their hopes to be realized.

Thank you, and I look forward to your questions.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Hearing on FY 2019 National Institutes of Health 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

Accompanied by

Diana W. Bianchi, M.D.
Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases

Norman E. "Ned" Sharpless, M.D.
Director, National Cancer Institute

Nora Volkow, M.D.
Director, National Institute on Drug Abuse

April 11, 2018

Good morning, Chairman Cole, Ranking Member DeLauro, and distinguished Members of the Subcommittee. I am Francis S. Collins, M.D., Ph.D., and I have served as the Director of the National Institutes of Health (NIH) since 2009. It is an honor to appear before you today.

Before I discuss NIH's diverse investments in biomedical research and some of the exciting scientific opportunities on the horizon, I want to thank this Subcommittee for your sustained commitment to NIH to ensure that our nation remains the global leader in biomedical research and advances in human health.

I want to personally express gratitude to this Subcommittee and its leadership for its support in crafting and passing the FY 2018 Consolidated Appropriations Bill. The FY 2018 Omnibus provides an incredible increase of $3 billion for NIH, including funding for opioid- and pain-related research, Alzheimer's disease, antimicrobial resistance, and development of a universal influenza vaccine. NIH has immediately set to work to invest those additional resources into groundbreaking research.

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. As some of you have witnessed first-hand on your visits to NIH, our leadership and employees carry out our mission with passion and commitment. This extends equally to the hundreds of thousands of individuals whose research and training we support, located in every State of this great country, and where 81 percent of our budget is distributed.

The FY 2019 Budget provides $34.8 billion for NIH to fund the highest priority scientific discoveries while also maintaining fiscal stewardship of Federal resources. This Budget will consolidate research functions across the Department, optimize available

grant dollars to fund research, invest in NIH's buildings and facilities, and support NIH priority areas including combatting the opioid epidemic, advancing Precision Medicine, and investing in translational research.

The FY 2019 Budget consolidates HHS research programs into three new institutes within the NIH. The Budget provides $380 million for the activities of the Agency for Healthcare Research and Quality (AHRQ), consolidated into the National Institute for Research on Safety and Quality. The National Institute for Occupational Safety and Health (NIOSH), including the Energy Employees Occupational Illness Program (EEOCIPA), currently administered by the Centers for Disease Control and Prevention, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), currently administered by the Administration for Community Living, are also proposed for consolidation into the NIH.

America's continuing leadership in conducting biomedical research requires infrastructure and facilities that are safe, compliant with all laws and regulations, and conducive to cutting edge research and research support. NIH owns 281 facilities, including a research hospital, laboratories, and offices. NIH's Backlog of Maintenance and Repair exceeds $1.8 billion. NIH is currently working with the National Academies of Sciences, Engineering and Medicine to identify NIH facilities and infrastructure most in need of repair. We look forward to providing that report to the Committee as soon as it is final.

The FY 2019 Budget makes much needed investments in NIH's facilities. The Budget proposes $200 million to support multiple biomedical research infrastructure priorities. The FY 2019 Budget will allow NIH to continue to repair and upgrade deteriorated infrastructure. In a recent analysis requested by this Committee, the condition

of NIH laboratories ranks near the lowest in the federal government due to the high likelihood of floods, power outages, and mechanical failures. Items on the backlog list include: install steam and chilled water distribution systems; conduct structural repairs to older buildings; upgrade plumbing systems; repair elevators; upgrade heating, ventilating, and air conditioning systems; replace deteriorated electrical systems, and more. In addition, due to the age and use of NIH facilities, NIH must invest funds in removing contaminants and hazardous waste before construction or capital repairs can begin in most of its buildings. The Budget will allow NIH to track what contaminants are being cleared from each of our buildings, which will ultimately help NIH do a better job of anticipating the cost and time required to begin new projects in existing buildings.

Truly exciting, world class science is taking place. I would like to provide just a few examples of the depth and breadth of the amazing research the FY 2019 Budget supports across the Institutes and Centers of NIH.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid misuse, addiction, and overdose. This Committee made a historic investment of $500 million in our work in FY 2018, and the FY 2019 Budget builds on that with an investment of $850 million to support a range of activities to advance research on pain and addiction. NIH has and will continue to support cutting-edge research on pain, opioid misuse, addiction, and overdose. Drug addiction is a complex neurological condition, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the crisis and informing future efforts. Pain is an equally complex condition affecting millions of Americans. NIH will: explore new formulations for overdose reversal medications capable of combatting powerful synthetic

opioids; search for new options for treating addiction and maintaining sobriety; continue to research how best to treat babies born in withdrawal through our ACT NOW trial; develop biomarkers to objectively measure pain; build a clinical trial network for pain research; and attempt to find non-addictive and non-pharmacological approaches to chronic pain. Thanks to your support, all hands are on deck at NIH for this public health crisis.

Another exciting area of continued investment in FY 2019, building on this Committee's long-standing support, is Precision Medicine. In a few weeks, NIH will officially launch the national roll-out of the *All of Us* Research Program. This program will partner with one million or more people across the United States to provide the most diverse biomedical data resource of its kind and gain unprecedented insights into the biological, environmental and behavioral influences of disease. The FY 2019 Budget, including resources from the 21st Century Cures Act, supports the ramp up of the program. After pilot testing system and forming partnerships with community organizations across the country, national enrollment is about to begin. *All of Us* will not focus on only one specific disease. Rather, it will be a national data resource to inform many research studies on a wide variety of health conditions. The data provided by one million participants will provide opportunities for researchers—including academics and citizen scientists—who want to understand how and why different people experience certain diseases and conditions while others do not, and why many people respond differently to treatments and prevention methods that will help accelerate medical breakthroughs.

NIH is the largest funder of basic biomedical research in the United States, providing a critical research foundation for both the public and private sector. Building on that solid foundation of basic research, NIH also supports translational research that turns observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public, whether those interventions be diagnostics, therapeutics, medical procedures, or behavioral changes. For example, Congress created the Cures Acceleration Network (CAN) at the National Center for Advancing Translational Sciences (NCATS) to advance the development of high-need cures and to reduce significant barriers between research discovery and clinical trials. For example, CAN currently supports NCATS' Tissue Chip for Drug Screening program, which was designed to revolutionize the process for predicting drug safety. Researchers developing miniaturized platforms that could support miniature models of living organs — such as the lung, liver, and heart — that could be integrated into connected organ systems. New Tissue Chip initiatives were funded in FY 2017 and this support will continue into FY 2019. CAN uses flexible research awards using the special authorization called other transaction authority to attract non-traditional government partners, and to expand, modify, and, if needed, discontinue activities to meet program needs. The FY 2019 Budget will allow NCATS, through CAN, to continue to invest in high-risk, high reward initiatives designed to address significant scientific and technical challenges that hinder translational research.

One of my personal priorities is developing the next generation of talented biomedical researchers. Last year, I shared with the Committee NIH's plans to build on our support for early-stage investigators through a new initiative known as the Next Generation Researchers Initiative. The FY 2019 Budget includes a dedicated fund of $100 million in the Office of the

Director to incentivize additional Institute and Center support for these researchers. NIH remains committed to the development, support, and retention of our next generation of investigators.

We have never witnessed a time of greater promise for advances in medicine than right now. Your support has been critical, and will continue to be. Thank you again for inviting NIH to testify today. We look forward to answering your questions.

Mr. COLE. Thank you very much.

I see during the course of your testimony, we have been joined by our chairman, who with typical modesty has taken the seat at the end of the dais. But I want to recognize the chairman of the full committee for any remarks he would care to make.

REMARKS FROM CHAIRMAN FRELINGHUYSEN

The CHAIRMAN. Well, thank you.

Very briefly, Mr. Chairman, and may I thank you and Ranking Member DeLauro for the great work you did in the 2018 budget.

I often say, when I come—and welcome, Dr. Collins and your distinguished panel. Thank you for the incredible job that the NIH does, and many times you have accommodated constituents in my congressional district that are faced sometimes with a child or an adult situation where you are willing to meet with their advocates to talk about your remarkable—thank you so much.

I often talk when I come and I am running from hearing to hearing that this is the Committee that has the power of the purse. May I say, the purse is rather full for you? [Laughter.]

The CHAIRMAN. So we anticipate, I think in a bipartisan way, and we hope that that will continue, that we will have every assurance from you that every dollar that we do give you will be spent, be spent well. That you will always be working within your 27 different institutes and centers to make sure that there is an element of obviously accountability and cross-pollination which benefit the American people.

So, Mr. Chairman, thank you very much for the time, and thank you for the good work you did carrying the largest, maybe it wasn't that big a burden, but the largest amount of money and making sure that it was all spent well.

Thank you very much.

Mr. COLE. Well, thank you, Mr. Chairman. We only get to appropriate what you give us. So thank you very much for the allocation.

The CHAIRMAN. Thank you.

TRANS-NIH INITIATIVE ON DOWN SYNDROME AND ALZHEIMERS

Mr. COLE. You bet. If I could, Dr. Collins, as we discussed last year, we had an extraordinary hearing, and the fiscal year 2018 Omnibus directed the NIH to develop a new trans-NIH research initiative to improve the health and well-being of individuals with Down syndrome. In fact, we have some of those people that participated in that hearing here. It is good to have you back. And as well to understand the linkages between Down syndrome and diseases such as Alzheimer's.

Dr. Collins, would you please tell us about the NIH's preliminary plans for implementing that initiative? And of course, Dr. Bianchi, would you give us an update on the NICHD's current research related to Down syndrome, as well as how you anticipate building on that research under this new initiative?

Dr. COLLINS. Well, we are very fortunate to have recruited an individual who has contributed personally in a very major way to research on Down syndrome as our new Director of the National Institute of Child Health and Human Development, and she has now

been charged by me to take this recommendation from Congress, which we take and embrace warmly, and turn this into a much more expanded plan for research on Down syndrome.

So, I am going to ask Diana to respond to your very appropriate question.

Dr. BIANCHI. Thank you, Chairman Cole, and we are very grateful for the added support for research on people with Down syndrome.

In my former life, as a pediatric geneticist, it was my privilege to take care of infants and children with Down syndrome. So, this new opportunity is incredibly exciting.

In the last 3 weeks, we have already had a meeting that included the 11 institutes and centers that currently participate in the Trans-NIH Consortium on Down Syndrome, and we have added some new centers, specifically NIAID as well as NCATS. And we have already drafted a proposal on how to spend the money, and it is a very visionary proposal that consists of three different components.

So, the first component includes some basic science really looking at initiatives that are likely to translate to clinical care in the next 5 years. So that includes, for example, silencing the third copy of chromosome 21, as well as examining why people with Down syndrome have differences in their immune system. So looking at components of the immune system that result in different reactions to infection.

The second component involves really knitting together existing registries. We know of many around the world that have large populations of people of all ages. So this is not just an NICHD effort. This is a trans-NIH effort that includes literally newborn infants to older people who have symptoms of Alzheimer's disease.

We are all working together to create these registries. We actually—even in the preparation of the proposal, we know of literally thousands of people that we could include in this registry. We also know that there is tremendous interest in people who have Down syndrome and their families, that they have tremendous interest in participating in research. And we know that through our currently funded DS-Connect program, where we already have over 3,700 people who are participating in clinical research right now. But we will be adding to that with these large registries.

And the third component really gets at what many of the families are interested in, and that is how do we improve the overall quality of life for people with Down syndrome and their overall health?

And so we—again, this is just in the last 3 weeks, but we thought that we could take some lessons learned from prior clinical trials that have been done in the pharma space, and they have not been successful. So we hope to be able to work with them and find out what are the lessons learned? Were they not successful when they were looked at as a group? Is there inter-individual variation that accounts for some of the reasons why it wasn't successful in one person, but it was successful in somebody else?

The second thing we need to look at is common conditions that are existing in people with Down syndrome that also exist in the general population and why they might react differently to current

medications. And the third part will be repurposing new medications.

Mr. COLE. To set an example to the rest of the Committee, since I am down to 20 seconds, I am going to enforce the 5-minute clock on myself. So I am going to be brutal to everybody else. But we now go to my good friend, the Ranking Member.

UPDATE ON NEW STRATEGIC PLAN FOR UNIVERSAL FLU VACCINE

Ms. DELAURO. You are a model of excellence, Mr. Chairman.

I just want to add a word with regard to if you haven't watched the testimony of the hearing that we held on Down syndrome, please do, because in my view, it is one of the most powerful personal testimonies that I think this Subcommittee has maybe ever seen. And one of the things I will just ask is I am also interested in how folks with Down are protected from solid tumors so that when you do your research, I will be interested in that, you know, as it expressed cancer and other things.

So thank you, and thanks for 3 weeks, you are gangbusters.

So what I would like to do is to ask Dr. Fauci to follow up on NIAID's recent announcement of a new strategic plan for research to develop a universal flu vaccine. I said it was a bad season. I will just tell you that this was the first week, the week ending March 31st was the first week since December that my State did not have a single flu-related death. So, you know, which is one of the reasons why we provided an increase in funding, no less than $100,000,000.

So let me just there are three questions that I want to ask you, Dr. Fauci. The announcement for your new strategic plan highlighted the identification of knowledge gaps in this area of research. Can you outline some of those knowledge gaps for the Subcommittee?

You also talked about a coordinated effort of guided discovery, product development, iterative clinical testing, consortium of scientists. Tell me about the process, Dr. Fauci, and translate for me what that means in terms of what you will be doing, and do you have any idea how soon we could develop a universal flu vaccine? What do you need, and how can we make clear this is a top priority?

Dr. FAUCI. Okay. Thank you very much.

As you said very correctly, this really has been a very bad year, the worst year that we have had in the last decade since the CDC has been recording the number of hospitalizations per 100,000 people and pediatric deaths. Also, this is the 100th anniversary of the 1918 pandemic flu, which was one of, if not the most important public health wise literally in history.

So with that as a background, the strategic plan and research agenda that you mentioned was formulated at the meeting that we held in Rockville in June of 2017, in which we brought people from all over the country and the world, experts to help us put together this plan to do what you said, namely, what are the gaps? What do we need to know? Because we are not doing as well as we can with regard to influenza vaccines.

Current vaccines are not very particularly effective. At best, they are 60 percent effective. At worst, they are 10 percent effective.

You recall the H3N2 influenza vaccine this year was overall effective 25 percent. That is not good at all, compared, for example, to measles, which is 97 percent effective.

So the gaps are in understanding why the body does not make a response against flu that essentially covers all the different isolates and all the different subtypes of influenza. And we believe we know the reason for that is that we selectively make response against the parts of the virus that seems to change or drift from season to season. What we have done with information we have gathered over the last several years is to identify the exact molecular structure of the parts of the virus that do not change from season to season.

So now we got to figure out how to induce the body to make that, coordinated systems. This is the same thing we did when we did the Vaccine Research Center at the NIH and we developed the coordinated groups to develop an HIV vaccine, it is to get people with different disciplines—immunologists, virologists, structural biologists, and vaccinologists—together to help us as a team, as opposed to using siloed approach.

And then, finally, the timeline. You cannot give a timeline for a vaccine when it is still in the scientific discovery stage. However, I can tell you what I think is going to happen. We are not going to all of a sudden have a universal flu vaccine next year or the year after. It is going to be an iterative process, which means in a few years, we might get universal influenza vaccine 1.0, which would cover some of, but not all of the strains. And then several years later, we will do better and get most of the strains. The ultimate end game and goal is to have a universal influenza vaccine that covers everything, and again, that will take several years.

Thank you.

Ms. DELAURO. And it will take resources.

Dr. FAUCI. It will take—and Thank you, the $40,000,000 add plus-up that you gave us to make it a total of $100,000,000 is going to get these teams of people together that we are talking about.

Ms. DELAURO. Thank you.

Mr. COLE. Thank you. On the basis of arrival, Mr. Fleischmann, you are now recognized for whatever questions you care to pose.

TRANSFER OF NIOSH TO NIH

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And to this distinguished panel I observed now for a couple of terms on the Appropriations Committee, and when I was first asked to serve on the Appropriations Committee, I wanted Energy and Water badly. We deal with our supercomputers I think that Dr. Collins had talked about at Oak Ridge. We are going to have the fastest in the world with the Summit supercomputer. But I was told I had to take Labor, Energy, and Health and Human Services.

And since that time, I fought very hard to remain on this Committee. Mr. Chairman and the ranking member, I thank you all. This is tremendous. What you all do as a group is tremendous for America. You alleviate suffering. You move our research forward. So thank you. It is a privilege to work with you all.

I have some questions. Your fiscal 2019 budget proposes to transfer certain research and sick energy worker compensation pro-

grams under the CDC NIOSH, specifically the Energy Employees Occupation Illness Compensation program run by NIOSH, to the NIH. My understanding, that this has been discussed before and rejected before. Certainly those of us that have former Department of Energy workers, and I do in Oak Ridge, that are sick and have applied to the program have serious concerns that such a move—with such a move.

CDC and NIOSH are successfully managing the program and responding to workers' applications. A move like this might well result in a negative impact to the program. This program started under NIOSH 15 years ago because they have the radiation expertise to handle the specific program and address former worker applications.

While the administration is now asking to approve a transfer of this and other budget authorities from NIOSH where there doesn't appear to be a strong justification for the request or confidence that it will be good for the program, why is this out there?

Dr. COLLINS. So, we appreciate the confidence that seems to be reflected in NIH's ability to carry out research with a number of these proposals to bring other parts of the Government under NIH's umbrella. I have to tell you, we are not particularly familiar with the EEOICPA, the program you are talking about, which is run by the Department of Labor, but where NIOSH has served as the setting of standards and the evaluation of exposures and determination about whether injury might have occurred, particularly in terms of radiation.

We would have to learn quite a bit more about that to understand the pros and cons of where it is currently located, but I appreciate your comments that from your perspective this seems to be working pretty well right now.

RESEARCH ON OPIOIDS AND OTHER SYNTHETIC SCHEDULE I DRUGS

Mr. FLEISCHMANN. Thank you. I would appreciate it if you all would look at that because it really has benefited literally thousands of workers who, over the years, were less careful, exposed to these contaminants, and they really have suffered. And they have benefited from this program, and it has had bipartisan support. So, I thank you for that.

Dr. Collins, we are all interested in encouraging research on opioids and various synthetic forms of those compounds, including synthetic fentanyl. I understand that support for the U.S. Government has been very aggressive in classifying some of those synthetic compounds like fentanyl as a Class I compound.

However, are you concerned that the restrictions on research that is associated with Class I drugs and compounds might make it difficult for scientists to conduct the research necessary to better understand the compounds and to develop antidotes to these compounds, sir?

Dr. COLLINS. Yes, we are concerned about that. I am going to ask Dr. Nora Volkow, head of the National Institute on Drug Abuse, who is the expert in this area, to respond to your question.

Dr. VOLKOW. Yes, indeed. And of course, this scheduling of substances is to try to protect the public. So it is very well intentioned. You don't want to make them available.

The problem is that at the same time, we need to do research in order to understand these drugs so we can develop treatments. And by having them on Schedule I, it is very difficult to get permission, and it is a very lengthy process. So we have been discussing and working with our colleagues at DEA to try to figure out if there is an opportunity of generating a subcategory for Schedule I that would allow it to make it easier for researchers to do the research.

We need to move rapidly. We are losing—the big increases in mortality are from the synthetic opioids. We need to have countermeasures, and the only way that we are going to have countermeasures is by doing research. But if it takes me at least a year to get those permissions, of course, everybody is going to be delayed.

So this is something that will be very, very helpful if we can figure out how to solve it.

Mr. FLEISCHMANN. Thank you, Doctor. And Mr. Chairman, I yield back.

Mr. COLE. Thank you very much. We now go to my good friend from California, Ms. Roybal-Allard.

NIAAA'S COLLUSION WITH ALCOHOL INDUSTRY

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

Dr. Collins, during the two decades I have served in Congress, the prevention of underage drinking has been one of my major legislative efforts. So, you can imagine how concerned I was by recent reports in the New York Times and the Boston Globe outlining NIAAA collusion with the alcohol industry in determining research funding choices.

It is my understanding that NIH policy prohibits its employees from requesting or suggesting donations to the NIH intended to support specific activities. Yet according to the Times, the NIAAA participated in soliciting funds from the alcohol industry for a randomized clinical trial of the effects of moderate drinking on heart health.

Even more disturbing is the Globe report that NIAAA, in the wake of those close partnerships with the alcohol industry, has stopped funding research into essential questions, such as the impact of alcohol advertising on youth drinking choices.

My question is why would the institute whose mission is to understand alcohol abuse and alcoholism be engaged in funding a clinical trial whose goal is apparently to produce evidence to promote drinking for health? And also who was responsible for sanctioning the solicitation of funding from the alcohol industry?

Dr. COLLINS. Congresswoman, I am also very concerned about the materials that have been reported in the New York Times and in the Globe about these circumstances, which I agree are alarming in terms of whether this steps across territory that NIH, with its reputation for the highest standards and objective science, should not be in a circumstance of being seen to have been influenced in a way that would be inappropriate.

We are looking into this in a very aggressive way. I have instructed my staff at the Office of Management Assessment to look at the details of exactly what happened in terms of the relationship

between NIH employees and the beverage industry in the formulation of a possible research plan.

And furthermore, I am putting together a working group of my highest-level advisory committee—that is the Advisory Committee to the Director—to basically ask the question, scientifically, what is the merit of conducting such a study? Does it, in fact, justify this kind of investment?

There are certainly those who would argue that there is evidence from other smaller studies that moderate alcohol ingestion—a glass of wine every evening, for instance—might actually be beneficial in terms of cardiovascular disease, but we don't have the rigorous kind of data that we would like to have. So, you could argue that a study of this sort could add to the body of knowledge and be useful and appropriate.

There are others I think who are quite concerned about what this might say in terms of NIH's stance about a substance, namely alcohol, which is clearly capable of doing a lot of harm to people who overindulge in it. So, I want my working group to look at those scientific questions and render an opinion, and we are going to do this all quite quickly.

I agree with you. This is a serious circumstance. We are going to look into it with great intensity and, if necessary, turn over anything we find that seems truly inappropriate to the Inspector General.

Ms. ROYBAL-ALLARD. So at this point, you don't know who actually approved of this solicitation? And secondly, I guess one of the concerns also is there is a process in place where you put out a request for collaboration, and apparently, again, based on these reports, by the time that the institute submitted the request for outside funding in—I believe it was in 2015, officials and outside scientists, you already had met with the alcohol industry executives.

And so, again, this shows that there was collaboration and contact even prior, before—before releasing the request for collaboration. And so the concern is, first of all, are you not aware then of who sanctioned this?

Dr. COLLINS. I have some of the facts, Congresswoman, and believe me, this is a matter of the highest priority. We are still digging deeper to try to understand exactly who was involved, what were the nature of the communications, how were decisions made? This is an active current investigation.

I promise you we will provide the greatest amount of attention to this as possible, and I will be glad, once we have those conclusions, to make them quite public. This is very serious.

Ms. ROYBAL-ALLARD. And let me just add, given the devastating consequences of alcohol use in our high school and college populations and the credible research on adolescent brain development, would you consider or support the NIAAA investing resources into important scientific questions such as the impact of alcohol marketing on young people drinking in college populations and the role of alcohol outlet density in alcohol problems?

Dr. COLLINS. We are deeply concerned how beginning in alcohol ingestion, particularly in large quantities during adolescence and during college, can have lifelong consequences. We certainly see that as a highly appropriate area for NIH research, particularly in-

terested in studying what kind of interventions could prevent that from happening.

Ms. ROYBAL-ALLARD. And let me just say——

Mr. COLE. I am sorry. The gentlelady's time——

Ms. ROYBAL-ALLARD. I have 28 seconds, Mr. Chairman.

Mr. COLE. No, the clock, you are 28 seconds past.

Ms. ROYBAL-ALLARD. Oh, past. Oh, darn.

Mr. COLE. That was a great try, though. [Laughter.]

Mr. COLE. We will next go to my good friend from Maryland, Dr. Harris.

RESEARCH ON SCHEDULE I DRUGS

Mr. HARRIS. Thank you very much. And thank you all for the work you do over at the NIH.

Let me just follow up a little bit about the—you know, that alcohol study issue, and I note in the nice handout you gave us here, the little colorful one, talks about the speeding drugs to market section, talks about the Accelerating Medicines Partnership. Now that is a public-private partnership where drug company monies are used to facilitate research. Is that right?

Dr. COLLINS. That is absolutely correct.

Mr. HARRIS. So certainly throwing the baby out with the bath water is not the solution here. I mean, we have decided that public-private partnerships leverage Federal dollars. Now whether or not there were rules broken is a question that has to be answered. But the idea that, a priori, this is an inappropriate thing for NIH to be involved with is kind of crazy because, I mean, we accessed the Mayo Clinic website today, and it says under its Nutrition and Healthy Eating section, it says "possible health benefits of moderate alcohol use." And says, "Even so, the evidence about the health benefits of alcohol is uncertain."

Well, why wouldn't we want to know with certainty, as long as we have the appropriate firewalls. Again, following the pharmaceutical industry model, I don't think it is inappropriate to have this partnership.

Regarding the goal is to produce evidence of benefit, my impression is the null hypothesis is there is no benefit, and that is actually what you are testing, whether the null hypothesis is correct.

Dr. COLLINS. That is correct.

Mr. HARRIS. So, you start from the premise of there is no difference, and if a study shows a difference, let us have the evidence. You know, there is an exact analogy, which brings up something that Dr. Volkow talked about, which is marijuana. I mean, there is this—this—this impression out there that marijuana helps all these medical problems. Oh, my gosh, oh, if we just license medical marijuana and make it available to everyone, all our problems go away, including opioid addiction, which is pretty amazing to me because there is almost no rigorously done medical evidence and resistance to doing it, which I can't understand.

But, Dr. Volkow, that brings up a question that I want to ask you is I am encouraged by the fact that you think we need to take some Schedule I drugs, create special categories where research could be done because I think marijuana is one of those that if we do the research, I mean, why wouldn't we want to? We talked

about adolescent brain development and the effects of alcohol. We know that it is harmed with marijuana. We should be doing more rigorous research on that.

And we certainly should be investigating the claims made, just like we should investigate the claims made of moderate alcohol being beneficial, the claims made of medical marijuana being this cure-all. And you know, Dr. Volkow, the list of diseases that are suggested, and the latest of which is opioid dependence.

So I am just going to ask you a specific question because I asked you this last year, I think. Is there any evidence that marijuana in a rigorously done study is effective at treating opioid dependence at known dosages and regimens, where as a physician I could prescribe—knowing a good, rigorous, I could say, okay, two joints a day, you know? I mean, I don't know what. Is there any evidence?

Dr. VOLKOW. There is no evidence whatsoever. There has not been a study that has shown that.

EARLY STAGE INVESTIGATORS

Mr. HARRIS. That is what I thought. And that is an absolute shame.

So, Mr. Chairman, I have cosponsored a bill, bipartisan bill. It is bicameral. Hopefully, we can get some of the rules changed on doing research on marijuana by creating a special category within Schedule I that actually might be a model for some of the research that you are talking about regarding other drugs.

Now, Dr. Collins, I came to Congress in 2011 and since then, and I think you were at the NIH in 2011, and since then, I will tell you we aren't the only things that have gotten older since then. The chart that looks at the average age and degree of NIH R01 equivalent first-time investigators, and of course, R01s are really the foundations of our investigators' careers, is higher now than it was in 2011.

So we have sent more money to the NIH—and this the last fiscal year I have is fiscal year 2016. You might have new data from fiscal year 2017. We sent more money. We sent more money last year. We sent more money with this Omnibus. But the data shows that in 6 years, we haven't—we not only haven't made progress, it has gotten worse.

I mean, the average age for the M.D. only, and that is what I was, is 45. The average age of starting, and you know, I have shown you the graph. That is not when people's most significant discoveries are, whether they are Nobel Prize winners, whether they are inventors. Is there any hope that this trend will—that next year, we will come back. You and I will have gotten older, but that number will have gotten younger?

Dr. COLLINS. Well, I sure hope so because I am totally with you on this, Dr. Harris. The fact that it has been so difficult to change that curve and that we still have investigators only achieving that kind of independence that is signified by the awarding of an R01 in their early to mid forties. And for M.D.s, it is about 45. For Ph.D.s, it is a bit less than that, maybe 40, 41. But that is still too late as well.

The thing that I think—two things that are going to help here. One is our ability to really emphasize the early-stage investigator

as our highest priority of where we want to invest funds, and we are going to do that in fiscal year 2018, thanks to the funds that you all provided. And that means that individuals who had failed to get that first grant by just missing the payline are going to have a better shot at it than they ever have had, at least in the last 15 years.

The other thing we have done is to try to create some new programs which specifically aim to achieve earlier independence, one actually called the Early Independence Award for individuals we don't think need that postdoc, who can go straight from a doctoral degree to independence. The average age of those investigators is 31. That is more like it. The New Innovator Award similarly, average age 37.

I promise you, when we sit around the table, all the institute directors, this is a topic that we are totally focused on. We need help from the universities. We have some levers to pull, but we need to help them pull theirs, too.

The National Academy of Sciences is going to issue a report on this later this week, and it will be interesting to see what they come up with as far as recommendations.

Mr. HARRIS. Thank you very much.

Mr. COLE. Okay. And we will go to my other good friend from California, Ms. Lee.

CONCERNS ABOUT HEALTH DISPARITIES, ALZHEIMER'S, AND LUPUS

Ms. LEE. Good morning. Let me first thank all of you for being here, but more importantly, for your life-affirming work. It is really good to see you.

And thank you on so many fronts. And I just have to associate myself with all of the remarks that have been made.

I wanted to ask you, of course, you know I am very focused on and concerned about health disparities as it relates to people of color. And I see now in this budget request $281,000,000, it is a cut of about $20,000,000 in the—for the National Institute of Minority Health and Health Disparities. And so I want to hear what do you think about being able to justify a cut like that, given the fact that we need so much more in terms of the research on health disparities?

And let me raise two of these issues very quickly. One is lupus in African-American women. Recent research indicates that lupus affects 1 in 537 young African-American women. There is lupus in minority populations that report nature versus nurture. This study supported the fact that African-American women lupus patients are more likely to have organ system involvement, more active diseases, and lower level of social input.

So I wanted to find out if NIH is doing anything as it relates to specifically to the disparities of lupus in African-American women because this is not an issue we have really talked about much in this Committee.

Secondly, Alzheimer's. Sixth leading cause of death in the U.S. and 5.7 million people living with Alzheimer's. But when you look at the racial disparities, older African Americans develop Alzheimer's at a higher rate than any other group of older Americans.

And the cut I think is the $1,900,000,000 from National Institute on Aging. That is about a $500,000,000 cut.

I am worried about just the general research on Alzheimer's, but the disparities as it relates to communities of color, specifically African Americans, how is this going to impact that research? And are you all really focused on and do you know what is taking place now in communities of color as it relates to lupus and Alzheimer's specifically?

Dr. COLLINS. Those are great questions. With regard to our focus on health disparities, as you know, the National Institute of Minority Health and Health Disparities has that as their major focus. But every institute at NIH is invested in research to try to understand the causes and, not just understand them, figure out what to do about them that will account for these differences in severity and incidence of conditions like lupus and like Alzheimer's disease.

The numbers you are quoting about budget, I don't have them in front of me, but again, remember the President's budget for fiscal year 2019 was put together before the fiscal year 2018 omnibus was passed. And so, at this point, we have to express our gratitude to this Committee and to the Congress for the fact that in fiscal year 2018 Alzheimer's research didn't go down. It went up by $414,000,000, raising it now to a total of $1,800,000,000.

This committee, through your efforts and which we have welcomed, has now more than tripled support for Alzheimer's disease research in just the last 5 or 6 years. That is remarkable.

And yes, health disparities is a very significant part of our focus. Dr. Richard Hodes, Director of the National Institute on Aging, just recently held a summit—this is the fourth one of these—to look at all of the scientific opportunities in Alzheimer's disease, and health disparities was, in fact, one of the areas of focus. And we can send you more information about some of the ideas that came out of that summit because we do now have resources to put into that.

With lupus, I agree with you there is no really good understanding why this is so much more common in African-American women than it is in other races, and we need to understand that. We have a big effort on lupus right now, which is actually a partnership with industry, trying to understand what is it that the immune system is reacting to to create this autoimmune disease that affects particularly the joints, the brain, and the kidneys, and that involves primarily participation by African-American patients because that is primarily where the disease is most devastating.

So we are totally dedicated to those issues, and again, as far as the dollar figures, I would say at this point it is probably more helpful to look at where we are with fiscal year 2018, and then we hope you all will figure out where we are going to be in 2019.

Ms. LEE. Then I guess, Doctor, as I want to ask you in terms of the specifics on the disparities as it relates to lupus and Alzheimer's, do you have a team or researchers specifically looking at these disparities as it relates to African Americans, or is it part of an overall?

Dr. COLLINS. No, I can get you specific examples of research projects that are focused on the area of health disparities for both Alzheimer's and for lupus. I don't have them at the tip of my tongue, but I would be glad to get those for you.

Ms. LEE. Okay. Okay. If we have a second go-around, I will save it. And thank you very much. Two seconds left? No, I am done.

Thank you.

Mr. COLE. Great job. Mr. Womack.

Mr. WOMACK. All right. Thank you, Mr. Chairman.

And thanks to the panel here today and specifically to Dr. Collins, who, as you saw in the picture, visited my district a week ago, and we did a lot of wonderful things. And I recommend those kind of visits to all of my colleagues who might have an interest in something.

I guess my favorite part of it all was the—was the symposium you had with the kids at Bentonville High School, one of my better-performing schools. And for my colleagues on the dais here, we just basically let the kids have at it with the Director, no adults.

Dr. COLLINS. And they did.

INSTITUTIONAL DEVELOPMENT AWARDS (IDEA) STATES

Mr. WOMACK. And asked great questions, and I thought it was very inspirational to see that interaction with the kids, and I truly appreciate that.

And you know, Dr. Collins, I am not going to miss an opportunity to talk about the Institutional Development Award, the IDeA program, which is purposed in safeguarding to ensure that NIH funding goes into places like Arkansas, where we don't have as high a success rate in applications. So what are you doing to ensure that IDeA States are remaining competitive when applying for these funds, which are critically important?

Dr. COLLINS. Well, I am a big fan of the IDeA program, and it was good to be in Arkansas with you to see some of the consequences of how that research is going forward. The talent that we need to conduct biomedical research, which is our most critical resource, is the people. They don't happen to just all live in the places that have the most research-intensive universities. They live all over this country.

They are in Arkansas. They are in Oklahoma. They are all around. And we want to be sure that those institutions that they are likely to want to learn research and do research are prepared to do so with support from the Federal Government through NIH. So when you look at the IDeA program, which is now $333,000,000 plus I guess an increment for 2018, it must be more than that now, this is one of the places where we can see some of the most impressive benefits of how those dollars are being spent.

And whenever I go to an IDeA State, I try to meet with the researchers who are doing that work. Some of them are supported by the so-called Centers of Excellence, the COBRE program. Every State that is an IDeA State also has a network that brings their institutions together, the INBRE program.

And then there are some very special circumstances. Arkansas, for instance, is critical in this new Clinical Trial Network that we have set up for pediatric research. In fact, you are actually—and Arkansas is the data center for managing that, and the big focus right now of that is on neonatal abstinence syndrome, and can we come up with better ways to treat these very unfortunate babies

that are born already addicted, and how can we help them get through that and have good developmental hopes and prospects?

So, when you look at all that, I think evaluating dollar for dollar, this is a really wonderful investment, and I could give you many other examples of it, but not to run out the clock too long. I just want to reassure you that we see this at NIH as something we want to support very strongly.

RESEARCH ON OPIOIDS

Mr. WOMACK. We are happy to hear that. My last question in this round is regarding opioids, and there is going to be a lot of discussion about it, already has been about it, but specifically about medication-assisted treatment. A lot of confusion and misinformation out there for healthcare providers, education on access to all FDA-approved treatment options for opioid dependence.

Would the NIH consider an interagency and stakeholder summit to review the science and data behind the existing FDA-approved opioid use disorder treatment medications? And then the follow-up question would be publishing the information, making it really transparent the findings of such a summit so that—so that the provider community could have access to this kind of information.

Dr. COLLINS. That is a great question, and I think we do have a lot of data about that, and I am going to ask Dr. Volkow to respond.

Dr. VOLKOW. Indeed, we have started. We agree that this would be incredibly useful not only because the science has shown that it has a fairly large impact in improving outcomes. And yet despite that, the communities are not using it, nor are we making it available for patients that need it.

Also, there is still a lot of stigmatization as it relates to the use of medications for the treatment of opioid addiction. So being able to generate a science-based analysis of what the data show in a way that is driven by all of the scientific experts with the voices of the patients themselves in an objective way would be very valuable. So we started discussions with the National Academy of Sciences and Medicine and Engineering to try to figure out if that could be one of the places where we could conduct such an analysis of the data and identify which would be the most important questions that they would want them to address.

So we are looking very seriously into it, and we want to move relatively rapidly because there is an urgency.

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

Mr. COLE. I want to give my friend the ranking member of the full committee an opportunity to sit down. Would you like us to go directly to you, which I advised the panel we would do, for any opening statement you would like to make, or do you want to catch your breath and have me go to Mr. Pocan next?

Mrs. LOWEY. Why don't we go to Mr. Pocan?

Mr. COLE. Okay. My friend from Wisconsin is recognized.

Mr. POCAN. Thank you very much.

And thanks to all of you for being here. It is nice. This is one of those hearings where everyone is so happy about the NIH, and I can just tell you last week, our Democratic whip, Steny Hoyer, came to my district, and we had a sit-down with a bunch of the

biotech and life science sort of companies. Almost everyone, it was their saying how much they work with NIH and how great it has been. So I just really want to thank you on behalf of my district in Madison, Wisconsin, and that area.

And Dr. Collins, I want to take Mr. Womack's advice. I would love to invite you to Madison, if you ever want to come. It is a great spot to come. We would love to have you. Be glad to host you.

And if you want high school students, whatever you want, we will get it if you come. So you got it. Cheese curds, anything, we will take care of it. [Laughter.]

COST OF PRESCRIPTION DRUGS

Mr. POCAN. Two subjects I would like to get to. One, you know, with all the companies like back home, they are talking about NIH, and we know, I think the stat is of the 210 new drugs that were approved by the FDA between 2010 and 2016, every single one of them had some federally funded research contributing to that science. And yet we see the cost of prescription drugs and this complete disconnect with what is going on.

And I think often, you know, as we try to make sure we have additional funding for NIH, which I think is crucial—I am and so glad that we have bipartisan support for it right now—the public doesn't always know that, right? So I guess two parts of this question, and I want to get to one other subject if I can real quickly.

One, is there anything we can do, and I know you can't do it directly, but what can we do to stop the disconnect that we pay so much more for prescription drugs in this country than other countries, and yet there is so much of the research is coming from NIH dollars?

And a second part of that is, is there a way that we could require an NIH inside label or something to really help promote this? Because I think, again, the public supports what the NIH is doing so much. If we could just reinforce that, it would be very helpful.

Dr. COLLINS. So very important and challenging questions. You are right. This paper recently published showing that virtually 100 percent of FDA-approved drugs between 2010 and 2016 had, at some point, benefitted from NIH research. Some of it in the very basic part, some of it getting even closer to an actual product, but all of that clearly necessary for the advances that are happening in therapeutics.

Unfortunately, NIH is not in a position, however, to pull levers about the cost of drugs. The way in which the current Bayh-Dole Act assigns intellectual property to our grantee institutions means that while we have to be informed about the discoveries they make, we don't have direct connections with the ability to influence what kind of licensing agreements are subsequently carried out.

What we can do and what we are doing is to try to figure out why is it so expensive to make a new drug, and the estimates are billions of dollars for one success. And a lot of that is because the failure rate is 99 percent, and the companies have to basically accommodate for that when they finally have a success.

The NCATS, the National Center for Advancing Translational Sciences, is set up to identify what those bottlenecks are and to try to see if there is a way to speed up that process. I happen to have

with me a kidney on a chip, which is one of the things they are doing, which is a way to try to assess toxicology of compounds before risking humans with those.

With this, you can find out whether a potential compound is going to do harm to your kidney tubules or not, and this is brand new. We wouldn't have been able to do this a few years ago. Just an example, that would speed up and increase the success rate for new drugs.

And your idea about labeling is one that Senator Durbin has also raised so the public would become more aware that there is NIH inside or whatever you want to use as your label to indicate that public support. Because NIH still doesn't have the kind of visibility in the public eye that maybe it should, considering the consequences for human health.

USE OF SCHEDULE I DRUGS IN RESEARCH

Mr. POCAN. I just think if we could keep thinking about how NIH could influence that? Because, again, there is a big disconnect. The public is paying so much more in this country, sometimes 20 more times than other countries, and yet so much of this is coming from the NIH, and we really need to continue the funding.

Second question, if I have got a little bit left, back to the Schedule I question Mr. Fleischmann started asking. And Andy Harris and I disagree on medical marijuana completely, and we were on a recent delegation together and had a good conversation about this. However, when you put something on Schedule I, you make it harder to research. They are about to do that with Kratom, another natural product that is, from many accounts, helping people get off of opioids.

Is there something we can do to be more proactive to stop something getting on Schedule I? Because by the time you get there, it is a mess, right? And now we have got this potentially happening with yet another item, Kratom, that a lot of people are using very successfully in this country.

Dr. VOLKOW. Yes, and this is one that has been a concern for us because, for example, in the case of Kratom, it is interesting because this drug has what we call biased properties, which means potentially it could be a useful analgesic that has less untoward effects. And we have researchers studying it, but the moment it goes into Schedule I, everything slows.

And right now, I think 20,000 people die from the synthetic opioids. This is not the time to slow it down. So generating—and that is outside our purview. But generating within the Schedule I a possibility of doing research rapidly and promptly with all of the surveillance that is necessary, but not delaying it, we right now need to accelerate, not stop.

Mr. POCAN. Or not getting it to Schedule I to begin. Correct?

Dr. VOLKOW. Yes. Now that is, I mean, one of the aspects, of course, that is driving this is the desperation of seeing people dying with more novel and novel synthetic opioids. So it is that we are in a corner. You are trying to protect people, but how do you in the process not do things that can actually in the long term harm our ability to treat them?

Mr. POCAN. And just for full clarification for the Committee, Kratom is a natural product. It is not a synthetic. We are just referring to——

Dr. VOLKOW. Correct. Absolutely, yes.

Mr. POCAN. Thank you.

Mr. COLE. Thank you. Is my friend from New York ready for whatever opening statement she would care to make?

IMPROVING EARLY DETECTION METHODS FOR KIDNEY, PANCREATIC, AND OVARIAN CANCERS

Mrs. LOWEY. You are very kind, Mr. Chairman. And first of all, I have had the pleasure of visiting with all of you for many years, and Dr. Collins, it is a pleasure to have you leading this group again. Thank you so much to all for your very, very important work.

We certainly have done a great job with the leadership of our chairman. A $3,000,000,000 increase, but we are still a long way from doubling the funding for the NIH. I was here when we did that in a bipartisan way. So let us keep going because your work is so very important.

Dr. Sharpless, welcome. When we met, we discussed my serious concern that there are not enough tools available for early detection of certain cancers, including kidney and pancreatic cancer.

Ms. DELAURO. Ovarian.

Mrs. LOWEY. And ovarian, too. Any others early?

Ms. DELAURO. That is it. [Laughter.]

Mrs. LOWEY. Could you share with us what is the NIH doing to make early detection a reality? It is such a challenge for all of us.

Dr. SHARPLESS. Thank you for the question, and it is good to be here this morning.

Early detection is a big part of our portfolio. We have a number of programs to investigate how to detect cancers earlier, particularly these very adverse cancers you discussed like pancreatic cancer and ovarian cancer that when diagnosed at an advanced stage are highly difficult to treat.

Mrs. LOWEY. Kidney as well.

Dr. SHARPLESS. Kidney as well, certainly. We have a number of exciting ideas. There was more kinds of cool novel radiologic imagings through MRIs and things like that. There are biomarkers in the urine or blood, so cell-free DNA, for example, that can be tested. So there are a lot of great ideas.

The challenge with early detection, as you know, is to find the bad cancers and not the indolent harmless cancers. Because what we have learned is that cancer can be quite indolent, and sometimes the treatment of an indolent malignancy is worse than the actual cancer itself.

So finding these cancers, it turns out, oftentimes is not that hard. But stratifying which ones need aggressive therapy versus which ones need observation is a challenge for us. I will say there is one particularly innovative program that I like on this at the NCI, in the intramural program where Marston Linehan is a surgeon who has discovered a lot about renal cancer, as you know, and he has really found these ways to follow these patients that are at

high risk for renal cancer using various radiologic criteria and other clinical criteria.

So it is very exciting, and I think we have similar kinds of stories in pancreatic cancer, ovarian cancer, and others.

Mrs. LOWEY. Thank you. This is such a great panel, Mr. Chairman, that I always get very tense because I have to limit my time. [Laughter.]

THOUGHTS ON E-CIGARETTES

Mrs. LOWEY. But I am so appreciative you are here. Of course, I always say you should be back in the lab and doing some other things.

But Dr. Volkow, last year we discussed the research showing that e-cigarettes are often a gateway to traditional combustible cigarettes. You know and I know, because I visit schools all the time, and I cannot believe the extensive use of e-cigarettes. Of course, on another opportunity of this Committee, we voted down an amendment that the FDA should not be allowing products on the market until they have tested them completely, and I have had this discussion with FDA as well.

Can you detail for the Committee what exactly happens to the brain when nicotine enters the system, what makes nicotine so addictive, particularly for young people, and do you consider e-cigarettes a public health threat for young people?

And I just want to say because I am on a real tear on this issue, talking to one youngster, 60 percent of the kids are using e-cigarettes. One of my high schools, and it was a combination of opioids and other things, nine kids have died. Nine have died.

And for many of the doctors with whom I have interacted, they feel that e-cigarettes has really become a gateway. When you walk into those stores, as I have, and I will say to the owner, "I want to put you out of business, sir," and they have the cigarettes called "whoopie-doopie" or "tutti-frutti," or I don't know how many adults want to buy tutti-frutti cigarettes.

And as I understand it also, the tobacco industries have bought up all these e-cigarette products. So just tell us about your views of e-cigarettes.

Dr. VOLKOW. Thanks for the question. This is an area of great concern for all of us because we have made major strides in decreasing cigarette smoking that has translated into a significant reduction in mortality associated with nicotine, including cancer. And what we are observing is that the entry of the electronic nicotine cigarettes is actually leading us to get individuals, particularly young people, that otherwise would have never smoked cigarettes to start to become addicted to it.

Nicotine by itself is highly addictive because what it does, it basically enhances the activation of the dopamine cells in your brain that make things salient, rewarding. So when you smoke, anything that you are doing is going to be much more pleasurable. And that is why researchers have shown that nicotine can act as a gateway drug, priming your brain to the rewarding and addictive effects of other drugs.

So our concern comes from two places. One of them the fact that we may get young people addicted to nicotine and then transition

to combustible tobacco cigarettes. And the data, the evidence is out there that that seems to happen among young people. But also that by becoming addicted to nicotine, that makes you more vulnerable to other addictions.

Mrs. LOWEY. So do you consider e-cigarettes a public health threat?

Mr. COLE. The gentlelady's—the gentlelady's time. Please answer the question, but short answer so we can move on.

Dr. VOLKOW. Particularly for young people, yes.

Mrs. LOWEY. Thank you, Mr. Chairman.

Mr. COLE. Thank you. Now go to my good friend from the State of Washington, Ms. Herrera Beutler.

SAFE MEDICATIONS FOR PREGNANT AND LACTATING WOMEN

Ms. HERRERA BEUTLER. Thank you.

And I will speak quickly. I would love to be able to sit and talk with each of you, honestly, and others who aren't here. This always makes your brain and your passions ignite because you think about the work you all get to do, and we play a small role in helping, helping you do what the folks we serve want you to do.

Let me ask a quick question. An area of significant need is with regard to pregnancy research, specifically for medications that a mom may safely take during her pregnancy. The reality is we don't know enough about this space. The Federal task force specific to research on pregnant women and lactating women has been working to address these areas of need and see what the research gaps are, and it has been doing great work.

I guess my question is, do you anticipate requesting renewal of the task force to allow them to continue doing the work?

Dr. COLLINS. I am going to ask Dr. Bianchi to answer because she is deeply engaged in those very issues.

Dr. BIANCHI. Thank you for your question, Representative Herrera Beutler.

The task force is on target. Our mission is to provide recommendations to both the Secretary of Health and Human Services and the Congress as to the status of research on pregnant women and lactating women with specific regard to the medications. We have had three of the four meetings. The last one will be next month, and we anticipate having a full set of recommendations.

I think what we have learned so far is there is a tremendous gap in knowledge in this area, particularly with regard to lactation. So women who are breastfeeding their infants oftentimes have to choose between either taking a medicine and not breastfeeding or not taking the medicine for their own health and breastfeeding.

So we will provide our report on time. We think it will be full of interesting information, and we will let the Secretary decide what the next steps will be.

Ms. HERRERA BEUTLER. So if you feel like it has been helpful, is it something that you can then request the Secretary consider renewing?

Dr. BIANCHI. We certainly can.

Ms. HERRERA BEUTLER. Okay. Great. You know, just in thinking about some of the conversations that have already taken place with regard—I mean, with regard to alcohol use, tobacco or cigarette, e-cigarette use and marijuana, both—I assume both recreational and to treat—you know, medical, to treat a condition. It is interesting to me that, you know, I had a conversation last week with—or 2 weeks ago now with it was open to all my superintendents, my sheriffs, and my police chiefs to talk about school safety, and I had conversations with mental health professionals who are in the school districts.

And the first probably 10 minutes of that I was—I threw it open. I wanted to know what they were hearing, feeling, thinking, needing from us with regard to school safety. And I expected—I knew what I expected, right, to hear was a lot of talk that I have heard all over the place. The first 10 minutes of the conversation was dominated by marijuana. You know, we are a State that has legalized it.

And one of the things I heard the ranking member say, which I completely agree with, she said, you know, she is not for allowing products or the FDA should not allow products on the market until they have been tested, have tested them completely was her quote. And I just keep coming back to the recreational use of marijuana.

I mean, Dr. Harris here is talking about medical marijuana and information behind that. We have no idea what is happening in the States that have allowed it, but I can tell you a lot of our schools who are dealing with these young people, their challenge is around mental health. And they said you want to impact mental health for children in schools and keep schools safer, this is a huge area where the adults in the system are failing. And that is a bit of a paraphrase.

I wanted to know if there is any area where we are doing any research at all to make this connection that there is hope for getting information that we can use as lawmakers?

Dr. VOLKOW. Yes. That is one of the areas that has us tremendously concerned, what are the consequences of legalization of marijuana as it relates to exposure to young people because their brains are the most plastic. And we know from studies that there is some evidence that use of marijuana can interfere with your cognitive ability, that it can make you more vulnerable for certain mental illnesses.

But all of these studies have been done without a very rigorous control of the variables. So because of that, we initiated in partnership with many of the institutes—in fact, NICHD, NCI—a longitudinal study to measure and prospectively 10,000 to 11,000 children as they transition from age 9 to 20 to understand how drugs may be influencing the development of the human brain.

And specifically to be able to unequivocally answer questions like how does alcohol—the National Institute on Alcohol Abuse and Alcoholism is very engaged on this—affect the brain developing? How does nicotine affect the brain? How does marijuana? And how do drugs in combination ultimately interact with one another, inter-

fering with the development of the individual, their education, their social development, and their success.

Ms. HERRERA BEUTLER. Well, and even with regard to pregnant mothers. A lot of the—it was so interesting to hear the school officials who are working with young people—oh, shoot, I am going up, aren't I?

Mr. COLE. Yes, you are. [Laughter.]

Ms. HERRERA BEUTLER. But with regard to the kids who are being born with different addictions, and our schools are not equipped to be the families, but that is what we are asking them to be. So I will yield back the time I don't have. [Laughter.]

Mr. COLE. Thank you very much.

Now go to my good friend from Massachusetts, Ms. Clark.

UPDATE ON FRAMINGHAM STUDY

Ms. CLARK. Thank you, Chairman Cole.

And thank this incredible panel not only for being here today, but for the work you do and the science that you produce that really helps inform our work and how we serve our communities in many ways.

I am going to go back. Just briefly, Congresswoman Roybal-Allard had to leave, but she did want me to express her concern, continuing the line of questioning, just that in the way that the alcohol industry was solicited, she believes really created an appearance that the outcome was predetermined of the studies around alcohol and just wanted me to highlight that for her.

I would like to ask you about something near and dear to me. Recently I got the chance to visit the Framingham Heart Study that is located in my district, and it really is amazing when you walk through the corridors, meet the researchers, look at their extensive records that go back now three generations. So much of what we all know now about good heart health was discovered there, and it is an incredible national treasure and I think has real relevance going forward for the fourth generation to be enrolled and to move forward.

And I wondered, Dr. Collins, if you could just tell me what NIH is doing to continue this study, to promote the Framingham Heart Study and the ongoing value of the research?

Dr. COLLINS. I am happy to because this is such a great story, starting in 1948 and now, as you say, stretching over multiple generations. Most of the things we now take for granted as if we always knew them, like blood pressure needs to be managed or like cholesterol needs to be managed, all of the things we have learned about heart disease that have resulted in a more than 70 percent drop in heart attack deaths and a more than 70 percent drop in stroke deaths, those came out of Framingham, recognizing those risk factors and how to intervene.

And we will continue to be learning things from those individuals as more and more technologies become available. Now most of those participants, if they have given consent, have had their complete genomes sequenced. And this will continue to yield up many exciting results.

We will continue to support this. There has been a bit of a change in terms of exactly how that support is being offered up be-

tween contracts and grants. I don't want to get into the weeds on that, but there has been no diminution in NIH's commitment or financial support of this program, just a slight change in the way that we are managing those funds, and we are deeply committed to this.

We are so deeply committed to it that we are learning from it how to conduct other studies that are even more ambitious, including the All of Us Precision Medicine cohort, which will start enrolling in the very near future, which will enroll a million individuals. So let us take Framingham and multiply it by 40 and actually look at cardiovascular disease and everything else, too. And everything we learned from Framingham is informing that study, and that is going to be very useful.

The other thing we are doing is making sure that all the data from Framingham is even more accessible to individuals who might have good ideas about how to use it while protecting privacy and security. And that is going to, I think, result in even more discoveries than we would have had if we had kept it within a narrower group.

ADOLESCENT AND YOUNG ADULTS STRUGGLE WITH SUBSTANCE USE DISORDERS

Ms. CLARK. Great. Thank you. Thank you for that.

And quickly, with my remaining time, Dr. Volkow, thank you so much for all your help and assistance and your tremendous voice in research in helping us deal with the opioid epidemic. I am specifically interested in what NIDA is doing to understand the adolescent and young adult who is struggling with substance use disorder.

In Massachusetts, our death rates trend very young, but this is a problem across the country. And do you have the support and latitude to act in this area of research, and how are you researching medication-assisted treatment for the adolescent?

Dr. VOLKOW. Yes, indeed. And one of the things that has always been challenging is actually to conduct clinical research in adolescents and children, and yet at the same time, it is very important because we need to cover them. As a result of that, for example, teenagers or young people that are addicted to drugs are much less likely to be given medication-assisted therapy, highlighting that this is an area that we have to emphasize.

And thanks to the increases of funding that we are getting for the opioid crisis, this will allow us to accelerate this type of clinical research in order that we can get the evidence that determines what are the optimal treatments for these populations.

Ms. CLARK. Great. And so some of that is underway as this new funding comes? You are looking specifically at the adolescent?

Dr. VOLKOW. This is one of the areas that we are very interested in because there is a gap on our understanding how to optimally treat kids that have become addicted to opioid use.

Ms. CLARK. Thank you very much. I did it, Mr. Chairman.

Mr. COLE. You did.

Ms. CLARK. It is rare.

Mr. COLE. I am increasingly proud of this committee. [Laughter.]

Mr. COLE. Three billion dollars and on time. Wow, pretty amazing.

Next, go for the last questions of the first round and my good friend from Michigan, Mr. Moolenaar.

LAUNCH OF HELPING TO END ADDICTION LONG-TERM INITIATIVE (HEAL)

Mr. MOOLENAAR. Thank you, Mr. Chairman. And I want to thank the panel also.

Dr. Collins and Dr. Volkow, I don't know who best to address this question, but I will leave it open to you. I wanted to follow up with you. Recently, the NIH launched the Helping to End Addiction Long-Term Initiative, and my understanding is this is an interagency effort with the goal of speeding up scientific solutions to the national opioid crisis and built upon established NIH research.

My district has, according to the CDC's recent report, three of the most at-risk counties in the country. So this, obviously, is very important to me and to my district, and I wondered if you could talk about which agencies are involved in this, and how does this relate to some of the BRAIN Initiative research you have been doing and other overlapping NIH initiatives? And how do we leverage all this with respect to the opioid crisis and ending addiction?

Dr. COLLINS. Well, it is a great question because there are a lot of potential partners, and we want to be sure that they are all linked up in the most optimal way. There was a retreat just two days ago where all of the parts of HHS that have equities in this space, which certainly includes NIH, but also SAMHSA, CDC, HRSA, CMS, FDA, Indian Health Service, AHRQ, all of them engaged in figuring out how can we be sure that the efforts we are all responsible for and deeply committed to are making the maximum opportunity of synergism?

And our HEAL Initiative, which is primarily focused on NIH's efforts and is only possible because of the Congress coming forward with $500,000,000 in this current fiscal year that we can utilize, is bold and ambitious, but it does need those linkages to succeed. One of the many things that we are talking about and aim to pursue is to see how we could identify areas that are particularly hard hit with opioid overdose and opioid use disorder and really, as a demonstration project, see whether we could link up NIH's research efforts, what SAMHSA is doing as far as funding MAT programs, get all of those as part of this.

The emergency rooms, the fire departments, the police, the criminal justice system, the social workers, the pharmacists, the State health departments, the other local entities and communities, faith-based organizations and say if we really were serious about linking all those things together in a defined area where this has been a particularly serious problem, could we see what we could do to drop the death rate, to drop the frequency of new addictions, to make sure that people who are addicted are actually in evidence-based treatment. That is something we want to push very hard. That is just one example.

Nora may want to say other things. I sort of got started, and I couldn't stop. But go ahead, Nora.

Dr. VOLKOW. No, and the other question that you asked about is how do we take advantage also of other projects that are ongoing at the NIH, and you are absolutely right. The BRAIN is an extraordinary opportunity because this epidemic started because we don't have sufficient treatments for managing severe pain, and it can be very devastating.

And so, for example, understanding what happens in the brain when you transition from acute to chronic pain where the insult is no longer there is extremely important because that knowledge could guide you to treatment that can prevent that transition. The same—but that requires tools and technologies, and that is what the BRAIN is actually doing.

And then another incredible opportunity is All of Us. Why do some people become addicted, and others do not? I mean, what are the vulnerability factors? Now if you look at it in terms of the type of study that you will require, it will be extraordinarily expensive. So, having the All of Us cohort, where you know you are going to have a significant number of those individuals going through surgical procedures, being given opiates, and being able to monitor them is another perfect example of our taking advantage of resources that the NIH has built.

[Pause.]

Mr. COLE. Is the gentleman's mic on?

Mr. MOOLENAAR. Good idea. Thank you, Mr. Chairman. That is why I am seated way down here. I am still learning the process.

How do you communicate this out to the stakeholders in the community? Because this is obviously very encouraging, the research that is going on, and then how do we communicate that out?

Dr. VOLKOW. Yes. I mean, that specific question was one of the questions that we struggled with on the meeting on Monday that the HHS conducted. What are the strategies, and what should we take advantage of?

So when you are speaking about the communication, it goes from the very perspective of educating the public about the dangers of these new synthetic drugs and how to actually engage them also in reaching out to those that may be in trouble and taking them to treatment. Also how to communicate with a treatment program so that they don't reject medication-assisted therapy.

And there were many innovative suggestions that were brought up, but obviously, taking advantage of what you have in your community is key. And the communities themselves are coming up with very creative ways—policemen, fire department, faith organizations. But how do we take that knowledge that has come out of grassroots and learn from it so that we can deploy and transfer it to other areas?

So the way that I view all of this is we are incredible at advertising for getting people to do things and buy things. So let us take advantage of all the infrastructure that we have to communicate much better what the dangers are and to take advantage of the organizations that we already have in our community.

Mr. MOOLENAAR. Thank you. Thank you, Mr. Chairman.

Mr. COLE. You bet. We will go ahead and start our second round now, and given the numbers, everybody should be able to have a full 5 minutes. So that is good news.

And then when we conclude, obviously, I will give the ranking member and myself a chance to make a final quick closing point or statement.

If I could, and I don't want to put you in a difficult spot, Dr. Collins, but—and Dr. Sharpless as well—21st Century Cures Act authorizes $400,000,000 in fiscal year 2019 for the Cancer Moonshot. Under the budget you propose, would you be able to fulfill that commitment and do that? If so, how would those funds be spent?

Dr. SHARPLESS. Sure. We could make use of such funding. You know, the Moonshot, the process is we would be talking about 2019 in about 12 months from now. But I think the Moonshot activities, as you know, are in these sort of 10 focused areas where we are poised to make rapid translation. So the idea is to take things that are almost ready for the clinic and then move into the humans as quickly as possible.

And so that has led us to fund really innovative stuff, and so, for example, immunotherapy, where we have these treatments that sort of take the patient's immune cells out of the body and soup them up and put them back in and cure patients that way. Or checkpoint inhibitors, where we actually give the patient an antibody that turns their immune system on. So in both cases, teaching the patient's own immune system to fight the cancer, and Moonshot funding has been very vital to that.

The Moonshot funding also includes big initiatives in big data. So how to create a data ecosystem. So one problem we have in cancer is that we have lots of datasets, but they are fragmented and disparate, and so, you know, the All of Us effort is a similar initiative to get big data. And in cancer, that would be particularly useful, and the Moonshot provides funding for that.

Lastly, the Moonshot includes some new initiatives around screening and early detection, which we spoke about earlier. One problem we have there, in particular, is getting these screening technologies that work, like colonoscopy for colon cancer, out in the communities so they are better used. So we have the sort of implementation science question about why is the screening rate lower than it ought to be? Because those are people that we can—it is a very effective way to screen for cancer, and we can cure a lot of cancer by making it never happen.

Mr. COLE. My question is really as much a budgetary question, to be fair to all concerned. Again, I want to point out, the administration, to be fair to them, didn't know what Congress was going to do in the Omnibus. So we have got one set of numbers.

But if we actually followed the budget that the administration proposes for fiscal year 2019, we would be—and believe me, our authorizers don't worry too much about whether or not we actually have the money to fund everything they authorize. That is just sort of lost to them somehow.

But could we still meet the commitments under 21st Century Cures on a 35-point-whatever it was billion dollar budget as op-

posed to what we have now, what we might be able to do next year?

Dr. SHARPLESS. I think that is at the NCI, we run out of money before we run out of good ideas. So what Congress disburses, we will figure out how to use, but I think the 2017 allocation has been phenomenally generous and very helpful to the war on cancer. And should we receive the full $400,000,000 as 21st Century Cures planned, as I said, that is an area where we could spend it wisely.

Dr. COLLINS. I think you may also be asking, though, in that circumstance sort of where does the rest of the NIH biomedical research portfolio land? And obviously, we have greatly benefited from the fact that Congress has been willing to allow scientists to figure out where the greatest scientific opportunities are and appreciate that. It continues to be the way in which this conversation has been going for all these years.

Mr. COLE. Yes, and we have had this discussion before. But under both parties, this is actually—NIH has been much more of a congressional priority, with all due respect to all administrations, than it has ever been, either Republican or Democratic administration priority. And I have often thought that is because maybe most of us working within our districts see the consequences and the possibilities here a little bit easier sometimes than the administrations do.

So I suspect that will continue, and hopefully, you won't have to live within the budget that you are proposing, which, you know, I think would be good.

PRIORITIES FOR $500 MILLION OPIOID RESEARCH

Just real quickly, Dr. Volkow, I will go to you. Obviously, $500,000,000 in new resources for NIH to conduct research related on opioids. You have touched on this, but could you give us, again, a quick overview of how you are going to use these funds to direct advances in the years ahead? What are your priorities?

Dr. VOLKOW. Well, the NIH has been working already on what are the top priorities that need to be addressed, and we can speak about it in two buckets. One of them that relates to interventions for prevention and treatment of opioid use disorder and overdoses, but the other very important bucket is that recognizing that we need to do much more research in pain and to develop medications that can help those suffering from pain so that we don't rely on opioids. That is an indispensable component of it.

So, we also are recognizing within these two buckets that there is an urgent need to come up with solutions right away. So the implementation project is one of the projects that we are moving forward in order to be able to show what we haven't shown yet, that we can revert the overdoses, that we can make a big impact if we integrate the knowledge that we have.

At the same time, the other bucket, the other strategy is what is it that we can do transformative that takes risks so that we can actually completely change the way that we treat, for example, addiction or pain? For addiction, wouldn't it be fantastic to have a vaccine that prevents addiction? In the way of pain, wouldn't it be fantastic to have a medication that prevents pain from emerging? Not treating it, prevents it.

So that is where the whole thinking is in terms of determining what may be the most meritorious project. We are very conscious that we are going to need to move this one rapidly because, again, I am going to reiterate we cannot afford to wait. We don't have the luxury of time.

Mr. COLE. Thank you very much. I go to my good friend, the ranking member, for the——

WHAT'S HAPPENED WITH MATERNAL HEALTH

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

Just a point, I wasn't going to ask about this, but Ms. Herrera Beutler made reference to maternity. And my interest has been around maternal mortality, which has, in essence, been declining in the developed world. However, in the United States, we have 26 deaths per 100,000 live births since 2015. This has more than doubled since 1987, and since 2015, the next country after the U.S., and this is the U.K., with 9. And these numbers, that African Americans higher.

I don't want you to have to address that now, but I would be very, very interested in getting a better sense and understanding of what is happening in the U.S. with the issue of maternal mortality.

Dr. COLLINS. Dr. Bianchi.

Dr. BIANCHI. Thank you for your question, Representative DeLauro.

We are very concerned about maternal mortality. This should not be happening in the United States in 2018. Our research at NICHD is focused on how we can prevent this from happening because, many times, it is happening due to conditions that the pregnant woman has. So, for example, cardiovascular disease, hypertension, preeclampsia, diabetes, depression. So we are doing a number of things through our maternal fetal medicine units, for example, where we are taking some of these big issues and either developing screening, better screening or better treatment.

So I will give you an example. For preeclampsia, which affects 7 percent of pregnant women and is certainly associated with maternal mortality, this is associated with hypertension and kidney, liver, and brain disease, we are testing pravastatin, which is a cholesterol-lowering drug. It has not previously been recommended during pregnancy.

We now have evidence through one of our obstetric and pediatric pharmacologic networks that it is safe to use, and it also prevented preeclampsia in a small study. So we are now translating that to a larger study within our maternal fetal medicine unit network and collaborating with the Heart, Lung, and Blood Institute. So the thinking is if we can prevent preeclampsia, we will prevent some of those maternal deaths.

UPDATE ON PROPOSED SALARY CAPS

Ms. DELAURO. I would love to continue that conversation there. You know, in listening to my colleagues, but listening to all of you and, you know, with the groundbreaking work that you are doing, that goes to something I mentioned in my opening statement. I do have a concern about the administration's proposal to cap the per-

centage of an investigator's salary, you know, at 90 percent, reduce the limit for salaries paid from grant funds from $190,0000 to $154,000.

I get concerned that we are going to see wonderfully early investigators, scientists, et cetera, move to the private sector rather than—or working in industry rather than working at the making academic research much less competitive. So is there—just your notion with regard to this about recruitment and retention is this view of what would you view as the potential effect?

Dr. COLLINS. So, it is certainly a time of great scientific opportunity. I think those early-stage investigators are pretty fired up about the chances they have in this climate to be able to make those breakthroughs that, Congresswoman, you talked about in your opening statement that we need more of. And I think most scientists who end up working in those laboratory settings are not driven primarily for financial reasons, or they would be doing something differently than working in biomedical research. But it is critical, to be sure, that we are in a circumstance where we cannot lose the opportunity to recruit the best and brightest and to retain them purely on the basis of a financial argument that we would continue to lose.

Obviously, universities where these folks are employed also have opportunities there to support them and do so. But in the current circumstances, I think it is fair to say that many of the people that we support, if they didn't have the grant funding would probably not be able to keep going because universities, for all of their own reasons, can't simply pick up the difference for all of their researchers who are primarily engaged and working in the laboratory.

Ms. DELAURO. I would just say that so much that we all question the amount of time we have to spend in fundraising in order to get re-elected to this institution. And I would much rather be working on policy rather than doing that, and I cannot imagine that researchers and scientists would much rather be looking at the investigative work rather than spending their time trying to have to do that.

So I thank you very, very much and will keep that filed as we proceed.

Thank you very much.

Mr. COLE. Thank you. We will now go to my good friend for a second round of questions, Ms. Herrera Beutler.

NEW TECHNOLOGY FOR TYPE 1 DIABETES

Ms. HERRERA BEUTLER. Thank you.

I am glad the congresswoman brought up the maternal mortality piece. That is also a huge one that has—we are now, we are increasing. It is not that we are even just at a high number, that we are increasing, and we do have legislation I think the congresswoman has recently signed on to that would assist the States.

Some have basically research teams, and some don't. And there is no standardization in terms of the data that we get. So we are hopeful to get the States engaged and involved to help with the work that we are doing so that we know why it is happening in certain areas and what the causes are.

I actually wanted to ask a question on behalf of a young constituent and her family, Paige from Washougal. She is 14 years old, and I am meeting with her tomorrow, and here is her question.

As a Type 1 diabetic diagnosed 7 years ago, I can tell you that living with diabetes is a daily pain. Thankfully, technology developed through the NIH research, including continuous glucose monitors and insulin pumps, has made my condition easier to manage. However, this technology is far from perfect.

What new technology is the NIH working on to improve the lives of people living with diabetes? What research is going on to better technology that will improve diabetes care, and what promising research is the NIH supporting that might eventually lead to a cure?

Dr. COLLINS. Thanks for the question, and I am glad you brought this in the context of an individual, Paige, who is living with this every day. Sometimes we get into the more general conversations, and we would always remember it is individuals with these illnesses or who are at risk for them that are counting on us to come up with that next set of breakthroughs.

For Type 1 diabetes, I think this is a very promising and exciting time. You mentioned already the opportunity for continuous glucose monitoring to replace what has been a very unpleasant part of the daily experience of having to prick your finger on an extremely regular basis and then adjust insulin doses. This has now been replaced for people who have access to that technology with much more regular measurements that are not so invasive.

But it still would benefit from going beyond that to what we might call a closed loop, where you have both the ability to sense glucose levels and then automatically adjust insulin doses, which is what your own pancreas does if it has not been attacked by the autoimmune consequences of Type 1 diabetes.

There are major advances happening in this so-called artificial pancreas, and FDA has already approved the first such device, which happened sooner than I thought it would. And clearly, there are opportunities for that to get better and better.

Ultimately, what many of us dream of is that that closed loop system would not be engineered by human hands in a direct way. It would be basically your own cells that have been convinced, maybe starting with a skin cell, that it could become a cell that could make insulin, and you could create an artificial pancreas made of your own cells derived by the remarkable advances that are happening with stem cell biology and which then would be in the best possible way responding in an essentially normal physiological way.

That is our best hope then for having the best way to regulate glucose and insulin and the greatest chance of reducing the consequences of long-term Type 1 diabetes, which includes all those things that we try to avoid, like eye disease and kidney disease.

I think it would be fair to say to Paige she is in a good position to probably be one of those who will see these advances happen in her lifetime and not that far. And I hope if she is interested, she might even consider participating in a clinical trial for one of these new ways to approach the management of the disease.

Ms. HERRERA BEUTLER. I appreciate that. I think what you are talking about, and Dr. Volkow—am I saying that right—who is a

bit of a spitfire, one of the things that you both expressed was where we hope to be, you know, pre-pain treatment, prevention of pain. And you are talking about, excuse me, in layman's terms, but reprogramming your own cells, right, to do what the other cells for whatever reason gave out on or quit doing.

Dr. COLLINS. Yes.

Ms. HERRERA BEUTLER. And that application is so exciting across so many disease states. I mean, that is what is thrilling is the ability to program cells within each individual. We are our own toolkits, and that is one of the reasons we have to continue to fight for funding for what you do and where the research is going to lead us. It is very exciting.

Mr. COLE. We will next go to my good friend from California, Ms. Lee.

UPDATE ON COPD, BRAIN INITIATIVE, AND MULTIPLE SCLEROSIS

Ms. LEE. Thank you very much.

First, let me just say thank you again for so much of what you are doing. As you know, and I have raised this a couple of times, my late mother had COPD, my sister has multiple sclerosis, and I have family members with sickle cell, sickle cell trait, you just name it. And what I have learned about these diseases is that the physicians, medical profession, don't know as much as I know, and that is because I have been there with my family members day and night during exacerbations and emergency rooms for many, many, many, many, many years.

So I want to thank you for the COPD plan of action. It is a very good report, the action plan, and I am wondering how this is going to be implemented, given I think that there is a proposed $250,000,000 cut in the National Heart, Lung, and Blood Institute, because I really want to see how this is going to move forward.

Secondly, with regard to multiple sclerosis, the BRAIN Initiative, how is the BRAIN Initiative engaging people living with MS and also trying to help us find a cure? And I don't know if there is a way to prevent MS, but certainly, the BRAIN Initiative gives me a lot of hope.

And finally, Cuba. I know you are well aware of the health incidents involving U.S. diplomats in Cuba. Three weeks ago, I asked Secretary Azar if CDC or NIH is involved in these ongoing investigations. I was there with the other Members in December and couldn't get a handle on whether or not our health agencies, NIH, are looking at these strange occurrences and if there is an action plan and how our diplomats are doing. Because I believe that NIH and CDC needs to be involved in this effort to determine the cause and the cure and how to treat these fine people who were really—who are suffering health occurrences.

And we don't know what they are, but our health agencies have not been involved in the investigation.

Dr. COLLINS. Those are all great questions. With regard to COPD, again, as I said earlier, in terms of the budgetary support since the President's budget was put together before the fiscal year 2018 omnibus, the numbers that you cite probably don't fit as well as they might for what we hope will happen in fiscal year 2019. And we are very invested in seeing that that particular strategic

plan for COPD gets implemented, and that is a lot what Dr. Gibbons and NHLBI is now planning to do.

Particular interest in trying to understand this consequence in rural communities, and there will be additional research opportunity for COPD implementation of appropriate bronchodilator studies, as well as trying to understand some of the genetic factors that predispose some people at a higher risk for COPD even with the same exposure as others. So, we are going to be big in pushing this.

With regard to multiple sclerosis, obviously, this is a circumstance where both the immune system and the brain are playing a role that doesn't turn out well once the autoimmune system kicks in and starts to do damage to the brain wiring. The BRAIN Initiative is going to teach us what that wiring looks like. The immune system is going to be critical for understanding exactly what we can do to block that attack.

Dr. Fauci's institute actually works quite a lot in that space. Tony, do you want to say something about HALT–MS?

Dr. FAUCI. Yes. We have had a very successful study, Congresswoman Lee. It was just called HALT–MS. It was high-dosed immunosuppressant followed by autologous stem cell transplantation, and the results were really breathtaking in the sense of people who have had severe relapsing multiple sclerosis. The overwhelming majority of them essentially went into what you would call a remission, a stabilization.

When you have severe relapsing MS, the course is almost always down. These individuals essentially all stabilized. So we are looking forward in the future to that being a major modality to treat severe multiple sclerosis.

Dr. COLLINS. And to answer your question about Cuba, we have now been asked to have the experts that NIH has to try to evaluate what some of the findings have been in these individuals who in the Diplomatic Corps now have suffered various neurological consequences. You may have seen that that has been evaluated already at the University of Pennsylvania, and there is a publication describing what some of those outcomes are.

And we are happy now to be drawn into that to see what our experts can do to try to make sense of what is clearly a surprising and still puzzling situation.

Ms. LEE. Will we be able to access the information, recognizing——

Mr. COLE. Microphone, please.

Ms. LEE. Recognizing the privacy issues, once you complete the evaluations, will we be able to read and look at the report and look at what the conclusions are?

Dr. COLLINS. I believe so. I don't know that I have specific guidance already about that. But given that the results from the University of Pennsylvania investigation were made public, I would think that is the trend we would want to follow.

Ms. LEE. Okay. Thank you very much.

Mr. COLE. And for our last round of questions today, we will go to Dr. Harris.

NIH'S ROLE IN ADDRESSING OPIOID DEPENDENCY

Mr. HARRIS. Thank you very much, and I am sorry I had to step out for a few minutes.

Let me go on to a topic that I think was broached while I was gone, which is the role of the NIH in the opioid dependency issue. And Dr. Collins, maybe you could say is the Accelerating Medicines Partnership, is this one of the focuses of it in developing new? Because I think we have to prioritize non-opioid pain medication development and both medication or devices, whatever works.

I mean, you know, obviously, in my practice for 30 years, I have been administering narcotics. But I think there is good evidence that we are on the verge of defining really groundbreaking ways to treat pain that will not subject individuals to the possibility of opioid addiction. So, is that something the Accelerating Medicines Partnership is looking at or vigorously investigating?

Dr. COLLINS. So, not specifically under the umbrella of the Accelerating Medicines Partnership, AMP, which has as its focus Alzheimer's disease, Type 2 diabetes, rheumatoid arthritis, lupus, and Parkinson's disease. There is another very related program under the NCI's direction called Partnership for Accelerating Cancer Therapies (PACT), which is about cancer immunotherapy. But we are explicitly looking at a partnership to try to address the opioid crisis, and we have been interacting over the course of the last year with no less than 33 companies that have equities and expertise in this space and have now developed, I think, a pretty exciting work plan, which we now need to put into specifics in terms of how it will be overseen and governed and making sure there is no conflict of interest involved.

But there are certainly some exciting things happening. I agree with you, particularly in coming up with nonaddictive, but potent pain medicines, things that, for instance, have already found their way into human trials like monoclonal antibody against nerve growth factor, which has had some concerns about side effects that are still a little murky, but certainly looks as if it could be pretty potent.

This recent development for migraine about anti-CGRP (calcitonin gene-related peptides). The effort to try to develop drugs that target a sodium channel called Nav1.7, which if you are born with that channel absent, you have congenital insensitivity to pain, which is not good for you. But if you had a drug that would do that temporarily, that could be very powerful, and it is a totally different pathway than opioids.

So, yeah, working with companies in details yet to be fully worked out, I think we can go faster than either sector can do alone, and that will be our determined effort to make that happen.

Mr. HARRIS. So for those products, I mean, one of the beauties of the Accelerating Medicines Partnership is its goal is to make sure that when things are designed, when the studies are designed, when the research is done, that it is going to satisfy the scientific rigor that the FDA is going to require so that, you know, we kind of expedite the development. So this other pathway is going to include this same, these same elements?

Dr. COLLINS. FDA is a very significant partner to all the discussions we have had. Exactly, we want to be sure that whatever comes out of this speeds up the process of developing these non-addictive pain meds.

MEDICATION-ASSISTED TREATMENT

Mr. HARRIS. Thanks.

Dr. Volkow, I had the opportunity to visit one of the treatment centers in my district in the last couple of weeks that does basically medication-assisted treatment and, you know, combine that with counseling and with other things. So not the traditional thing we think of sometimes as medication-assisted which is, you know, methadone. I mean, it is the new techniques.

Are we—my impression is, is that we still need a fair amount of research to see exactly which of those medication-assisted treatments are going to be effective and under what circumstances, which patient populations. Do you have the resources in your institute to do that, to look at, to answer these questions? Because I think, you know, we can stop the pipeline into addiction, but we still have to deal with the treatment of the millions of people who are in addiction right now.

So do we have the answers? Is this—do we need a substantially larger body of information before we know how we are really going to help these people with addiction?

Dr. VOLKOW. Definitely, we need—unfortunately, we don't have many answers to very important questions, like what patient would benefit from a particular intervention, what associated behavioral treatments are necessary, how long do you keep someone in treatment? Why is it that 50 percent of individuals that are given medication-assisted therapy relapse? So, there are many scientific questions.

With the money that is being given to address the opioid crisis, this will allow us to accelerate research in these particular areas, and we are also forming partnerships with other agencies to try to maximize what we can do with the dollars that we have.

So the answer I would—this is why it is so very welcome right now because these would be some of the scientific questions that we want to address, research so we can provide the evidence, and then the communities can utilize them.

Mr. HARRIS. Okay. Thank you very much. Yield back.

Mr. COLE. Appreciate that. And I want to recognize the gentlelady from Connecticut for whatever closing remarks she cares to make.

RANKING MEMBER ROSA DELAURO'S CLOSING REMARKS

Ms. DELAURO. Well, Mr. Chairman, I am going to take these closing remarks to say one thing with regard to relapsing, et cetera, on the opioid issue, is when I have talked to my communities, one, we do not have enough—this is not your problem—not enough beds for treatment. We do not have any services that when people do go through a treatment, I have been to the correctional institutions, and when they come out, there is no job. There is no place to live, et cetera. They are back out onto the street.

So, it is as much about what you do as it is about what happens in the community to provide those support services for people to get back onto their feet, and there are no recovery coaches to help people access services.

Didn't get to ask the question, Dr. Fauci, on the research on HIV and vaccines and your commentary on 50 to 60 percent effective was what we can look for. But it is a whole area that maybe that we can chat about and talk about. I would like to find out where we are on that because I think we have an opportunity with the investments that are being made to really take that and get to help to eliminate HIV transmission, and how we can do that. I think remarkable efforts in there.

And one thing I would like to probe at another point, you know that I am all for the BRAIN Initiative, Cancer Moonshots, the big initiatives that are out there. I also do get concerned about are we going down a road of earmarking in this in these efforts. What—and I will get the questions in to you, but what are we missing in terms of looking around at other—my colleague mentioned COPD, which is something, but other areas that we need to be looking at in terms of basic science across the institutes. And are we moving too far in the direction of earmarking funds instead of allowing that the highest quality of research proposals to be funded wherever that might be found? And that has really been a mainstay of this committee.

I end where I started. It is thrilling to listen to what can be done, and the ultimate piece of this is, is that we talk about roads. We talk about bridges. I talk about helicopters. We talk about all of this, whatever it is in our particular districts. What you do and what you talk about is saving lives. Let us push the edge of the envelope in this institution where we have the power to be able to do that with providing you with the resources that you need.

Thank you very, very much for today.

Mr. Chairman, thank you.

CHAIRMAN TOM COLE'S CLOSING REMARKS

Mr. COLE. I thank the gentlelady and certainly associate myself with her comments.

And I want to begin by thanking all of you, Dr. Collins, all of your colleagues. You always bring us an all-star cast, and you have done it again.

I also want to recognize that in a very contentious and polarized political time how important the NIH has been as something that there has been a focus that both parties and people across the political spectrum have been willing to work on together, and that testifies, frankly, to the confidence that all of us and the Congress have in the institution and in the men and women there that are doing such spectacular work on behalf of the American people, on behalf of humanity.

And I want to particularly compliment my good friend, the ranking member, who is, frankly, always a delight to work with, but particularly in this area, where she has been extremely effective and very passionate for a very long period of time. And the American people have much to be grateful for in terms of her advocacy.

So, again, thank each and every one of you. We look forward to having another good hearing. And hopefully, as we work through the 2019 budget, another good result where this institution is concerned.

So thank you. We are adjourned.

House Appropriations Committee

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Budget Oversight Hearing: National Institutes of Health

Wednesday, April 11, 2018

Chairman Tom Cole Questions for the Record

Salary Cap

Cole 1: Your fiscal year 2019 budget request proposes a new policy that would cap the percentage of a researcher's salary that may be paid for using NIH grant dollars. What is the goal of this policy, and what is the projected impact of covering these additional costs on academic institutions?

Answer: Because federal research funds are limited, reductions in the NIH contributions to the salary of researchers on NIH grants leaves more funds for additional scientists along with the equipment and resources they need to carry out their critically important work. This may also provide funds that may be used to fund additional grants.

NIH is aware of varying degrees of salary support for its funded scientists. In some institutions, scientists are expected to seek external grant funds to support most of their salaries. Other institutions provide most, if not all, of the salary support.

Based on a NIH enumeration study[1], the NIH supports approximately 313,049 full-time and part-time positions, or the equivalent of 121,465 full-time employed individuals each year. We believe that approximately half of these full-time researchers are affected by the salary cap. Institutions may choose to increase tuition, utilize funds from their endowments, or solicit state level support to absorb some of the costs engendered by the salary cap. Some stakeholders have voiced concern that stringent salary caps may lead to disincentives for certain highly-skilled clinician scientists who may be well-positioned to conduct the kind of science solicited by NIH. The selective pressures on such individuals may lead to a lower number of them willing to engage in NIH-funded research. The NIH is cognizant of these potential effects, but in no way intends for the policies included in the President's Budget to hinder the critically important biomedical research funded by NIH.

[1] Pool, Lindsay R., et al. "Size and characteristics of the biomedical research workforce associated with US National Institutes of Health extramural grants." *The FASEB Journal*30.3 (2015): 1023-1036

Early-Stage Investigators

Cole 2: Your budget proposes a $100 million set-aside within the Office of the Director to support the Next Generation Researchers Initiative. Would you please describe how this funding will be used by the Institutes and Centers to support and maintain early-stage investigators in biomedical research?

Answer:
The National Institutes of Health (NIH) plans to continue prioritizing meritorious research proposals from early-stage investigators. We anticipate that these additional resources will be used to help fund more early stage investigators, compared to what we otherwise could through established programs within the NIH Institutes and Centers. This could be achieved, in part, through more R01 (or equivalent) research grants being awarded, which will help them launch independent careers.

In addition, we will work with the NIH Institutes and Centers to promote expansion of other programs that have been particularly successful for early stage investigators, including:

1) NIH Director's New Innovator Award Program (DP2), which supports early-stage investigators of exceptional creativity who propose bold and highly innovative new research approaches with the potential to have a major impact on broad, important problems in biomedical and behavioral research.

2) The Maximizing Investigators' Research Award (R35) for early-stage investigators to enhance their ability to take on ambitious scientific projects, spend time on research, and reduce the time spent writing grant applications.

3) The NIH Pathway to Independence Award (K99/R00) program to facilitate a timely transition of outstanding postdoctoral researchers to independent, tenure-track, or equivalent faculty positions and help awardees to launch competitive, independent research careers.

4) The Director's Early Independence award (DP5), as part of the NIH Common Fund's high-risk high reward initiative, aims to support more bold and innovative research activities with the opportunity for rapid progress. Specifically, this program accelerates the entry of exceptional junior scientists into an independent research career by forgoing the traditional post-doctoral training period. These select investigators have established a record of scientific innovation and research productivity as well as demonstrated unusual leadership, drive, and maturity,

5) The High Priority, Short-Term Project/Bridge Awards (R56) for early-stage investigators, which provide limited, interim research support to gather additional data for revised grant applications.

NIH remains strongly committed to supporting early-stage investigators in biomedical research. We will continue to develop, monitor, and optimize programs to help early career investigators succeed and advance their careers.

2018 Funding Increases All of Us Initiative

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: In fiscal year (FY) 2018, the *All of Us* Research Program will finish its beta phase and launch nationally on May 6, 2018. The program will continue its enrollment and retention activities as well as the collection of individual data and biospecimens by expanding the geographic reach of the program through new partner sites within the direct volunteer and the health care provider organization network. Additionally, the program is facilitating enrollment of communities historically underrepresented in biomedical research by building a national network of trusted leaders to motivate a variety of communities to join *All of Us*. The program will ensure that the data is shared back with participants according to their preferences. In addition, *All of Us* will coordinate the implementation of Sync for Science, a pilot to allow individuals to access their electronic health record and send it to researchers in collaboration with federal and academic partners. With the funding provided in FY 2018, the program also plans to fund *All of Us* Genome Centers, using Other Transaction Authority, to generate both genotyping and whole genome sequencing data from biospecimens from this cohort.[2]

The FY 2019 President's Budget request for the program is $357.570 million, including $186 million from the NIH Innovation Account. In FY 2019, the program plans to continue enrollment and retention of participants from across the United States, accelerate the generation of genomic data, and start a pilot on the responsible return of genetic results to participants. In addition, in FY 2019, *All of Us* will open the research portal, allowing researchers access to the data to ask key questions about health and disease, and begin enrollment of children in the spring/summer of 2019.

[2] https://grants.nih.gov/grants/guide/notice-files/NOT-PM-18-002.html

2018 Funding Increases Alzheimer's Disease Research

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: Since passage of the National Alzheimer's Project Act in 2011, an extraordinary increase of funding directed at Alzheimer's disease and related forms of dementia (AD/ADRD) has enabled NIH, led by the National Institute on Aging (NIA), to make tremendous inroads toward our goal of precision medicine to prevent and effectively treat AD/ADRD. In FY 2018, NIH is using these funds to build a series of bold and innovative research programs, infrastructure, and new partnerships. We are:

- Harnessing the tremendous power of analyzing massive, and differing types of, data sets across many studies ("Big Data") to gain insight into the basic biology of AD/ADRD, as well as factors that may confer resilience to these diseases;
- Accelerating the discovery of the next generation of new targets and biomarkers through the open science research model of the Accelerating Medicines Partnership for AD;
- Establishing new translational infrastructure programs, including the groundbreaking Alzheimer's Clinical Trial Consortium (ACTC), to enable rapid sharing of data and research models and enhancing research rigor and reproducibility; and
- Supporting over 140 active clinical trials of interventions to enhance cognitive health in older individuals and to prevent, treat, or manage symptoms of AD/ADRD.

Guided by input from researchers and advocates worldwide through key scientific conferences, including periodic Summits on Alzheimer's Disease, Alzheimer's-Related Dementias, and AD/ADRD Care and Supports, we estimate our total FY 2019 resource needs for AD/ADRD research to be $1,516,000,000. These funds will allow us to build upon the foundation currently being laid, including continuation of high priority programs such as the ACTC as well as:

- **Molecular Mechanisms of the Vascular Etiology of Alzheimer's Disease (M^2OVE-AD) Initiative,** which explores the vascular system's involvement in AD/ADRD;
- **Alzheimer's Biomarker Consortium – Down Syndrome (ABC-DS),** in which researchers use biomarkers to track disease progression in people with DS, a uniquely vulnerable population;
- **Alzheimer's Disease Preclinical Efficacy Database (AlzPED),** a web-based portal for housing, sharing and mining of preclinical efficacy data; and
- The **Model Organism Development and Evaluation for Late-onset AD (MODEL-AD)** project to develop a better mouse model of late-onset AD.

Other priorities for FY 2019 include development of caregiver support interventions; implementation of a national recruitment strategy that ensures inclusion of diverse populations in AD/ADRD research; creation of a connectivity atlas for neuronal cell lines, which will help us

predict brain cells' response to interventions; training for investigators in AD/ADRD bioinformatics; and harmonization and distribution of data from large datasets. NIH's research implementation milestones for AD/ADRD[3] will continue to frame our most critical research priorities. NIH appreciates the continued support of the Congress in this critical area of research. Sustained funding will enable NIH to continue to address the complex challenges of AD and ADRD.

[3] https://www.nia.nih.gov/research/milestones

2018 Funding Increases BRAIN Initiative

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: The NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative aims to revolutionize our understanding of the human brain by accelerating the development and application of innovative technologies that will allow researchers to produce comprehensive and dynamic maps of the brain, deepen our understanding of how neural circuit activity can produce behaviors, and lay the foundation for understanding how its circuitry is disrupted in brain disorders.

NIH BRAIN Initiative funding decisions have been guided by external scientific expertise at every step. Informed by *BRAIN 2025: A Scientific Vision*[4] and regular discussions with the scientific experts on the BRAIN Multi-Council Working Group, the NIH BRAIN Initiative is a flexible, multi-faceted science program focused on understanding the dynamics of information flow occurring in neural circuits.

Since the NIH BRAIN Initiative began, more than 345 awards have gone out to 504 investigators, reflecting an investment of $550 million. Maps of whole brains in action, the ability to identify thousands of brain cells at a time, and innovative brain scanners are just a few of the exciting areas that received fiscal year (FY) 2017 BRAIN Initiative support. Investments in FY 2018 include plans for large-scale recording and modulation of the nervous system, development of next-generation invasive devices, studies of the biology and biophysics of neural stimulation, the development of tools to target, identify, and characterize non-neuronal cells, and early stage next generation human brain imaging.

A signature BRAIN Initiative effort from FY 2017 is the BRAIN Initiative Cell Census Network[5] which aims to provide researchers with a comprehensive reference atlas of diverse cell types in human, monkey, and mouse brains. With $250 million invested over the next five years, BRAIN Initiative funding will support a network of centers, collaborating laboratories, and data resources to integrate information about individual brain cell types and map them onto a common framework. In FY 2018 and increasingly in 2019, BRAIN Initiative investments will support efforts aimed at generating reference brain cell atlases from postmortem healthy adult human and/or non-human primate brain samples, including efforts to both produce and mine these data to gain deeper understanding of the functions of these specific cells and the circuits they form.

---

[4] https://www.braininitiative.nih.gov/pdf/BRAIN2025_508C.pdf

[5] https://www.nih.gov/news-events/news-releases/nih-brain-initiative-launches-cell-census

In FY 2017, NIH supported a group of separate but interrelated research projects to create: 1) standards for the different types of experimental data being collected using tools developed by the BRAIN Initiative; 2) data repositories to hold these data; and 3) software to allow integration of the data in multiple archives, allowing the visualization and analysis on a central platform. These projects may be amplified by additional investments in FY 2018 and FY 2019 to support development of standards for additional data types, new repositories, and analytic software, so that the broad array of sequencing, recording, imaging, and behavior data being generated by the BRAIN Initiative are able to be shared and analyzed among researchers across the broad neuroscience community.

Importantly, though the BRAIN Initiative is primarily focused on unlocking the secrets of how the normal human brain functions, it is also actively interested in pursuing projects to better understand and correct brain dysfunction. For example, the NIH BRAIN Initiative issued a FY 2018 Notice[6] to support research on the fundamental neurobiology of pain processing as part of NIH's multi-pronged approach to address the nation's opioid crisis. BRAIN Initiative investigators aim to produce maps of pain and reward circuits and use newly-developed tools to monitor and modulate pain and reward circuit activity, potentially transforming our understanding of pain and addiction and opening the door to new treatment avenues. In addition, the BRAIN Initiative currently includes projects that use cutting-edge technologies to record and modulate brain circuit activity to improve conditions such as Parkinson's disease, obsessive compulsive disorder, depression, and recovery from stroke.

In order for the BRAIN Initiative to succeed in transforming our understanding of the brain, there must be efforts to promote rapid dissemination of the novel tools, technologies, and associated resources being developed, and efforts to foster their integration into neuroscience research. Beginning in FY 2018 and continuing in FY 2019, NIH plans to fund research teams to distribute tools and provide access to resources relevant to achieving BRAIN Initiative goals, as well as train users in these new technologies and refine these products so they meet the needs of a broader user community.

Novel BRAIN Initiative technologies or resources with commercial potential may also be further developed and disseminated through the Small Business Innovation Research (SBIR) program or the Small Business Technology Transfer (STTR) program. Looking ahead to FY 2018 and FY 2019, the NIH BRAIN Initiative plans to support small business funding opportunities.

With the $400 million provided to NIH by Congress in FY 2018 through a combination of regular appropriation and funds from the 21st Century Cures Act, NIH has made substantial progress in reaching the funding target laid out in the *BRAIN 2025* Report through FY 2020. In charting the second phase of the Initiative, the NIH is embarking on a process of obtaining input from the public, patients, and the wider scientific community. A new Working Group of the NIH Advisory Committee to the Director will use the *BRAIN 2025* report as a guide and identify new specific topics and questions for high priority research areas that now can be pursued given

[6] https://grants.nih.gov/grants/guide/notice-files/NOT-NS-18-008.html

recent advances in BRAIN Initiative-funded tool and technology development. The advisory group is on track to deliver an updated strategic plan in time to shape FY 2020 funding opportunities, and it will propose new budget estimates that reflect the scope of the new research topics of the NIH BRAIN Initiative.

2018 Funding Increases Combating Antibiotic-Resistant Bacteria Initiative

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) continues to prioritize research to address the increasing public health threat of antibiotic resistance. NIAID supports a comprehensive portfolio of basic, clinical, and applied research to better understand the mechanisms of drug resistance and to develop interventions to combat it. NIAID plays a lead role in addressing the goals of the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), including the development of diagnostics, therapeutics, and vaccines for drug-resistant bacteria. Additional CARB funding provided by Congress in the fiscal year (FY) 2018 Consolidated Appropriations Act will enhance ongoing CARB research activities and enable NIAID to support additional innovative research focused on CARB.

In FY 2018, NIAID will fund highly meritorious research projects on antimicrobial resistance by issuing new targeted CARB research initiatives focused on developing: (1) clinical diagnostics; (2) tools to facilitate discovery of novel therapeutics; and (3) vaccines and prevention strategies that target the immune system. New awards will build on successes in NIH-supported CARB research in FY 2018 including: 1) identifying two common, inexpensive antimicrobials that can help patients heal from methicillin-resistant *Staphylococcus aureus* (MRSA) skin abscesses; 2) launch of the second phase of the joint NIH-BARDA CARB diagnostic challenge seeking to identify innovative, rapid point-of-care diagnostics to combat the development and spread of drug-resistant bacteria; and 3) support for more than 35 clinical studies investigating diagnostic devices, optimized treatment regimens, new drugs, and projects on antimicrobial stewardship, through the NIAID Antibacterial Resistance Leadership Group (ARLG). NIAID continues to collaborate with BARDA on CARB-X, a unique public-private partnership dedicated to accelerating the development of innovative antibacterial products.

The FY 2019 President's Budget provides $478 million for CARB research at the NIH. The NIH anticipates that its ongoing CARB research and partnerships across government, as well as new activities enabled by FY 2018 funding, will continue to support progress against antibiotic-resistant bacterial infections in FY 2019. NIAID remains committed to further advancing robust efforts aligned with the goals of the National Action Plan for CARB, including stimulating the field and recruiting new scientists to enter this area of research. NIAID appreciates the support of the Congress in the critical area of antimicrobial resistance research. Sustained funding will enable NIAID to continue to address the perpetual challenge of antibiotic-resistance bacteria.

2018 Funding Increases Clinical and Translational Science Awards (CTSAs)

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: The FY 2018 omnibus provided $542.8 million for the National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards (CTSA) Program, an increase of $26.7 million over fiscal year (FY) 2017. This funding level provides stability to awarded academic institutions and enables additional funding to support important research priorities and programmatic needs. NCATS will use these funds: to continue to support new and competing awards to CTSA Program hub institutions[7]; to provide supplemental funding to hub institutions to address the NCATS' research priorities; to support the continued dissemination of NCATS Streamlined, Multisite, Accelerated Resources for Trials Institutional Review Board (SMART IRB) initiative[8]; and to reinforce collaboration and innovation across the network with additional support through Collaborative Innovation Awards and Supplements.

NCATS will be able to fund 16 meritorious competing hub applications that scored well in peer review, thereby increasing the total number of CTSA Program hub awards by one compared with fiscal year 2017.

Supplemental funding (per the posted notice NOT-TR-18-022)[9] will be available to hub institutions for proposals that address high program priorities. NCATS anticipates that this supplemental funding will contribute to significant progress in the following priority research areas: 1) development of models of care for Opioid Use Disorders within medical settings including primary care, emergency departments, and neo-natal units, 2) development of research software applications and standards to facilitate the exchange of clinical data between systems, making clinical trials management across multiple sites more efficient, 3) development of machine-assisted decision technologies that support the diagnosis of rare diseases, 4) enhancement of electronic health record data capture to speed patient assessments, 5) development of novel telemedicine-enabled technologies to evaluate patients remotely, 6) testing of wearable devices for clinical data collection from patients in their own environment, 7) access to novel training and education for the translational science workforce using open educational resources such as online courses, and 8) development of advanced cutting-edge instrumentation technologies that would transform the translational science process. For more information see: CTSA Governance, Guidance, and Policies.[10]

---

[7] https://ncats.nih.gov/ctsa/about
[8] https://ncats.nih.gov/ctsa/projects/smartirb
[9] https://grants.nih.gov/grants/guide/notice-files/NOT-TR-18-022.html
[10] https://ctsa.ncats.nih.gov/policies?type=guidelines&date=2018-04-10&title=priority-research-areas

The additional funding will also support the continued development, demonstration, and dissemination of NCATS SMART IRB, a platform designed to ease common challenges associated with initiating a clinical research study across multiple sites. SMART IRB provides a roadmap for institutions to implement the NIH Single IRB Review policy, to enhance and streamline the ethics review process for a multi-site clinical study so that research can proceed as effectively and expeditiously as possible. This high profile, high value initiative will streamline the conduct of multi-site clinical trials on a national scale and foster collaboration among academic health centers across the U.S. Presently 417 institutions, including all CTSA Program hubs, have signed the IRB master reliance agreement and the process of testing and implementation is under way, including the use of the CTSA Program Trial Innovation Network as a test bed.[11]

NCATS will be able to support and strengthen innovative, collaborative research in the CTSA Program through Collaborative Innovation awards and supplements that address high priority translational science questions. NCATS expects the additional funding will result in research progress in the following areas: 1) the timely diagnosis of acute graft rejection through repurposing of existing high throughput technologies to the new paradigm of sequencing activated immune cells, 2) a predictive toxicology system that is animal-free and utilizes human liver and brain cells linked in series to test promising human therapeutics 3) a robust predictor of clinically important surgical outcomes including mortality and hospital readmission rate that utilizes readily available clinical and demographic parameters, 4) advance the use of gene sequencing as standard of care by comparing it to usual care in newborns at high risk of a genetic disorder, and 5) enable the use of "exercise" as an outcome measure in multi-site clinical trials involving children by supporting standardization and interoperability of pediatric exercise testing protocols.

The President's FY 2019 budget provides $500.9 million for the CTSA Program, a reduction of $41.9 million from the FY 2018 level. At this budget level, providing stability to the hub program would be a top priority. NCATS would also prioritize dissemination of the results of the research funded in FY 2018 and other advances in translational science broadly across the CTSA Program and the nation to improve the health of individuals and the public. This would be accomplished through continued support of two coordinating centers that amplify and promote advances from the CTSA Program hubs: The Center for Leading Innovation and Collaboration employs a robust communications infrastructure for the hubs and for the public that reaches across the nation; the National Data to Health Coordinating Center leverages informatics discoveries from across the CTSA Program to benefit health.

[11] https://smartirb.org

2018 Funding Increases Institutional Development Awards (IDeA)

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: NIH appreciates the Committee's continued support for the Institutional Development Award (IDeA) program. NIH believes that the IDeA program is a valuable mechanism for helping to encourage biomedical research programs in a broader range of institutions and states.

I. Overall *Goals and Outcome Expectations*

The overarching mission of the IDeA Program is inclusive *Biomedical Research Capacity-building* – to develop and strengthen biomedical science research in States/Jurisdictions of the country that are underrepresented in the NIH portfolio, to enable increased engagement and participation of these states in scientific areas that are supported by NIH, and to promote biomedical research capacity and capabilities in these states that are competitive and sustainable. Consequently, the goals and outcome expectations of the IDeA program are as follows:

- Growth in the pool of next generation scientific leaders and innovators through targeted professional development efforts.
- Development and enhancement of research facilities and resources in eligible States/Jurisdictions that will enable investigators to expand their contributions to scientific discovery, innovation, and learning.
- Establishment of inclusive and sustainable biomedical workforce development pathways that will equip human resources with the appropriate intellectual and technical scientific skills.
- Meaningful engagement of both the research and the at-large communities in addressing vital and urgent scientific questions and societal priorities including those of the medically underserved and/or the health concerns that are prevalent in eligible states.

II. Allocation of FY 2018 Appropriated Funds for the IDeA Program

The IDeA Program, administered by the National Institute of General Medical Sciences (NIGMS) at NIH, has 4 major ongoing initiatives in pursuit of its goal of strengthening biomedical research capacity and competitiveness in eligible states[12] In FY 2018, the IDeA Program received $350.6 million in appropriation (an increase of $17 million from FY 2017 appropriation). The interventional initiatives and the awards being made in FY 2018 include the following:

(1) IDeA Networks of Biomedical Research Excellence (INBRE). The INBRE initiative enhances, extends, and strengthens the research capabilities of biomedical research faculty in IDeA states

[12] Alaska, Arkansas, Delaware, Hawaii, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Rhode Island, South Carolina, South Dakota, Vermont, West Virginia, Wyoming.

through a statewide program that links a research-intensive institution with primarily undergraduate institutions. Only one award is made per IDeA-eligible state. In FY 2018, the IDeA Program is supporting 24 INBRE awards (22 continuing awards, 2 competing renewals)[FY 2018 budget allocation: $81.2 million].

(2) *Centers of Biomedical Research Excellence (COBRE – Phases I, II, and III).* The COBRE initiative develops and strengthens institutional biomedical research capabilities in IDeA states through three 5-year phases of infrastructure and faculty development of multidisciplinary research centers around a specific biomedical science theme (e.g. infectious disease, neuroscience, cancer, cardiovascular, diabetes). In FY 2018, the IDeA Program is supporting the following COBRE awards [FY 2018 budget allocation: $200 million]:
   a. Phase I (53 continuing awards, 11 new awards)
   b. Phase II (17 continuing awards, 13 competing renewals)
   c. Phase III (34 continuing awards, 5 competing renewals)

(3) *IDeA Program Infrastructure for Clinical and Translational Research (IDeA-CTR).* The IDeA-CTR initiative develops network infrastructure and capacity in IDeA-eligible states to conduct clinical and translational research focused on health concerns that affect medically underserved populations and/or that are prevalent in IDeA states. In FY 2018, the IDeA program is supporting 11 IDeA-CTR awards (7 continuing awards, 3 competing renewals, 1 new award) [FY 2018 budget allocation: $43.7 million].

(4) *IDeA Co-funding.* Funds are provided to eligible applications that have already been judged meritorious by NIH peer-review
   a. Investigator Research Co-funding – Priority are given to investigators early in their career (R01) and those in primarily undergraduate institutions (R15). In FY 2018, the IDeA Program is expecting to co-fund 59 R01/R15 investigator research awards nominated by 17 NIH ICs [FY 2018 budget allocation: $16.7 million].
   b. Shared Instrumentation Grant (SIG) and the High-End Instrumentation (HEI)(S10 mechanism)Co-funding – These awards are administered by the NIH Office of Research Infrastructure Programs (ORIP). In FY 2018, the IDeA Program is co-funding 4 of these S10 awards [FY 2018 budget allocation: $3.1 million]. This is the first year that the IDeA Program is co-funding these awards.

(5) *Administrative Supplements.* For FY 2018, the IDeA Program is allocating $1 million to fund administrative supplements (to IDeA-CTR awardees) specifically focused on addressing the opioid epidemic, a major public health concern in many of the IDeA states.

The $17 million increase in FY 2018 appropriation for the IDeA program allows NIGMS to fund additional meritorious grant applications that would not otherwise be possible without the budget increase. Table 1 shows the impact of the FY 2018 appropriation on the different IDeA Program initiatives.

Table 1. Impact of FY 2018 Appropriation on New and Renewal IDeA Program Awards.

IDeA Program Initiatives	Planned awards, without the FY 2018 budget increase	Additional Awards enabled by the FY 2018 budget increase	TOTAL Awards for FY 2018
INBRE, renewal awards	2	No increase	2
COBRE Phase I, new awards	5	**6**	11
COBRE Phase II, renewal awards	11	**2**	13
COBRE Phase III, renewal awards	5	No increase	5
IDeA-CTR, new awards	0	**1**	1
IDeA-CTR, renewal awards	3	No increase	3
Investigator Research (R01/R15) Co-funding	59*	No increase	59
SIG/HEI (S10) Co-funding	None	**4**	4
Administrative Supplements (Opioid-related)	None	**4***	4

*anticipated number of awards (as of this writing, 05/08/18)

The increase in IDeA program appropriation has enabled funding of the following additional grant applications:

- COBRE Phase I, new awards:
  - [DE] *Center for Translational Neuroscience* (Alfred I. du Pont Hospital for Children)
  - [NE] *Nebraska Center for Molecular Target Discovery and Development* (University of Nebraska Medical Center)
  - [RI] *Center for Antimicrobial Resistance and Therapeutic Discovery* (Miriam Hospital)
  - [RI] *Center on Opioids and Overdose* (Rhode Island Hospital)
  - [VT] *Translational Research to Prevent and Control Global Infectious Diseases (Translational Global Infectious Diseases Research Center, TGIR)* (University of Vermont)
  - [WV] *Tumor Microenvironment* (West Virginia University)
- COBRE Phase II, renewal awards:
  - [MS] *Center of Biomedical Research Excellence in Pathogen Host Interactions* (Mississippi State University)
  - [RI] *Center for Central Nervous System Function* (Brown University)
- IDeA-CTR, new award:
  - [ND] *Dakota Cancer Collaborative on Translational Activity* (University of North Dakota)

III. IDeA Program FY 2019 Budget

The FY 2019 President's Budget was built on the FY 2018 Annualized CR level. The NIGMS total program level decreases by 2.29% in the FY 2019 PB from the FY 2018 Annualized CR level to $325.7 million

IV. FY 2019 Programmatic Plans

For FY 2019, the IDeA Program appropriation will be utilized to fund continuing awards (about two-thirds of the IDeA appropriation goes to committed projects) and new meritorious applications to the COBRE, IDeA-CTR, and co-funding initiatives. The program will continue to build research capacity though ongoing and new INBRE, COBRE and IDeA-CTR awards in eligible institutions and there are still many opportunities for the IDeA Program to make an impact in these institutions and their investigators. The IDeA Program hopes to continue its research capacity-building mission and to fund more of these awards. NIGMS will continue to evaluate the IDeA Program to identify best practices and new approaches to impact the targeted research and at-large communities in these states/jurisdictions and to address any unmet needs such as this year's administrative supplements aimed at the opioid crisis.

Opioid Research

Cole 3: The fiscal year 2018 omnibus provided significant funding increases for several NIH initiatives and programs. For the following initiatives and programs, please describe how NIH will spend these additional resources, what outcomes NIH expects to achieve, what level of funding NIH is requesting in fiscal year 2019, and how NIH proposes to build off of this progress in fiscal year 2019:

Answer: In April 2018, the National Institutes of Health (NIH) launched the Helping to End Addiction Long-term (HEAL) Initiative [13]to speed scientific solutions to stem the national opioid public health crisis. This Initiative will build on extensive, well-established NIH research, including basic science of the complex neurological pathways involved in pain and addiction, implementation science to develop and test treatment models, and research to integrate behavioral interventions with medication-assisted treatment for Opioid Use Disorder (OUD). Successes from this research include the development of the nasal form of naloxone, the most commonly used nasal spray for reversing opioid overdose, the development of buprenorphine for the treatment of opioid use disorder, and evidence for the use of nondrug and mind/body techniques such as yoga, tai chi, acupuncture, and mindfulness meditation to help patients control and manage pain.

The NIH HEAL Initiative will bolster research across NIH to:

- *Prevent Addiction through Enhanced Pain Management:* More than 25 million Americans suffer from daily chronic pain. NIH will support research to understand how chronic pain develops, making patients susceptible to risks associated with OUD. NIH will work with partners from the biopharmaceutical industry to develop a data sharing collaborative, new biomarkers for pain, and a clinical trials network for testing new pain therapies. NIH will also enhance the pipeline of treatments for pain and enhance clinical practice for pain management.
- *Improve Treatments for Opioid Misuse Disorder and Addiction:* More than 2 million Americans have OUD. Millions more misuse opioids, taking opioid medications longer or in higher doses than prescribed. NIH will support research that can prevent and treat opioid misuse and addiction, and that will help people with OUDs achieve and maintain a meaningful and sustained recovery.

[13] https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative

Childhood Cancers

Womack 1: Federal funding for pediatric cancer research has been historically low considering the high prevalence of childhood cancers, usually around 4% of the NCI budget.

a. How much of the FY18 NCI appropriation was be allocated to pediatric cancers?

b. And how much under the proposed FY19 budget request?

Answer: Pediatric cancer research remains a top priority for the National Cancer Institute (NCI), and each year the Institute identifies the best research opportunities to build upon the foundation of basic science, further develop the scientific understanding of genetic drivers of childhood cancers, identify effective therapies, and enhance the quality of life for pediatric cancer survivors.

Funding figures that NCI and the National Institutes of Health (NIH) report each year reflect only research projects identified as specifically focused on childhood cancer, such as the research data reported in the NIH Research, Condition, and Disease Categorization (RCDC)[14] database. While RCDC is a useful tool, it does not provide the complete picture of NIH and NCI investments that advance childhood cancer research. For example, approximately half of the NCI budget – and half of the overall NIH budget – supports basic research that cuts across many disease areas.[15] Sustained support of basic research builds scientific knowledge of the biology of cancer, allowing researchers to capitalize upon this foundation to develop future therapies.

Recognizing that childhood cancers are distinct from adult cancers, NCI supports numerous targeted programs aimed at advancing research in pediatric oncology. These efforts include:

- The Children's Oncology Group (COG)[16], part of NCI's National Clinical Trials Network (NCTN), develops and coordinates pediatric clinical trials across more than 200 member institutions. In addition to conducting late-phase clinical trials, the COG receives NCI support for the Phase 1 and Pilot Consortium,[17] which conducts early-phase trials and pilot studies to rapidly introduce new anticancer agents into pediatric care.
- The Pediatric Oncology Branch (POB)[18] in NCI's Center for Cancer Research, part of NCI's intramural research program, conducts high-risk, high-impact basic, translational, and clinical research.
- The NCI-COG Pediatric MATCH Trial[19], launched in July 2017, tests molecularly targeted therapies in children and adolescents with advanced cancers who have few other treatment options. This nationwide trial is open to children and adolescents from 1 to 21 years of age and currently has eight treatment arms.

---

[14] https://report.nih.gov/rcdc/
[15] https://nexus.od.nih.gov/all/2016/03/25/nihs-commitment-to-basic-science/
[16] https://www.childrensoncologygroup.org/
[17] https://www.childrensoncologygroup.org/index.php/phase-1-home
[18] https://ccr.cancer.gov/Pediatric-Oncology-Branch
[19] https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/pediatric-match

- Other efforts include the Pediatric Preclinical Testing Consortium (PPTC),[20] the Therapeutically Applicable Research to Generate Effective Treatments (TARGET)[21] program, the NCI Experimental Therapeutics (NExT) Program,[22] the Childhood Cancer Survivor Study (CCSS),[23] the Pediatric Provocative Questions (PQ) Program, [24] the Pediatric Brain Tumor Consortium (PBTC),[25] the Pediatric Cancer Immunotherapy Trials Network (CITN),[26] and the New Approaches to Neuroblastoma Therapy (NANT)[27] Consortium.

In addition to these well-established programs, the Institute is enthusiastic about the scientific opportunities provided by the Cancer Moonshot[SM] to stimulate further investigation of pediatric cancers. Current programs supported by the Cancer Moonshot[SM] include the Fusion Oncoproteins in Childhood Cancers (FusOnC2) Consortium, which will seek to develop models of, and therapeutic agents for, fusion-driven childhood cancer;[28] the Pediatric Immunotherapy Translational Science Network, which will aim to identify targets for immunotherapy treatments for pediatric patients;[29] and the Rare Tumor Patient Engagement Network,[30] which aims to study rare tumors, including pediatric tumors, and develop a network of clinical trials.

NCI also encourages you to visit the "Childhood Cancers Research" page on its website for additional information about current research, including more comprehensive descriptions of some of the programs mentioned above.[31] Research on childhood cancers will continue to be a top priority in fiscal year 2019 and beyond.

---

[20] http://www.ncipptc.org/
[21] https://ocg.cancer.gov/programs/target
[22] https://next.cancer.gov/
[23] https://www.cancer.gov/types/childhood-cancers/ccss
[24] https://grants.nih.gov/grants/guide/pa-files/PAR-16-217.html
[25] https://www.pbtc.org/
[26] https://ctep.cancer.gov/MajorInitiatives/cancer_immunotherapy_trials_network.htm
[27] http://www.nant.org/
[28] https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-049.html
[29] The foundation of this initiative began in 2017, with the release of two FOAs to establish the Pediatric Immunotherapy Discovery and Development Network (PI-DDN): https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-051.html; https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-050.html
[30] https://ccr.cancer.gov/research/cancer-moonshot
[31] http://www.cancer.gov/researchandfunding/areas/childhood

Pediatric Cancer

Womack 2: I understand that there has been little improvement in the treatment of pediatric cancers over the last thirty (30) years.

a. Would you agree with this statement and if so, why?

b. What can Congress do to help?

Answer: There are many types of pediatric cancers, and while advances in cancer research have led to tremendous improvements in outcomes for some types, the progress is uneven. Overall, pediatric cancer death rates declined by approximately 40 percent between 1985 and 2015,[32] and five-year survival rates increased from 72 percent in 1987-89 to 84 percent in 2008-2014.[33] Unfortunately, there has been little to no improvement in survival for some types of pediatric cancer. Additionally, most childhood cancer survivors experience significant late effects from their treatment. The National Cancer Institute (NCI) is committed to supporting the most promising research to help provide better outcomes for children and adolescents with all types of pediatric cancers, and to reduce late effects of treatment and improve quality of life.

For decades, the foundations of both childhood and adult cancer treatment were surgery, chemotherapy, and radiation therapy. Recently, immunotherapy, in which a patient's own immune system is harnessed to fight cancer, has emerged as a new pillar of cancer treatment. While some immunotherapy approaches have been effective in treating certain pediatric cancers, many immunotherapy treatments being developed for adult cancers will likely not be applicable to childhood cancers. Therefore, this area remains a critical research area.

Recent clinical advances in immunotherapy include the 2017 Food and Drug Administration (FDA)-approval of Keytruda® (pembrolizumab), a checkpoint inhibitor, for pediatric and adult patients with classical Hodgkin lymphoma that cannot be cured with existing treatments, as well as pediatric patients with solid tumors that have specific genetic features known as mismatch repair deficiency and high microsatellite instability. This approval is significant because targeting genetic characteristics, rather than where the cancer originates in the body, creates new options for patients who might otherwise not be considered candidates for a drug. NCI is now sponsoring early-phase clinical trials of pembrolizumab in children with aggressive brain tumors.

Another recent advancement is the 2017 FDA-approval of Kymriah™ (tisagenlecleucel), a chimeric antigen receptor (CAR) T-cell therapy, for children with acute lymphoblastic leukemia (ALL). This NCI-supported discovery was first published in the New England Journal of Medicine in 2014.[34] NCI is currently sponsoring nearly a dozen clinical trials of CAR T-cell therapy in pediatric patients with other types of cancer.

---

[32] Cancer Statistics Review 1975-2015, Table 28.3, Ages 0-14, https://seer.cancer.gov/csr/1975_2015/results_merged/sect_28_childhood_cancer.pdf

[33] Cancer Statistics Review 1975-2015, Table 28.8, Ages 0-14, https://seer.cancer.gov/csr/1975_2015/results_merged/sect_28_childhood_cancer.pdf

[34] https://www.ncbi.nlm.nih.gov/pubmed/26962747, http://www.nejm.org/doi/full/10.1056/NEJMx160005

NCI is also supporting pediatric immunotherapy research through the Cancer Moonshot. In 2017, NCI released funding opportunity announcements for the Pediatric Immunotherapy Discovery and Development Network (PI-DDN),[35] which will aim to advance immunotherapy concepts for children and adolescents with cancer toward clinical applications. Additional relevant Cancer Moonshot programs include: creation of a consortium to study drivers of childhood cancer, creation of a Rare Tumor Patient Engagement Network, and identification of approaches to identify and care for individuals with inherited cancer syndromes.[36]

Another promising area of childhood cancer research is precision medicine. In July 2017, NCI launched the NCI-Children's Oncology Group Pediatric Molecular Analysis for Therapy Choice (NCI-COG Pediatric MATCH), a nationwide clinical trial for that is testing the use of precision medicine for pediatric cancers. In the study, DNA sequencing is used to identify patients whose tumors have a genetic change for which a targeted therapy exists. This provides an opportunity to test therapies in children and adolescents with advanced cancers who have few other treatment options. To date, over 180 children/adolescents have enrolled for screening across 95 COG sites.

Despite the promising recent advances in some childhood cancer types, progress against all cancers that affect children and adolescents is urgently needed. To find treatments for the cancers that have proven resistant to therapy, scientists need to better understand the basic drivers of disease. Decades of basic research investments from NCI and NIH have laid the groundwork for the clinical achievements discussed above, even though the basic research often lacks a direct initial connection to a specific disease. Basic research will remain vital for making progress in the cancer types for which little or no progress has been made.

Additionally, the life-saving advances in childhood cancer treatment discussed in this response have led to a growing number of survivors of childhood and adolescent cancer. NCI supports research to understand the adverse side effects of cancer treatment and how to prevent or mitigate them. For instance, the Childhood Cancer Survivor Study (CCSS)[37] is examining the long-term adverse effects of cancer therapy on approximately 35,000 survivors of childhood cancer across the United States. By characterizing the experience of childhood cancer survivors, the CCSS provides guidance for the medical community on best practices for current and former pediatric cancer patients. NCI also funds a second childhood cancer survivor cohort, St. Jude Lifetime, that is smaller (approximately 4,000 participants) but complementary to the CCSS.

NCI remains committed to making progress against all types of childhood cancers, and to improving the quality of life for childhood and adolescent cancer survivors.

Congress's sustained bipartisan support of the NIH and the NCI has been, and will continue to be, critically important to progress in cancer research.[38] Translating basic science discoveries into meaningful clinical advances can take decades to achieve, and the sustained support NIH

---

[35] https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-051.html, https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-050.html

[36] For these and other Cancer Moonshot funding opportunity announcements, see: https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding

[37] https://www.cancer.gov/types/childhood-cancers/ccss

[38] http://www.pnas.org/content/early/2018/02/06/1715368115

and NCI receives from Congress is critical to ensuring such progress continues to benefit patients, including children with cancer and their families.

Pediatric Cancer Clinical Trials

Womack 3: How many NCI-funded clinical trials are focused on pediatric cancers?

a. Will this increase under the new budget?

Answer: The National Cancer Institute (NCI) is supporting 100 trials currently open to enrollment focused exclusively on pediatric cancers. Many of these trials are also open to young adults with cancers that are also diagnosed among children (i.e. the upper age eligibility criteria may extend above age 21). In addition, NCI is supporting 47 trials currently open to pediatric patients and other patient populations, but not explicitly focused on pediatric cancers (i.e. the lower age eligibility criteria may extend below age 18). For example, NCI supports multiple trials focused on cancers that occur more frequently in older adults but also are diagnosed in the adolescent and young adult population. NCI makes a deliberate effort to extend age eligibility criteria when appropriate, so that adolescents and young adults can participate in clinical trials most appropriate for their diagnosis.

These figures represent clinical trials that NCI supports through several extramural research efforts that it funds across the country – including the Children's Oncology Group (COG),[39] its Phase 1 and Pilot Consortium,[40] other members of NCI's National Clinical Trials Network (NCTN, of which COG is a member), the Pediatric Brain Tumor Consortium (PBTC),[41] and the New Approaches to Neuroblastoma Therapy (NANT) consortium – as well as clinical trials conducted by NCI's Center for Cancer Research at the NIH Clinical Center, part of the NIH intramural research program. Many of these intramural clinical trials are led by NCI's Pediatric Oncology Branch (POB).[42]

NCI leadership collaborates within and across these extramural and intramural research programs to ensure that the Institute is supporting clinical trials that represent the best science and that have the highest likelihood of advancing progress for children and adolescents with cancer and their families. The number of children diagnosed with a specific type or subtype of a pediatric cancer can be relatively small, therefore it is critical that NCI, in partnership with COG, other NCTN members, and other collaborators, develop the right clinical trials. For some types and subtypes of childhood cancers, it will be more beneficial for the research community to identify the one or two clinical trials that represent the most promising scientific approaches, rather than opening several trials that will ultimately compete to enroll children from the small population diagnosed with that cancer type or subtype each year.

During fiscal year 2018, NCI will continue to develop and support clinical trials based on scientific opportunities in the pediatric oncology clinical research field. In addition to its intramural POB trials, NCI will rely on the expertise of its National Clinical Trials Network

---

[39] https://www.childrensoncologygroup.org/
[40] https://www.childrensoncologygroup.org/index.php/phase-1-home
[41] https://www.pbtc.org/
[42] https://ccr.cancer.gov/Pediatric-Oncology-Branch

(NCTN) Steering Committees[43] to evaluate and prioritize clinical trial concepts to be conducted nationwide through the NCTN, which includes the Children's Oncology Group.

Two particularly important examples of the unique types of clinical trials NCI is supporting for children with cancer are highlighted below: the NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) trial, and the NCI POB's leadership of first-in-children clinical trials of CAR T-cell immunotherapy approaches.

The NCI-COG Pediatric MATCH Trial[44] launched in July 2017. This nationwide clinical trial for children and adolescents is testing the use of precision medicine for pediatric cancers, and provides an opportunity to test molecularly targeted therapies in patients with advanced cancers who have few other treatment options. DNA sequencing is used to identify pediatric patients whose tumors have a genetic change for which a targeted therapy exists. The trial is accessible to patients at around 200 sites across the United States. Approximately 200-300 patients are expected to enroll each year, and approximately 1000 pediatric patients will be screened in total. The genomic data captured in the trial will also produce an invaluable resource for studying the genetic basis of pediatric cancers.

NCI's POB is the intramural arm of NCI's childhood cancer clinical trials portfolio. In addition to developing and conducting clinical trials, the POB also conducts basic and translational research. An area of expertise within the POB is the development of CAR T-cell immunotherapy approaches for certain high-risk leukemias and lymphomas in children and young adults. The POB has conducted trials evaluating CAR T-cell immunotherapy to target different cell surface proteins.[45, 46,47]

In 2017, the Food and Drug Administration (FDA) granted approval of the first CAR T-cell therapy, tisagenlecleucel (Kymriah™) for childhood acute lymphoblastic leukemia (ALL), the most common cancer among children in the United States. This therapy engineers the patients' immune cells to target and treat their cancer. However, NCI recognizes that this therapy is not effective for every patient, and POB researchers are using a multi-factorial approach to address some of the current limitations of CAR T-cell therapy to maximize the benefit that this treatment may offer.

---

[43] https://www.cancer.gov/about-nci/organization/ccct/steering-committees/nctn
[44] https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/pediatric-match
[45] https://www.ncbi.nlm.nih.gov/pubmed/25319501
[46] https://clinicaltrials.gov/ct2/show/NCT02315612 and https://www.ncbi.nlm.nih.gov/pubmed/29155426
[47] https://clinicaltrials.gov/ct2/show/NCT03448393

Human Fetal Tissue Research

Harris 1: Research involving human fetal tissue is classified in two categories: basic and therapeutic. Basic research focuses on basic biological processes. Therapeutic research is aimed at developing new treatments.

Federal law (42 USC 289g-1) requires the annual submission to Congress of a report describing what research the National Institutes of Health (NIH) supported or conducted that involved therapeutic transplantation of human fetal tissue.

Based on this reporting, NIH has not funded clinical trials using aborted fetal tissue since FY2009. This is because clinical trial results showed fetal tissue transplants in patients failed, and in many cases made their conditions worse.

Now all NIH-funded projects on fetal organs and tissues are basic laboratory research projects. Basic fetal tissue research is funded at an estimated $81 million for FY18.

Aborted fetal tissue research is antiquated science. NIH funds could be more effectively used for modern science and patient-centered research. Modern alternatives (organoids, iPS cells, cord blood and other adult stem cells) are more effective and productive. For example, modern vaccines do not use fetal tissue or fetal cell lines. (For example, the new shingles vaccine [Shingrix] made in Chinese hamster cells, replaces old vaccine made in fetal cell line and is a much better vaccine.)

Question 1:

Research/Disease Areas (Dollars in millions and rounded)	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Estimated (Enacted)	FY 2018 Estimated	2015 US Mortality 1/	2015 US Prevalence (Standard Error) 1/
Human Fetal Tissue 11/	$67	$76	$60	$103	$107	$81	-	-

The NIH annual categorical spending table states that the NIH will spend an estimated $81 million on human fetal tissue research in FY 18. Will the NIH consider halting fetal tissue research?

Answer: NIH conducts and funds basic, preclinical, and clinical research involving the study, analysis, or use of human fetal tissue for a wide range of diseases and conditions, such as retinal degeneration, pregnancy loss, disorders of human development, and early brain development. Human fetal tissue has also served as a critical resource for the development of models of human disease, such as for studying Zika virus infection of neural stem cells. Cell lines previously derived from fetal tissue have also played an essential role in the creation of new vaccines and remain valuable in efforts such as the pursuit of a vaccine for Ebola. The NIH conducts and funds this research under its general legal authorities as outlined in Title IV of the PHS Act, which are consistent with NIH's mission to conduct biomedical research to enhance health, lengthen life, and reduce illness and disability. The PHS Act also has specific sections

governing the conduct of research with human fetal tissue[48] and research involving transplantation of human fetal tissue,[49] therefore NIH will continue to consider highly meritorious research proposals using human fetal tissue.

Question 2: I served on the Select Investigative Panel on Infant Lives, which made numerous criminal and regulatory referrals of entities engaged in abortion and fetal tissue procurement. In light of these alleged violations, NIH must lead the way in transparency about compliance. How do you intend to ensure compliance? I request that you follow up with me on efforts to ensure compliance.

Answer: 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, the 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.[50] 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. On August 14, 2015, NIH issued a reminder of the legal requirements regarding the acquisition and use of human fetal tissue for research purposes.[51] Also, on February 11, 2016, NIH issued a policy on the informed consent for the donation of human fetal tissue for NIH-funded research.[52]

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, the NIH retains the authority and discretion to conduct, or arrange for the conduct of, other audits and/or evaluations of NIH awards.

The HHS Deputy Inspector General for Investigations, who heads the Office of Investigations in the Office of the Inspector General of HHS, has authority to conduct investigations of alleged cases of criminal wrongdoing by HHS employees, grantees, contractors, and other persons doing business with the Department. Complete information about the procedure used when the NIH becomes aware or suspects a grantee is in violation of the law can be found online.[53]

---

[48] 42 USC §§289g and 289g-2.
[49] 42 USC §289g-1.
[50] http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[51] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-143.html.
[52] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-033.html.
[53] http://oma1.od.nih.gov/manualchapters/management/1754/.

Investigators within the 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. There are several policies that pertain to research with human fetal tissue, which are posted to the NIH sourcebook.[54] The NIH Deputy Director of Intramural Research, in concert with the Scientific Directors of each NIH Institute or Center, 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 Institute or Center also certifies compliance of all investigators on an annual basis. The NIH Office of Human Subjects Research Protections provides additional guidance to intramural principal investigators who are using or considering using fetal tissue in their research.

[54] https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research/oversight-fetal-tissue-research.

HIV/AIDS Portfolio Review

Harris 2: Please provide a breakdown of the AIDS portfolio over the last five years, specifically indicating how much of the money was dedicated to a vaccine, cure, or improvement treatment.

Answer: The trans-NIH HIV/AIDS portfolio includes research objectives targeted to end the HIV pandemic and improve the health of people with HIV. In fiscal year 2016, NIH realigned the HIV/AIDS portfolio with the highest research priorities. This began a review process to better support the new HIV/AIDS research priorities: reduce incidence, including vaccine development; develop next generation therapies; conduct research toward a cure, including durable viral suppression; and support research on HIV-associated comorbidities, coinfections, and complications.

Some of the shifts in the funding reflect the new prioritization, however it is also the case that shifting occurs when scientific projects reach their conclusion. The HIV/AIDS portfolio increased approximately 3% from $2.898 billion in fiscal year [FY] 2013 to $3 billion in FY 2015. While the portfolio remained at $3 billion during FY 2016 and FY 2017, redirecting resources from low priority projects provided increased investment in vaccine research and research for a cure, including durable viral suppression.

Over the years, advances in scientific research in HIV/AIDS have produced highly effective methods of HIV treatment and prevention resulting in important strides in reducing the burden of HIV in the United States and globally. However, even with scale-up of the currently available prevention approaches and treatment tools, a safe and effective vaccine is essential to substantially decrease the rate of new HIV infections. As effective treatments extend the lifespan of people with HIV, the increased burden of comorbidities, coinfections, and complications by HIV treatments requires research to improve their health. Continued investment will assure that the objectives for trans-NIH research in HIV/AIDS are achieved.

Table 1. National Institutes of Health, Office of AIDS Research Funding: FY 2013 - 2017

HIV/AIDS Funding for Vaccine, Cure, and Next Generation Therapies

(Dollars in Thousands)

Research Priorities	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Reduce Incidence					
Vaccines	$518,170	$532,671	$534,987	$605,236	$561,857
Non-Vaccine Prevention and Microbicides	205,540	178,877	165,784	126,767	125,638
Develop Next Generation Therapies (Improved Treatment)	458,151	465,260	449,716	360,085	362,820
Conduct Research Toward a Cure*	-	-	65,206	108,337	170,375
Support Research on HIV-Associated Comorbidities, Coinfections and Complications	544,335	600,646	588,444	614,090	556,608
Cross-cutting Research in Basic Sciences, Health Disparities, Behavioral and Social Sciences, and Traini	1,171,669	1,200,125	1,195,924	1,185,546	1,222,763
Total	$2,897,865	$2,977,579	$3,000,061	$3,000,061	$3,000,061

** Cure Research transitioned into a separate research priority in FY 2017. The FY 2015 and FY 2016 figures above represent comparable budget figures. Prior amounts for Cure Research is included in Next Generation Therapies and Cross-cutting Research. Funding amounts were:*

(Dollars in thousands)

FY 2013	*FY 2014*
$75,439	*$114,367*

Young Investigators

Harris 3: Dr. Collins, in your oral testimony, you made reference to the National Academies' anticipated and eventual release of the report, "Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through." Will these steps alone be adequate to reducing the average age of first time R01 or R01-equivalent recipients? What funding mechanisms can help you to bring down the average age of these recipients?

Answer: The National Institutes of Health (NIH) is currently assessing the recommendations of a National Academies Next Generation Researchers Initiative (NGRI) committee, convened in early 2017, to study and recommend solutions to any barriers that may extend periods of training, time to independence, or impede sustained success in research. A final report, titled "Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through" was released in April 2018. As we consider the recommendations from the National Academies committee[55], we are also awaiting a related report from a working group of the Advisory Committee to the Director focused on the next generation of researchers, expected in June 2018. NIH plans to incorporate guidance from both groups to prioritize further actions to bolster the careers of early-stage investigators. Taken together, we believe acting on such recommendations will help us continue to address the concerns around the age at which an investigator receives their first R01-equivalent award.

In the interim, NIH continues to pursue previously-established policies to ensure that emerging early-stage investigators have opportunities to receive R01 (and equivalent) research grants at an early age and without undue delay. This includes clustering applications from early stage and new investigators in peer review. In scoring these applications, reviewers are instructed to focus more on the proposed research question, significance, innovation, and approach and less on preliminary data and the investigator's track record. Additionally, NIH Institutes and Centers are considering various approaches, such as prioritizing funding of meritorious proposals from early-stage investigators, as yet another direct way to support the career path for these researchers.

NIH also continues to support specialized programs that focus on early stage investigators that lead to research awards at a lower age. Examples include the Pathway to Independence award (K99-R00), Early Independence Award (DP5), and NIH Director's New Innovator Award (DP2). Some NIH Institutes and Centers are also making R35 "outstanding investigator" awards to early-stage investigators to provide them with longer term and more stable research support. Preliminary data from the NIGMS R35 program for early-stage investigators suggests that these awardees are about two years younger than comparable early-stage investigator R01 awardees. We are taking a look at lessons to be learned from this type of program.

[55] https://nexus.od.nih.gov/all/2018/05/04/the-issue-that-keeps-us-awake-at-night/

Down Syndrome

Roby 1: Last October, this subcommittee held an important hearing on biomedical research as it relates to Down syndrome and the potential for links to discoveries across other major diseases, including Alzheimer's, Cancer, and Autoimmune diseases. I was so pleased to have the McLendon family from Dothan, Alabama, join us for that hearing.

While Down syndrome is the most frequent chromosomal disorder in the U.S. population, it is surprisingly one of the least funded genetic conditions at the NIH –receiving only $28 million out of the $32 billion dollar NIH budget in 2016, for example.

Additionally, there have been troubling reports from medical communities in Iceland, Denmark, and South Korea encouraging abortion as a means to eradicate Down syndrome. I am staunchly pro-life and urge the medical community in the United States to never engage in the slippery slope of eugenics by way of selective terminations.

Dr. Collins, I have two questions for you regarding this important topic:

(1) Could you please expand on why the NIH has allocated such a small percentage of the NIH budget to Down Syndrome research?

(2) And, are you committed to ensuring that the NIH doesn't fall down the slippery slope of engaging in research practices that encourage the practice of eugenics?

Answer: Down syndrome (DS) is a set of cognitive and physical symptoms that result from having an extra copy of chromosome 21, which changes the body's and the brain's typical development.

One of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's (NICHD) longest standing research priorities is to improve the lives and health of people with Down syndrome and other intellectual and developmental disabilities. In FY 2017, prior to passage of the FY 2018 omnibus appropriations legislation, NIH funding for research related to Down syndrome had increased by approximately 30 percent since FY 2014.

Common co-occurring conditions in people with DS include congenital heart disease; problems with hearing, vision, intestinal, immune, thyroid, and skeletal function; and, in adults, dementia akin to Alzheimer's disease. With the funds provided in the FY 2018 omnibus appropriations legislation, NIH will engage in a multi-institute, major new initiative, the INCLUDE Project: INvestigating Co-occurring conditions across the Lifespan to Understand Down syndromE. Planning is underway for this project, and as requested, NIH will be providing a report to the committee on its progress within 180 days of enactment of the FY 2018 omnibus appropriations legislation.

In addition, NICHD leads the public-private Down Syndrome Consortium, which includes 11 NIH Institutes and Centers, 13 national and international organizations whose missions focus on Down syndrome, and family members of and individuals with Down syndrome. Consortium members provided valuable input to *DS Directions: The NIH Down Syndrome Research Plan.* Among the plan's major objectives is the call for research on the co-existing conditions commonly experienced by people with Down syndrome. For example, studies show that virtually all middle-aged adults with Down syndrome exhibit the neuropathological hallmarks of Alzheimer's disease, 50 percent of whom will develop this type of change to the brain by age 40. Funded jointly by NICHD and the National Institute on Aging, a new project, the Alzheimer's Biomarker Consortium – Down Syndrome (ABC-DS), seeks to identify biomarkers and use brain imaging to help us understand the progression of the disease. The research teams will make their data and samples freely available to qualified researchers worldwide, with the goal of accelerating the testing of potential interventions, which in turn may have widespread implications for Alzheimer's and other conditions.

Research shows that prospective parents in the United States value the option of prenatal genetic testing that will allow them to obtain information and prepare for the birth of a child with Down syndrome. NIH remains fully committed to improving the lives of people with Down syndrome at all ages and their families.

Opioids

Roby 2: Dr. Collins, the opioid crisis in my home state of Alabama is particularly acute; where opioid drugs are prescribed at a higher ratio than any other state in the nation. Alabama averages an alarming 1.2 opioid prescriptions per person according to the CDC.

I am fully committed to provide the necessary resources to tackle this horrific crisis in our country, and I was pleased to support the inclusion of an additional $500 million for NIH research related to opioid addiction as part of the funding bill Congress passed last month.

Dr. Collins, how do you plan to ensure that the additional grant funding provided for FY 2018 will be used for research in states with a disproportionately severe opioid problem?

Answer: Addressing the opioid crisis is a top priority for the Department of Health and Human Services, including the National Institutes of Health. We will continue to prioritize research to develop solutions for this crisis and strive to accelerate progress, including geographic areas with severe opioid problems.

One example of allocating funding to projects in locations where opioids have had a severe impact on geographic areas involve a National Institute on Drug Abuse partnership with states and several other federal agencies to address the opioid crisis in rural U.S. regions. Funding opportunities were created to help communities develop ways to comprehensively prevent and treat substance use disorders, overdoses, and infectious disease transmission related to injection drug use. These projects support the work of state and local communities in developing best-practice responses that rural public health systems can implement. The grants are co-funded by the Appalachian Regional Commission, the Centers for Disease Control and Prevention, and the Substance Abuse and Mental Health Services Administration.

As always, funding decisions will be made on the basic of scientific merit of the proposals we receive.

Pediatric ESRD

Herrera Beutler 1: There are over 7000 pediatric patients aged 0-21 years of age with end-stage renal disease (ESRD). Not only do these patients require specialized supplies and care teams, they also are more likely to receive a kidney transplant. Research is needed to better understand prognostic indicators such as personalized medicine, novel diagnostics, and therapeutics in the pediatric population. I am pleased that the Institute has invested in the CKiD study, but more work needs to be done.

What additional steps can be taken to further the understanding of pediatric kidney disease and how to advance treatments in this population?

Answer: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has made major investments in pediatric chronic kidney disease research. The Chronic Kidney Diseases in Children (CKiD) study has been renewed to continue investigation into growth, neurocognitive development, early evidence of cardiovascular disease, and progression of chronic kidney disease to transplantation and dialysis in children with congenital and acquired kidney disease. The CKiD study will be extended to follow the cohort into young adulthood where they represent a unique group with different needs and outcomes compared to those with adult-onset kidney disease. The CKiD study continues to refine the newest and most reliable measures of kidney function and outcomes of kidney disease in children.

NIDDK will continue to support research investigating glomerular diseases, a subtype of kidney diseases, in children. The Cure Glomerulopathy Network (CureGN) consortium will conduct translational and clinical research that includes children. One of the main recruitment centers for CureGN is the Midwest Pediatric Nephrology Consortium, assuring robust pediatric participation. The Nephrotic Syndrome Study Network (NEPTUNE), a multi-site, multidisciplinary collaborative research network that complements CureGN, includes many children with nephrotic syndrome, a condition resulting in high protein levels in the urine. This study is developing a personalized medicine approach to glomerular disease that will promote therapeutic developments and will benefit children with kidney disease.

Recognizing the unique needs of children to learn to assume responsibility for their chronic disease as they transition into adulthood, the NIDDK funds research in medication adherence in pediatric and adolescent patients with chronic kidney disease and kidney transplants.

In March 2018, the Kidney Interagency Coordinating Committee (KICC) convened a meeting to review the current state of knowledge in congenital anomalies of the kidney and urinary tract, including renal agenesis (the absence of a kidney). The meeting also including a discussion of further possibilities for collaboration among NIH Institutes and federal agencies involved in kidney research.

Preterm Birth

Herrera Beutler 2: Preterm birth affects approximately 380,000 babies each year in the United States and is the leading cause of infant mortality. NICHD is engaged in critical research examining the causes of preterm labor and birth and methods of prolonging pregnancy in women at risk of preterm birth. This work also involves the study of potential methods to improve survival and minimize disability among babies delivered very early.

Given the tremendous impact this research has on mothers in my district and across the county, what is the outlook for future investment in this area of research?

Answer: The causes of preterm labor and delivery are a critical scientific focus for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) as it represents the primary cause of neonatal mortality with significant short- and long-term morbidities for those who survive. In addition, NICHD supports studies that evaluate programs and treatments to improve the care, health and developmental outcomes of newborns, including infants born preterm and at low, very low, and extremely low birth weight. Many of these studies are conducted through the NICHD-funded Neonatal Research Network. Specific areas of focus include sepsis, intraventricular hemorrhage, chronic lung disease, pulmonary hypertension, perinatal asphyxia, and nutrition.

One recent scientific study funded by the NICHD of nearly 10,000 preterm births found that, even if they had given birth before, women who were obese were more likely to develop preeclampsia, a potentially serious medical condition that may require immediate preterm delivery to save the life of the woman and her child. An ongoing sub-study funded by the National Heart, Lung, and Blood Institute is following women from this cohort for 2-5 years after delivery to evaluate reported links between adverse pregnancy outcomes, sleep and future maternal cardiovascular health.

Another NICHD-supported study determined that women with high blood levels of a specific protein (retinol-binding protein 4 or RBP4) in blood serum, and overall blood fat (lipids), at less than 22 weeks of pregnancy were about eight times more likely than others to develop preterm preeclampsia. The results suggest that measuring RBP4 early in pregnancy may enable clinicians to identity patients at risk for preeclampsia early in pregnancy and monitor these patients more closely.

In a NICHD-supported study of children who were born preterm and treated early with medications to protect their developing brains, investigators found evidence that certain drugs had lasting positive effects on neurocognitive function. The drugs, erythropoiesis-stimulating agents (ESAs), stimulate production of red blood cells. These findings suggest that ESAs may have the potential to improve neurocognitive outcomes for preterm infants.

Future research efforts will focus on discovering the causes of the high preterm birth rates and on improving medical and behavioral-based care for preterm infants as well as counseling and support for parents of fragile infants whose very early birth threatens their survival. The NICHD's National Child and Maternal Health Education Program supported an effort involving

a variety of public-private partners to prevent preterm birth, including prevention of elective late preterm delivery (35-38 weeks of gestation). The program aimed at increasing both women's and health care providers' knowledge about late preterm birth and to discourage delivery for non-medical reasons before 39 weeks of gestation.

In 2017, the NICHD launched its PregSource® registry, which uses a crowd-sourcing approach that enables participants to enter information regularly and directly about their pregnancies throughout gestation and the early infancy of their babies into online surveys and trackers via a website and/or a mobile application. Participants will be able to track their data over time, print reports to share with their health care team, and see how they compare with other women. In addition, PregSource® provides participants with links to trusted, evidence-based information about pregnancy management, issues and complications.

Zika

Herrera Beutler 3: Could you provide an update on the status of research on long-term and developmental health impacts of Zika? What level of investment is needed in order to understand how this virus continues to affect parents, pregnancy, and children?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) is supporting research to identify and better understand the biology of diverse conditions linked to Zika virus infection. In particular, infants born to women infected with Zika virus during pregnancy may be affected by congenital Zika syndrome, which can include microcephaly, brain damage, eye defects, and joint and muscle problems, as well as the potential for delayed mental and physical effects among infected babies born in apparent good health.

NIAID-supported researchers are investigating these Zika-related conditions in infants and children. The ongoing Zika in Infants and Pregnancy (ZIP) study is supported by the National Institutes of Health and the Brazilian research organization Instituto Oswaldo Cruz. The ZIP study, which has enrolled more than 6,000 mothers and more than 3,000 infants to date, is evaluating the effects of Zika virus infection during pregnancy on the health of the pregnancy and development of the newborn and is following the infants' development for at least one year. An additional NIAID-supported study in Guatemala is examining infants and children for the clinical and neurological manifestations of Zika infection acquired after birth. These natural history studies form one piece of a larger research portfolio, which includes the development of countermeasures, including vaccine and treatment candidates, that could be used to quickly respond to future Zika virus outbreaks.

The level of investment required to reach scientifically valid conclusions from the natural history studies will be largely dependent on how the Zika virus outbreak evolves. NIAID's mission includes the ability to quickly launch a research response to newly emerging and re-emerging infectious diseases such as Zika, and the Institute appreciates Congress' continued support of its mission. NIAID will continue to support efforts to advance our understanding of congenital Zika syndrome and develop medical countermeasures for Zika virus disease, including a preventive Zika vaccine.

Awarding Increased Appropriations

Herrera Beutler 4: What mechanisms are likely to be the primary ones used for awarding the significantly-increased appropriations for research, especially in this latter half of FY 2018?

Answer: NIH anticipates that the FY 2018 increases will be reflected primarily in extramural grant and contract mechanisms. Research Project Grants (RPGs) are the largest component of the NIH budget, and increased investments in new and competing RPGs over the past few years will result in more spending on noncompeting RPGs in FY 2018 (most NIH grants are awarded for multiple years and funded incrementally, so there are substantial prior-year grant commitments). NIH will seek to increase the number of new and competing RPGs, which topped 10,000 in both FY 2016 and FY 2017 (levels had been lower since FY 2007). NIH also plans to increase the total number of principal investigators and early stage investigators, through the Next Generation Researchers Initiative and other means. The NIH Innovation Account has a significant increase due to higher authorized levels for FY 2018 in the 21st Century Cures Act. Most of these funds will be transferred to the Institutes managing the Cancer Moonshot (National Cancer Institute) and the BRAIN Initiative (National Institute of Neurological Disorders and Stroke and the National Institute of Mental Health), with the remainder being managed by the Office of the Director (All of Us Research Program and Regenerative Medicine).

Public Health Concerns

Herrera Beutler 5: What are your greatest concerns in the realm of public health and the role of the NIH in addressing those concerns?

Answer: Addressing the nation's most pressing public health concerns is central to the mission of the National Institute of Health (NIH). NIH supports research that both responds to emerging public health threats, such as the opioid crisis or Ebola virus, and addresses longer-term public health needs, such as Alzheimer's disease, cardiovascular disease, or influenza. In pursuit of its mission, NIH strives to maintain both a broad enough scientific portfolio to capture new breakthroughs, and nimbleness in allocating resources where public health needs or scientific opportunities arise.

For example, the current opioid crisis is an ongoing and increasing public health emergency. In 2014, almost 2 million Americans had an addiction to prescription or illicit opioids. NIH has been deeply invested in efforts to help counter this crisis through research, but we are determined to do even more. Over the last year, NIH has worked with stakeholders and experts across scientific disciplines and sectors to identify areas of opportunity for research to combat the opioid crisis. In April of 2018, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative, which focuses NIH's efforts to prevent addiction through developing better pain management strategies, including developing effective non-opioid therapies for pain management, and improving treatments for opioid misuse disorder and addiction by expanding therapeutic options for treating addiction.

Another grave public health concern is Alzheimer's disease (AD). Based on 2010 estimates, 5.5 million Americans are projected to have Alzheimer's disease by 2018, and there are currently no drugs available that can cure it or effectively slow its progression. NIH supports a broad portfolio of research aimed at enabling us to better understand, diagnose, prevent, and treat AD and related dementias, from basic research on disease mechanisms to a new, expanding clinical trials consortium. NIH has also assembled a precompetitive partnership among government, industry, and nonprofit organizations called the Accelerating Medicines Partnership-Alzheimer's Disease (AMP-AD), which focuses on discovering novel, clinically relevant therapeutic targets and on developing biomarkers to help validate existing therapeutic targets. NIH is also involved in efforts to track and coordinate AD research across the variety of public, private, and international organizations that support it, including helping to launch an international database of AD research projects.

These examples illustrate how NIH sets priorities to address emerging public health threats and advance our understanding of longstanding public health issues. NIH believes that the ability to strategically allocate resources based on public health needs, built on a foundation of fundamental scientific advancement and rigorous peer review, allows NIH to most effectively accomplish its mission.

FY 2019 Proposed Cuts

Herrera-Beutler 6: Following final resolution of the FY 2018 budget, the FY 2019 proposed budget would represent a significant cut for NIH. What effects would the FY 2018-to-FY 2019 cut have on NIH's extramural research funding priorities in FY 2019 and beyond?

Answer: The FY 2019 President's Budget request for NIH (program level) is approximately $2.5 billion less than the FY 2018 enacted amount. The Budget recognizes the importance of funding the highest priority scientific discoveries while also maintaining fiscal responsibility of Federal resources.

One of NIH's highest extramural priorities, opioids/pain research, would receive an increase under the FY 2019 President's Budget. While the NIH request is $100 million (compared to a $500 million increase in FY 2018), the Department of Health and Human Services has requested an additional $750 million for opioids/pain research at NIH, for a total of $850 million.

Non-addictive Pain Medication

Herrera Beutler 7: Today, opioids are sometimes the safest option for a pregnant woman, for whom ibuprofen is contraindicated. In your view, do we need more data on non-addictive pain medication that is safe to use during pregnancy?

Answer: The National Institute of Health's (NIH) current research efforts include basic research to understand pain mechanisms, why acute pain becomes chronic, and how to prevent and treat chronic pain based on biological mechanisms. NIH also funds translational research to develop non-opioid analgesics and safer opioids from early stage drug discovery focused on targeting pain signaling pathways, screening novel and existing compounds to determine their potential as analgesics, optimizing the structure of promising molecules for drug formulations, and safety and toxicity testing of drugs. NIH supports research on a number of novel analgesic drug targets, in part through the Blueprint Neurotherapeutics Program for small molecule drug discovery and development.

Some of the most promising potential therapies include:
• *Abuse Resistant Opioid Analgesics:* Efforts are underway to identify new opioid pain medicines with reduced misuse, tolerance, and dependence risk, as well as alternative delivery systems and formulations for existing medications that minimize diversion and misuse (e.g., by preventing tampering) and reduce the risk of overdose deaths.
• *Non-Opioid Medications*: Some non-opioid targets with promising preliminary data include fatty acid binding proteins, the G-protein receptor 55, cannabinoids, and transient receptor potential cation channel A1.
• *Brain Stimulation Therapies:* Several non-invasive brain stimulation therapies – including transcranial magnetic stimulation and transcranial direct current stimulation, as well as electrical deep brain stimulation and peripheral nerves/tissues stimulation – have shown promise for the treatment of chronic pain. These devices have been approved by the Food and Drug Administration for treatment of other conditions, but more research is needed on their effectiveness for pain.
• *Neurofeedback*: Neurofeedback is a novel treatment modality in which patients learn to regulate the activity of specific brain regions by getting feedback from real-time brain imaging. This technique shows promise for altering the perception of pain in healthy adults and chronic pain patients and may also be effective for the treatment of addiction.

On average pregnant women in the United States take between three and five prescription medications during their pregnancies, very few of these therapies have ever been tested in pregnant or lactating women. The purpose of the Task Force on Research Relevant to Pregnant Women and Lactating Women, which was mandated by the 21st Century Cures Act (P.L. 114-255) is to gather data and develop plans for addressing this shortfall in our medical knowledge. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is leading implementation efforts. The panel includes representatives of the Federal

agencies required by the 21st Century Cures Act, representatives of professional societies that serve pregnant and lactating women, patient advocates, and industry delegates.

The report on the Task Force's findings and recommendations is due to the Department of Health and Human Services Secretary and Congress by September 2018. An analysis of currently supported Federal research in this area, a discussion of the ethical issues surrounding the inclusion of pregnant and lactating women in clinical research, how to communicate information about therapies to pregnant and lactating women and their health care providers, and a series of recommendations for the Secretary's consideration will be included in the final report. All meetings have been open to the public, include a period for public comments, and are videotaped for concurrent or future viewing. In addition, a web page was created on NICHD's website to ensure that any interested parties can access information about the Task Force's deliberations, including information about how to submit comments.[56]

[56] https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx

Pandemic Diseases

Moolenaar 1: In recent years, the Ebola and Zika virus outbreaks demonstrated that global infectious diseases emergencies are unpredictable and that outbreaks in distant countries can quickly reach our shores. I am concerned that we are not adequately prepared for dealing with significant outbreaks or a potential pandemic. Last year, a Time Magazine cover story highlighted the fact that "the simple truth is that neither the world as a whole nor the U.S. in particular is at all prepared to handle a major infectious disease - and a significant reason for that is a failure to invest in things now that can keep us safe later." One of the things we can invest in now that will keep us safe later is biomedical research infrastructure.

Several years ago, a NIH Working Group on Construction of Research Facilities identified a disturbing trend that much of the nation's biomedical research infrastructure - including laboratories and research facilities at academic institutions, nonprofit organizations, and hospitals- is fast becoming outdated or insufficient. Highlighted in this report was the need for specialized facilities such as high level biocontainment facilities and facilities for primate research. It is our understanding that funds to support upgrades to such facilities have not been issued for some time.

1) Is there a need for upgraded or additional extramural biomedical research facilities in order for the United States to be better prepared to handle major outbreaks and maximize the increased federal investment in medical research?

2) Have the increases in research funding provided by Congress in recent years put on a strain on the capacity of nation's specialized biomedical research facilities?

3) Is it true that as a result of emerging disciplines and new technologies in the biomedical sciences, the expected lifespan of research facilities has been reduced and that facilities once expected to last for two or three decades are becoming technologically obsolete in significantly less time?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research to address emerging and re-emerging infectious diseases such as Ebola, Zika, and influenza. The goals of this research are to gain a basic understanding of the pathogens and to develop new and improved diagnostics, vaccines, and treatments for these diseases. In supporting this research, NIAID provides funding for state-of-the-art facilities where the research is conducted. Research on dangerous pathogens is performed in specialized biosafety laboratories designed to protect the laboratory workers as well as the surrounding community from an unlikely accidental exposure to infectious agents. These facilities must be carefully maintained to ensure the safe conduct of this research. In the last 15 years, NIAID has supported the construction of additional biosafety level (BSL)-3 and BSL-4 laboratories capable of housing research on pathogens requiring high levels of containment such as multidrug-resistant tuberculosis and the Ebola virus. These laboratories include several government owned and operated facilities. At this time, the capacity of these laboratories is sufficient to carry out the National Institutes of Health (NIH) mission to develop countermeasures for biodefense and emerging and re-emerging infectious diseases. Currently, there is not a need for additional high-

level biocontainment facilities in the United States to conduct NIH-funded research. If there is a high-priority need to conduct time-sensitive research pursuant to an outbreak, the current NIH-supported BSL-3 and BSL-4 facilities allow for surge capacity to address such an ongoing outbreak.

Infectious disease outbreaks can lead to an increase in the number of biomedical scientists proposing to conduct research that requires the use of biocontainment laboratories. However, the current capacity of NIH-supported BSL-4 laboratories has been capable of accommodating increases in NIH-funded research in recent years, including during the 2014-2015 Ebola virus outbreak in West Africa. There is an ongoing need for these laboratories to be properly staffed and maintained to ensure their specialized research capacity will continue to be available to respond to future outbreaks.

All research laboratories and associated infrastructure, like any other buildings, require periodic updating and upgrading to maintain their intended purpose. Research facilities do not necessarily become obsolete any sooner because of technological advances, since advanced state-of-the-science equipment can often be housed in existing buildings. Existing NIH funding mechanisms provide for facilities and administrative costs and permit consideration of advanced equipment purchases based on the scientific needs proposed in research applications.

Trisomy 21

DeLauro 1: The fiscal year 2018 omnibus includes report language that directs the NIH to develop a new trans-NIH initiative that involves, at a minimum, NICHD, NIA and NCI to study trisomy 21 with the aim of yielding scientific discoveries to improve the health and neurodevelopment of individuals with Down syndrome and those typical Americans affected by diseases that people with Down syndrome are highly predisposed to or protected from. The committee's intention was that the funding for this initiative supplement, not supplant, existing NIH funding levels for Down syndrome research. What specific institutes will contribute to such funding for fiscal year 2018 and what spending mechanisms (e.g., RF1s, RFPs, RFAs) will be used for these research initiatives?

Answer: Down syndrome (DS) is a set of cognitive and physical symptoms that result from having an extra copy of chromosome 21, which changes the body's and the brain's typical development.

One of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's (NICHD) longest standing research priorities is to improve the lives and health of people with Down syndrome and other intellectual and developmental disabilities. NICHD leads the public-private Down Syndrome Consortium, which comprises 11 NIH Institutes and Centers (including the National Institute on Aging (NIA) and the National Cancer Institute (NCI)), 13 national and international organizations whose missions focus on Down syndrome, and family members of and individuals with Down syndrome. Consortium members provided valuable input to *DS Directions: The NIH Down Syndrome Research Plan.* Among the plan's major objectives is the call for research on the co-existing conditions commonly experienced by people with Down syndrome. For example, studies show that virtually all middle-aged adults with Down syndrome exhibit the neuropathological hallmarks of Alzheimer's disease, 50 percent of whom will develop this type of change to the brain by age 40. Other common co-occurring conditions in people with DS include congenital heart disease; leukemia, and problems w/ hearing, vision, intestinal, immune, thyroid, and skeletal function.

With the funds provided in the FY 2018 omnibus appropriations legislation, NIH will engage in a multi-institute, major new initiative, the INCLUDE Project: INvestigating Co-occurring conditions across the Lifespan to Understand Down syndromE. Fourteen of the NIH Institutes and Centers and the Office of the NIH Director are participating in this new effort, including but not limited to NICHD, NIA, and NCI. Planning is underway for the INCLUDE project, which will involve a wide range of funding mechanisms, including research project grants, cooperative agreements, and conference grants, to accomplish its goals over the next few years. As requested by the committee, NIH will be providing a report on its progress within 180 days of enactment of the FY 2018 omnibus appropriations legislation.

HIV Research

DeLauro 2: Dr. Fauci, what is the current status of research to find a cure for HIV infection? And how does this research relate to research to find cures for other infectious diseases?

Last year, you wrote that "[d]evelopment of an effective HIV vaccine will likely be necessary to achieve a durable end to the HIV pandemic." You further elaborated that a vaccine does not need to be 100 percent effective to have a sizeable impact on halting transmissions. Can you explain why a vaccine that is at least 50 to 60 percent effective would help to eliminate HIV transmission?

Answer: The National Institutes of Health (NIH) supports a broad portfolio of basic, translational, and clinical research on HIV/AIDS with the goal of bringing an end to the pandemic. In pursuit of this goal, the National Institute of Allergy and Infectious Diseases (NIAID) funds HIV/AIDS research in a number of critical areas, including mechanisms of infection and immune system response, as well as the development of novel diagnostics, therapeutics, and vaccines.

Although antiretroviral therapy (ART) has significantly improved the length and quality of life for persons living with HIV, challenges associated with lifelong ART treatment have prompted research toward a cure for HIV. NIAID HIV cure research is investigating the fundamental nature of HIV reservoirs (groups of HIV-infected cells and/or tissues not actively producing new virus) within the body, developing improved diagnostic assays and robust biomarkers to monitor HIV, and evaluating interventions that may be capable of achieving eradication or sustained remission of HIV. As part of this effort, NIAID has funded the Martin Delaney Collaboratory, which works to foster public- and private-sector collaborations to develop new curative strategies for HIV. In addition, NIAID released two solicitations in 2017 to encourage research focused on better understanding the nature of and potential treatment options for HIV reservoirs in the body.

NIAID is supporting development of several new HIV regimens that have the potential to contribute to a cure. An ongoing NIAID-supported Phase 1/2 study is evaluating whether early intensive treatment of HIV-infected infants can lead to HIV remission. Research in animal models has shown proof-of-concept that innovative strategies can help control HIV infection. For example, NIAID-supported researchers have shown in a non-human primate model of HIV that vaccination with a vector containing a specific protein from the virus results in durable control of a highly pathogenic strain, with a loss of measurable signs of infection.

Many common viruses that result in acute infection are cleared by an individual's immune system in a few days. However, some viruses including HIV, herpes, hepatitis, and others, establish persistent infections that can evade the immune system for many years and may result in lifelong infection. Many of these viruses share common mechanisms of infection and immune system evasion. Research into a cure for HIV that explores strategies for inhibiting these common mechanisms will help inform the development of similar strategies for combating other persistent viral infections, facilitating the discovery of new treatments and vaccines. In addition,

since the discovery of the virus, NIH-sponsored HIV/AIDS research has been at the forefront of efforts to combat other infectious disease in many ways. Approaches pioneered in the fight against HIV/AIDS have provided tools to fight a variety of infectious threats to the public health. A few key examples include the investigation of structure-based vaccines, the use of rational drug design, the wealth of knowledge about the immune system and its ability to fight infection, and the development of rapid and sensitive diagnostic tests.

In addition to the remarkable gains in the treatment and prevention of HIV infection, the development of an HIV vaccine will be necessary to achieve an end to the HIV/AIDS pandemic. A vaccine with 50 percent effectiveness would reduce new infections in vaccinated populations by 50 percent. When combined with other methods to reduce transmission, such as the use of treatment as prevention strategies and pre-exposure prophylaxis, even a moderately effective vaccine could play a significant role in ending the HIV/AIDS pandemic.

In addition, vaccination of at-risk populations in areas that are not amenable to other treatment and prevention options would help to curb the spread of the infection. Globally, more than 17 million people living with HIV are without access to effective ART. The wide geographic dispersion of individuals living with HIV throughout the world – especially in certain rural areas – makes reaching all those who need HIV treatment and prevention services extremely difficult. Partly due to a lack of access to these services, in 2016 alone, an estimated 1.8 million individuals were newly infected with HIV. A vaccine, even one of moderate efficacy, would help reduce the number of people in these areas that become HIV infected. The development of a moderately effective vaccine used in combination with implementation of the existing treatment and prevention strategies would make an end to the HIV/AIDS pandemic more attainable.

NIAID is making important strides toward the development of an HIV vaccine and is currently supporting a clinical trial of an updated version of RV144, the only HIV vaccine candidate that has been shown to date to be modestly effective in preventing HIV infection. NIAID also funds the HIV Vaccine Trials Network (HVTN), which conducts clinical trials of promising HIV vaccine strategies. The HVTN currently is implementing a clinical study of a novel vaccine supported by Janssen Vaccines & Prevention, B.V., in partnership with the Bill & Melinda Gates Foundation. In addition to the development of novel vaccine candidates, NIAID is supporting the development of other strategies to prevent HIV infection, including a long-acting injectable therapy and a drug-infused vaginal ring that has shown promise in clinical studies. Together, these efforts are building toward the possibility of ending HIV transmission worldwide.

Computational Science – Collaboration and Training

DeLauro 3: Advancements in data science hold significant promise for progress in the field of biomedicine. However, these advancements will require significant investment in data science, computational modeling, and training. As the nation's premier agency for supporting biomedical research, the NIH is uniquely positioned to successfully facilitate collaborations between the computational science and biomedical science communities to enable this progress. But I am concerned that NIH is not doing enough to foster these collaborations. What steps is NIH taking to encourage these collaborations and how do you plan to encourage training so that future researchers are equipped to work together to solve biomedical research challenges using increasingly powerful computational tools?

Answer: On March 5, 2018, the National Institutes of Health (NIH) issued a public Request for Information[57] on a draft NIH-wide Strategic Plan for Data Science.[58] This plan was developed by the NIH Scientific Data Council and will be revised to address comments received via the public comment process as well as during clearance within the Department of Health and Human Services. The Scientific Data Council is the trans-NIH body that represents key NIH leadership on matters pertaining to data science and scientific computing, including training. The Scientific Data Council, which is a sub-committee of the NIH Steering Committee, is composed of Institute and Center directors and deputy directors, as well as key NIH subject matter experts. The Council develops recommendations for the NIH Director and Institute and Center leaders on strategic objectives to address critical long-term needs for data science and plans to attain these objectives. The new NIH Chief Data Strategist (position to be filled later in 2018), in collaboration with the Scientific Data Council is responsible for overseeing the execution of the plans once they are approved by the NIH Director.

The FY 2019 President's Budget request for NIH includes a request for $30 million for the Office of Data Science Strategy, which will be headed by the NIH Chief Data Strategist. The Chief Data Strategist will collaborate closely with the Scientific Data Council to implement the NIH Strategic Plan for Data Science. The Chief Data Strategist also will take the lead in creating a new data science ecosystem at NIH, including coordinating policies and practices surrounding data management and development of data standards and cloud-based approaches for making data findable, accessible, interoperable, and reusable (FAIR). The Chief Data Strategist will be responsible for forging data partnerships outside of NIH, including with:

- Federal advisory bodies, such as the HHS Data Council and the HHS Chief Information Officer Council;
- Other HHS agencies, including the Office of the Chief Technology Officer, the Office of the National Coordinator for Health Information Technology, and the Office of the Chief Information Officer;

[57] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-134.html

[58] https://grants.nih.gov/grants/rfi/NIH-Strategic-Plan-for-Data-Science.pdf

- Other Federal agencies, such as the National Science Foundation and the Department of Energy;
- International funding agencies; and
- The private sector.

These collaborations are essential to ensure synergy and efficiency across data systems and to prevent unnecessary duplication of efforts. The ODSS will also support novel internships to bring additional computational expertise from outside of the traditional biomedical research community. We anticipate that the scale of the trans-NIH big data activities will expand significantly over the next several years.

Sex Gender Balance

DeLauro 4: Please provide an update on NIH's efforts to ensure that research includes both male and female animals in preclinical studies, as well as NIH's efforts to ensure that pre-clinical research includes both male and female tissues and primary cells.

Answer:
In June 2015, NIH introduced the NIH Policy on Consideration of Sex as a Biological Variable (SABV) in NIH-funded Research (NOT-OD-15-102)[59]. The policy, which applies to all stages of the research continuum – from basic science to clinical trials, communicates NIH's expectation that SABV will be factored into research designs, analyses, and reporting in vertebrate animal and human subject studies. As previously announced, the SABV policy will be implemented in phases, with parallel changes in peer review activities and requirements.[60] The NIH Office of Research on Women's Health (ORWH) and the Office of Extramural Research (OER) coordinate NIH policy initiatives and resource development related to SABV.

NIH continues to work with the larger scientific community following the publication of the SABV policy to help guide implementation[61] as well as develop scholarly articles[62], FAQs[63], commentaries, workshops[64], and blog posts that provide preclinical researchers with strategies for considering sex in research with vertebrate animals and humans, including tissues and primary cells. NIH is also developing new FAQs that reflect field-specific questions identified during the peer review of applications using males and females (e.g. guidance on preclinical research using primary cells). NIH has also developed a series of free web-based courses that provide a scientific understanding of the major physiological differences between the sexes and their influence on illness and health outcomes.[65] NIH staff also answer questions related to SABV directly from individual applicants and researchers. Finally, the Trans-NIH SABV Working Group was formed and meets regularly to monitor the implementation of the policies and assess the need for updates.

In addition to policy-related efforts, NIH also funds research to further understand the influence of sex and gender on human health. We continue to fund supplements to existing grants to add subjects, tissues, or cells of the opposite sex than was proposed in the original grant, as another step in advancing our understanding of sex and gender influences. The supplement program also allows researchers to add additional animals or human subjects of either sex to more robustly investigate sex differences. NIH recently sponsored a workshop in which researchers who were awarded a supplement presented their latest discoveries, including those in animal models[66]. The Specialized Centers of Research on Sex Differences program[67] has been expanded to support Centers of Excellence for interdisciplinary collaborations on sex and gender influences in health and has expanded the training opportunities available in sex and gender considerations in

[59] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html
[60] https://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195
[61] https://orwh.od.nih.gov/resources/pdf/NOT-OD-15-102_Guidance.pdf
[62] https://orwh.od.nih.gov/sites/orwh/files/docs/ConsideringSexAsABiologicalVariableInPreclinicalResearch.pdf
[63] https://grants.nih.gov/reproducibility/faqs.htm#IV
[64] https://doi.org/10.1096/fj.201600781R
[65] https://orwh.od.nih.gov/sex-gender/online-courses-sex-gender-differences
[66] https://orwh.od.nih.gov/sites/orwh/files/docs/ConsideringSexAsABiologicalVariableInPreclinicalResearch.pdf
[67] https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-18-004.html

experimental design and analysis. NIH has formed a new Sex and Gender in Health and Disease Scientific Interest Group[68] within the Intramural program to update investigators on current topics in SABV-related research relevant to health and disease.

NIH continues to support researchers to ensure the consideration of sex across the continuum, including research using tissues and primary cells. ORWH will also continue to identify the implications of evidence-based research for policy development, medical research initiatives, and health care.

[68] https://oir.nih.gov/sigs/sex-gender-health-disease

Tuberculosis Funding

Roybal-Allard 1: Tuberculosis is the leading global infectious killer, ahead of HIV/AIDS, taking 1.7 million lives annually around the world. Here in the U.S., every state continues to report TB cases each year, and my state of California is one of the most highly burdened in the country, including having the highest number of life-threatening and highly expensive drug resistant TB cases.

In an article published last month in The American Journal of Tropical Medicine and Hygiene, you spoke of the need to develop faster and improved diagnostics, shorter and more tolerable treatments, and more broadly effective vaccines for all strains of TB.

1. Can you update the subcommittee on the progress NIAID is making to meet each of these goals?

2. What funding investment do you need in order to keep our TB research efforts on track with the 2015 National Action Plan for Combating Multi-Drug Resistant (MDR) TB?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) supports a comprehensive portfolio of basic, clinical, and translational research on tuberculosis (TB) to better understand the natural history of TB and the development of resistance to drugs used to treat it. NIAID also provides resources and animal models to investigators worldwide to facilitate the development of new TB diagnostics, therapeutics, and vaccines.

Diagnostics
NIAID supports research to develop rapid, cost-effective, and accurate "point-of-care" tests to distinguish between drug-sensitive and drug-resistant *Mycobacterium tuberculosis* (*Mtb*), the causative agent of TB. NIAID research investments contributed substantially to the World Health Organization-endorsed GeneXpert MTB/rifampicin resistance diagnostic currently in use, as well as improvements in the test's sensitivity and its expansion to detect drug resistance beyond rifampicin, which is essential for identification of extensively drug-resistant TB (XDR-TB). NIAID also is supporting the development of novel diagnostics for TB in adult and pediatric patients, incuding rapid detection of microbial biomarkers in blood and the use of easier to obtain specimens to facilitate the use of available PCR-based diagnostics.

Therapeutics
There continues to be an urgent need for new and improved TB treatments. To address this need, NIAID-sponsored investigators have engaged in cross-disciplinary, international collaborations designed to advance TB drug discovery. NIAID is supporting clinical trials evaluating shorter TB treatment regimens, strategies to prevent TB in contacts of multidrug-resistant (MDR) TB patients, and treatments for adults and children with MDR-TB as well as individuals with latent TB infection. NIAID-supported investigators recently completed a Phase 4 clinical trial evaluating the safety of TB preventive therapy using the antibiotic isoniazid for HIV-infected pregnant and postpartum women in high TB incidence settings. Of note, NIAID has supported two-thirds of the TB therapeutic candidates that are undergoing clinical study around the world.

Vaccines

NIAID supports basic, preclinical, and clinical research to facilitate the discovery and development of innovative vaccines to prevent TB infection and disease. The goal is to develop vaccine candidates that show improvement over the current Bacillus Calmette-Guérin (BCG) TB vaccine, which does not protect adults against active pulmonary TB. NIAID has contributed to the preclinical and clinical development of 10 of the 12 TB vaccine candidates currently in clinical trials. NIAID-supported investigators recently completed a Phase 1/2 clinical trial evaluating the safety and tolerability of an experimental recombinant TB vaccine, AERAS-404, in infants also vaccinated with the BCG vaccine. NIAID also supports research on the mechanisms of protective immunity against TB, both from the perspective of the pathogen and the host, that may inform the development of new, more effective TB vaccines.

NIAID appreciates Congress' ongoing support for TB research. As the lead institute of the National Institutes of Health (NIH) for research on TB, NIAID is playing a critical role in the implementation of the *National Action Plan for Combating Multidrug-resistant Tuberculosis.* NIAID will continue to leverage current and past investments in basic, clinical, and translational research to inform critical scientific areas in TB research and to facilitate development of new diagnostics, therapeutics, and vaccines to help treat and prevent TB and the emergence of MDR- and XDR-TB. NIAID is committed to sustaining the progress of its TB research efforts to help meet the goals of the *National Action Plan.*

NIAID's TB research portfolio is built on the principle of collaboration and coordination with relevant stakeholders, agencies, and global funders of biomedical research and are positioned to complement global research and development. We can reach the aspirational goal of ending TB by leveraging sustained resources for robust, innovative, and aggressive research efforts that are translated rapidly into global TB control strategies.

Stillbirth and Maternal Mortality

Roybal-Allard 2: NICHD has a very broad and important mission, and your science impacts some of the most vulnerable in our communities. But within that research portfolio you also have the distinction of overseeing an area of health in which the United States falls significantly behind most other wealthy nations in several recognized measures of health status.

I am referring, of course, to the Maternity cycle, where as you know, more American women are dying of pregnancy-related complications than in any other developed country. What is worse is that maternal mortality is rising in the U.S. as it declines elsewhere.

Additionally, the US ranks 25th in the world, below most other industrialized nations, in our rates of stillbirth; and we are 155th out of 159 countries in our progress in reducing stillbirths.

Questions:

1. What percentage of the NICHD budget is directed towards improving outcomes in the maternity cycle?

2. What specific research can you point to that addresses these unacceptable statistics?

Answer: Maternal health spans a vast array of topics related to the health of mothers and mothers-to-be, including fertility and infertility, pre-conception care, substance use disorders, pregnancy-related disorders such as preeclampsia and gestational diabetes, perinatal and postpartum depression and anxiety, maternal obesity, and mother-to-child HIV transmission. In FY 2017, NICHD funded over $156 million in research related to maternal health, 11.35% of its budget for that year, and about 62% of NIH's spending on maternal health research overall. Maternal health is complex, and the associated conditions are often interrelated. For example, some diseases, such as gestational diabetes, can put women at increased risk of other disorders such as preeclampsia, a potentially fatal disorder involving dangerously high blood pressure. Complications during pregnancy can pose a serious risk to maternal health, and are associated with various adverse outcomes, including miscarriage, stillbirth, and preterm labor. Although maternal mortality is rare in the United States, its effects are devastating for the partners and families of women lost to fatal pregnancy complications. The prevalence and potential severity of pregnancy complications, for women as well as for the fetus and newborn, make research to inform better treatment and prevention interventions to protect maternal health a high priority.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports essential research designed to overcome many of the complex challenges that women encounter in trying to achieve and maintain healthy pregnancies. NICHD programs and resources for research on maternal health include:

- The Maternal-Fetal Medicine Unit Network, which designs and evaluates programs and treatments for the prevention of preterm birth and for the improvement of maternal and

infant outcomes using evidence-based medical practices. This network conducted a major clinical study of 10,000 women expecting their first child, and data are being analyzed that will yield critical information on several common adverse pregnancy outcomes.

- The Obstetric-Fetal Pharmacology Research Network, which provides the expert infrastructure needed to test therapeutic drugs during pregnancy. The Network allows researchers to conduct a whole new generation of safe, technically sophisticated, and complex studies that will help clinicians protect the health of women, while improving birth outcomes and reducing infant mortality.
- The Global Network for Women's and Children's Health Research, which is dedicated to preventing maternal and infant deaths and illnesses worldwide. Research areas addressed by the Global Network include preventing postpartum hemorrhage (massive blood loss after childbirth); improving childbirth practices; and reducing infections such as malaria, tuberculosis, and sepsis. Lessons learned from global research where the prevalence of these conditions is higher also can be applied to women in the United States.
- The Pelvic Floor Disorders Network (PFDN), which conducts clinical research on pelvic floor disorders to improve patient care. Pelvic floor disorders are a common complication of pregnancy that can arise soon after or years after childbirth.

Recent scientific advances addressing complications of pregnancy or delivery include a NICHD-supported study of a drug to prevent preeclampsia in high-risk pregnant women. Similarities in pathological characteristics of cardiovascular disease (CVD) and preeclampsia, a dangerous spike in a pregnant woman's blood pressure, prompted NICHD-supported researchers to conduct a small, preliminary clinical trial, in at-risk pregnant women, of a drug used to lower CVD risk. Women receiving the drug, Pravastatin, beginning in the second trimester, did not develop preeclampsia while those receiving a placebo drug did develop this serious pregnancy complication at the same rate as in the general population. NICHD-supported researchers also recently demonstrated in a large cohort of pregnant women with unplanned cesarean deliveries that adding a second antibiotic to standard preventive treatment against infection reduced post C-section infections by 50 percent. Infection is the fourth most common cause of pregnancy-related death in the U.S.

NICHD will continue to support a large portfolio of research on the diverse aspects of maternal health, including complications of pregnancy that may impair the health of women during pregnancy and after delivery. Just launched in January, NICHD's new pregnancy registry, PregSource®, will use a crowd-sourcing approach, asking pregnant women who wish to participate to enter information regularly and directly about their pregnancies throughout gestation and the early infancy of their babies, into online surveys and trackers via a website. A large, collaborative research endeavor, the Human Placenta Project, will continue advancing research on the least understood human organ and arguably one of the most important for the health of both woman and fetus during pregnancy and thereafter. The overall objectives are to:

- Develop and apply new technologies to understand and monitor, in real time, placental development and function in normal and abnormal pregnancies.
- Develop and evaluate non-invasive markers for prediction of adverse pregnancy outcomes.

- Develop interventions to prevent abnormal placental development, and hence improve pregnancy outcomes.

In addition, the congressionally mandated Task Force on Research Specific to Pregnant Women and Lactating Women, led by NICHD, will be providing recommendations to the HHS Secretary and Congress by September 2018 on how to address research gaps on prescription medications commonly used by these populations, but not tested or labeled specifically for them.

Underage Drinking and Alcohol Use Research

Roybal-Allard 3: During the hearing, we spoke about the reports of an NIH partnership with the alcohol industry in funding the study on moderate drinking and heart health. One of my concerns was that because of this partnership, there were reports that NIH was making decisions about not funding other essential alcohol use research that was in conflict with industry priorities. I have a couple of follow-up questions:

Questions 1: Since 2014, have there been any funded NIAAA studies on the surveillance and impact of alcohol marketing on young people, drinking in college populations, and/or the role of alcohol outlet density in alcohol problems?

Answer: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) funds a broad portfolio of epidemiological and intervention research with the goal of preventing and reducing alcohol misuse and related consequences among diverse populations across the lifespan, including among underage and college populations. In FY 2017, NIAAA funded more than 70 grants focused on underage and/or college-age drinking. Examples of research and findings from NIAAA's portfolio in this area include:

- A longitudinal study to examine trajectories of alcohol and drug use from adolescence into young adulthood, and the influence of individual, peer, family, and neighborhood factors such as alcohol outlet density.
- Research demonstrating that youth who initiate alcohol use prior to age 15 are at greater risk for alcohol use disorders later in life.
- The *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide* to provide resources to practitioners seeking to intervene with youth 9- to 18-years old at risk for or using alcohol. The Guide's effectiveness is being evaluated in primary care settings, emergency departments, juvenile justice settings, schools, and among youth with chronic medical conditions.
- *CollegeAIM*,[69] a tool to assist colleges and universities in choosing among nearly 60 evidence-based college drinking interventions and policies based on their effectiveness, anticipated costs, and barriers to implementation.

Question 2: Have there been any studies on these issues that were submitted but not funded, and if so, what criteria were used to make those decisions?

Answer: NIH funding decisions are driven by public health needs, scientific opportunity, and a two-tiered peer review system to evaluate meritorious applications. Grant applications submitted to the NIH are evaluated on evaluated by a two-tier peer review system. The first level of review

[69] https://www.collegedrinkingprevention.gov/collegeaim/

for scientific merit is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards composed of scientific and public representatives who consider the public health relevance and the overall portfolio balance of the IC, in addition to the scientific merit of the applications. Final funding decisions are made by the IC Directors.

Infectious Diseases and Opioid Use

Roybal-Allard 4: The opioid epidemic is driving increasing rates of multiple infectious diseases, including HIV, hepatitis B and C, and infections of the heart, skin and soft tissue, bones, and joints outbreaks among people who inject drugs. A number of jurisdictions already report increases in HIV cases linked to injection drug use and the Centers for Disase Control and Prevention (CDC) estimates a 133% increase in acute HCV infection due to opioid use. While there are less available data on many other infections due to insufficient reporting and surveillance, regional and state data analyses indicate a significant increase in hospital infections due to endocarditis (an infection of the heart valve) linked to injection drug use.

The administration's plan speaks to the opioid crisis, but not to expectations that significant outbreaks of HIV and hepatitis will continue to follow its path without focused and evidence-based public health resources that must include access to primary care and preventive services.

Question:

1. How will NIH ensure the federal response to the opioid epidemic includes greater emphasis on public health interventions, research, and workforce support to prevent, track, and treat opioid-related infectious diseases?

Answer: Infections related to injection drug use remain a core focus of the National Institute on Drug Abuse (NIDA) mission, and current research is addressing not only the mechanisms and treatment of infections such as HIV and viral hepatitis, but also novel strategies to establish best practices for the prevention, diagnosis and treatment of these conditions in regions where opioids have had a heavy impact on the community. NIDA funds hundreds of research projects focused on these consequences of injection drug use, and plays a key role in the strategic development, planning, and coordination of high priority research through the National HIV/AIDS Strategy,[70] the Trans-NIH Plan for HIV-Related Research,[71] and the National Viral Hepatitis Action Plan.[72]

Recent notable activities include:

- A funding opportunity[73] focused on HIV and hepatitis C virus (HCV) co-infections in substance users intended to fill gaps in the understanding of (a) the impact of addiction on HIV, HIV/HCV co-infection associated disease progression, (b) the pathogenic interactions between HIV and HCV, (c) hepatic and non-hepatic co-morbidities associated with HIV/HCV co-infections in people with substance use disorders (SUDs), and (d) the effectiveness of interferon-free direct acting antiviral (DAAs) drug regimens to treat HIV/HCV co-infections in people with SUDs.
- Project HOPE-HCV, which uses a hospital-based HIV cohort as a research platform for a randomized clinical trial assessing the effectiveness of an intervention to ensure that

[70] https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview
[71] https://www.oar.nih.gov/strategic_plan/fy2018/OAR_18_StrategicPlan_P10_508.pdf
[72] https://www.hhs.gov/hepatitis/action-plan/national-viral-hepatitis-action-plan-overview/index.html
[73] https://grants.nih.gov/grants/guide/pa-files/PAS-17-311.html

HIV/HCV co-infected substance users receive clinical evaluation and treatment for HCV infection.

- Supplements to NIH Centers for AIDS Research (CFAR) sites to support pilot studies addressing opioid injection and its infectious disease consequences in non-urban areas of the United States.
- An update to the National HIV Behavioral Surveillance among persons who inject drugs, which involves 22 Centers across the U.S., and Puerto Rico. Plans for 2018 include improvements in recruiting people younger than 30 years old who inject drugs, HCV testing, and expansion of recruitment outside the urban core.

In addition, NIDA has partnered with states and several other federal agencies to address the opioid crisis in rural U.S. regions, issuing funding opportunities to help communities develop ways to comprehensively prevent and treat SUDs, overdoses, and infectious disease transmission related to injection drug use. These projects support the work of state and local communities in developing best-practice responses that rural public health systems can implement. The grants are co-funded by the Appalachian Regional Commission, the CDC, and the Substance Abuse and Mental Health Services Administration.

The National Institute of Allergy and Infectious Diseases (NIAID) maintains a longstanding program of basic, translational, and clinical research into the development of vaccines, therapeutics, and diagnostics for HIV and viral hepatitis. NIAID-supported researchers are exploring ways to prevent the spread of HIV and viral hepatitis infections, efforts that could help to reduce the prevalence of these infections and limit the risk that they could be transmitted by injection drug use. For example, NIAID, along with NIDA and the National Institute of Mental Health (NIMH), is co-funding clinical trials to prevent HIV acquisition in drug-using populations through the use of opioid substitution therapy and other treatment and prevention methods. NIAID-funded HIV prevention research also includes the first large-scale clinical trial of a long-acting injectable medication that could provide a less burdensome alternative to existing daily pre-exposure prophylaxis medications. In addition, NIAID is pursuing new or improved vaccines to prevent hepatitis B virus (HBV) and HCV infections. NIAID scientists also are investigating the use of nanoparticle technology to design recombinant vaccines that could be used to prime the immune system against multiple HBV viral proteins, enabling the investigation of a wide variety of new HBV vaccine designs. NIAID also is supporting a Phase 1/2 clinical trial of a vaccine candidate to prevent acute and chronic HCV infection in injection drug users.

NIAID Resources Devoted to Antimicrobial Resistance (AR)

Roybal-Allard 5:

Both the NIAID and the CDC have acknowledged that we are in the midst of a public health emergency regarding antimicrobial resistance.

1. Given that the public health crisis of rising antibiotic resistance necessitates both increased R&D as well as public health interventions, please describe how closely NIAID is working with agencies such as the CDC, FDA, BARDA, and DoD on the federal response.

2. Please describe the NIAID resources currently allocated to AR R&D, and in particular, how they have fluctuated as the crisis has escalated.

3. Can you share how these efforts would be impacted by the proposed $114 million cut in overall NIH funding in FY2019 proposed by the Administration?

4. Additionally, how effectively is NIAID engaging industry in efforts to generate new antibiotics and rapid diagnostics?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) continues to support basic, clinical, and translational research to address the public health threat of antibiotic resistance. As a key player in the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), NIAID works closely with other federal agencies to support the development and evaluation of diagnostics, vaccines, and therapeutics for antibiotic-resistant bacteria. The National Institutes of Health (NIH), including NIAID, is working to populate the National Database of Resistant Pathogens in partnership with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). This sequence database is a publicly available resource for researchers to enhance understanding of antibiotic resistance mechanisms and to facilitate the development of new and improved diagnostics and targeted interventions. NIAID also collaborates with the Biomedical Advanced Research and Development Authority (BARDA) on CARB-X, a public-private partnership dedicated to accelerating the development of innovative antibacterial products. The NIH also partners with BARDA on the Antimicrobial Resistance Diagnostic Challenge. CDC and FDA provide technical advice for this Challenge competition. The Challenge recently launched the second phase of the competition, which seeks to identify innovative and rapid point-of-care diagnostic tests for drug-resistant bacteria.

Since fiscal year (FY) 2015, NIAID funding for CARB has increased from approximately $243 million in FY 2015 to approximately $431 million in FY 2018. This includes increased appropriations for CARB provided by Congress in FYs 2016, 2017, and 2018. NIAID has and will continue to use these funds to enhance existing CARB research efforts and to support innovative new research focused on the development of unique and improved diagnostics, therapeutics, vaccines, and prevention strategies.

The FY 2019 President's Budget, which was released prior to the enactment of the FY 2018 Consolidated Appropriations Act, provides $478 million for CARB research at the NIH. NIH anticipates that its ongoing CARB efforts and partnerships across government, as well as new activities enabled by FY 2018 funding, will continue to support progress against antibiotic-resistant bacterial infections in FY 2019.

NIAID values its partnerships with industry and strives to build strong, productive partnerships in both the private and public sectors to advance the goals of the National Action Plan for CARB. In addition to NIAID funding for specific research projects investigating new antibiotics, treatment strategies, and diagnostic tests, NIAID provides unique "push" incentives through its preclinical and clinical services that enable researchers in industry and academia to de-risk antibacterial product development. These no-cost services include screening tests for antimicrobial activity and access to organisms and research reagents to assist in product testing. NIAID also engages industry, as well as other Federal agencies, international partners, academic institutions, nonprofits, and healthcare providers through various partnerships, such as the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) and the NIAID Antibacterial Resistance Leadership Group (ARLG). To date, the ARLG has supported more than 35 clinical trials to evaluate new diagnostics, therapeutics, optimized treatment regimens, and projects on antibiotic stewardship strategies. NIAID is committed to supporting these valuable partnerships to further advance research efforts to combat antibiotic resistance.

Supporting Young Investigators

Roybal-Allard 6: Challenges in securing research funding are discouraging people from pursuing research careers. Without sufficient investment, I'm concerned we will not have the next generation of scientists we need to develop new vaccines, diagnostics and therapeutics.

1) Can you describe NIH's efforts on this issue—including the Next Generation of Researchers Initiative announced last week?
2) How would these activities be impacted by the administration's proposed $114 million funding cut?

Answer: In response to the 21st Century Cures Act (P.L. 114-255), NIH launched the Next Generation Researchers Initiative (NGRI) in September 2017.[74] This initiative aims to bolster opportunities for early-stage investigators.[75] Early-stage investigators are defined as those within ten years of completing postgraduate clinical training or their most recent advanced research degree. Through this initiative, NIH Institutes and Centers are requested to prioritize funding for additional early-stage investigators. Furthermore, NIH will track the impact of funding decisions for early-stage investigators to ensure that this new strategy is effectively implemented.

Further, an NGRI working group has been convened under the Advisory Committee to the NIH Director to assess the success of the new programs as well as offer additional suggestions to promote and sustain successful research careers. The working group's recommendations for enhancing training, mentorship, and the diversity of the biomedical workforce are expected in June 2018.

NIH appreciates the Congress' commitment to helping promote the next generation of researchers, as this is also an issue of great importance to NIH.[76] The fiscal year 2018 appropriation, along with other recent budget actions, allows NIH the opportunity to support additional meritorious research applications, including those innovative ideas conceived by investigators early in their careers. The President's Budget request for fiscal year 2019 also seeks additional funding specifically for NIH to support the next generation of researchers. Even as Institute and Center priorities evolve, NIH can support more programs with such resources for training, career development (especially for physician scientists), helping transition to independence, and diversifying the biomedical research workforce.

[74] https://grants.nih.gov/ngri.htm
[75] https://grants.nih.gov/ngri.htm
[76] https://nexus.od.nih.gov/all/2018/05/04/the-issue-that-keeps-us-awake-at-night/

Fogarty International Center Infectious Diseases

Roybal-Allard 7: The Fogarty Center plays a critical role in global health security and emergency preparedness, and conducting studies that will help predict and contain future pandemics. Fogarty grants also support research in every state in a wide array of disease areas including HIV, tuberculosis, brain and nervous system disorders, cancer, cardiovascular disease and stroke, diabetes, mental illness, and substance abuse. Breakthroughs made possible by Fogarty funding directly benefit U.S. patients and researchers.

Can you share the critical role the Fogarty Center plays in addressing infectious diseases, ensuring global health security and preparedness, and advancing research into cures?

Answer: t NIH trains scientists in developing countries to detect pandemics at their point of origin, contain outbreaks, minimize their impact, and prevent or limit spread of disease to the U.S. The Fogarty International Center supports research and research training programs for U.S. and low- and middle-income country *(LMIC) scientists, including long-standing programs addressing infectious diseases.*

A major barrier to improved treatment and control of infectious diseases is the lack of capacity to conduct locally relevant infectious disease research often due to the scarcity of scientists and health professionals in LMICs with relevant research expertise. For more than 15 years, the Global Infectious Diseases (GID) program has supported research training to generate scientific knowledge and skills that enable LMIC institutions to conduct research directly related to prevention, treatment and control of infectious diseases causing major morbidity and mortality. For example, scientists in Brazil and Mexico, initially trained with Fogarty support for research on diseases such as dengue and Chagas, were quickly able to redirect their skills to understanding and controlling the emerging threat from Zika. Researchers in Brazil applied their experience with Chagas disease to better understand how Zika impacts the brain, while researchers in Mexico determined why some insecticides used in Brazil and the U.S. were ineffective at controlling the spread of mosquitos carrying the virus.

In 2016, Fogarty launched the Emerging Epidemic Virus Research Training for West African Countries with Widespread Transmission of Ebola program. These grants fund collaborations between U.S. and African research institutions in Guinea, Liberia, and/or Sierra Leone to plan research training and capacity building programs for the Global Infectious Disease Research Training Program (GID), with a focus on emerging viral epidemics. These efforts will strengthen the skills needed for early identification, transmission prediction and modeling, conducting clinical trials and laboratory work, biosecurity regulations, public health response testing, and assessing long-term health effects of emerging viral diseases that have the potential for regional and global pandemics.

In addition to infectious disease preparedness, research conducted in a global context can inform diagnosis or treatment of other health challenges that affect Americans. For example, hydrocephalus – excessive accumulation of fluid in the brain – is one of the most common birth

defects in the U.S and is the most common reason for brain surgery in children. The traditional treatment for hydrocephalus is the surgical placement of a shunt, which requires follow up and monitoring. Shunts often involve complications like mechanical failure, obstruction, and infection and require surgical revisions. Fogarty's Global Brain program supported researchers working in Uganda to develop and validate a new treatment for infant hydrocephalus. They combined endoscopic third ventriculostomy and choroid plexus cauterization (ETV/CPC) into one cost-effective treatment, where a small hole drains fluid from the brain and heat is applied to brain tissue to reduce the amount of fluid. Both procedures have been practiced separately, but scarce medical expertise and health resources in Uganda inspired researchers to combine the two practices. This combination treatment has been very effective and has helped to avoid shunt dependence in most Ugandan infants treated for this condition. Due to the project's success, the use of ETV/CPC treatment has expanded and is now being practiced in the U.S.

Myalgic Encephalopathy /Chronic Fatigue Syndrome

Roybal-Allard 8: ME/CFS is a complex, debilitating, chronic, neuro-immune disease afflicting 836,000-2,500,000 million Americans, and costs individuals, the U.S. health care system, and our economy $17-$24 billion annually, $9.1 billion of which has been attributed to lost productivity.

In 2015, the National Institutes of Health (NIH) announced it would increase activity and funding for ME/CFS and subsequently take progressive actions including collaborating with the CDC to produce common data elements and funding the creation of multiple ME/CFS Collaborative Research Centers (CRCs) and a Data Management Center. Nevertheless, NIH funding for ME/CFS remains clearly inadequate at $13 million/year.

Questions:

1. Does the NIH have a cross-institute strategic plan for ME/CFS? If so, could you provide us a copy of that plan?

> The causes and underlying biology of Myalgic Encephalopathy /Chronic Fatigue Syndrome (ME/CFS) remain unknown. Currently, NIH-funded research is focused upon identifying clinical abnormalities and then validating them in multi-center studies. At NIH, 24 institutes, centers, and offices coordinate their efforts through the Trans-NIH ME/CFS Working Group which allows NIH to cast a wide net to identify biologic determinants. This Working Group meets regularly to discuss best approaches to fostering ME/CFS research across NIH, identifies research needs and gaps, and the discusses the best ways for NIH to address these. Discussions in the Working Group on the need for and ways to advance interdisciplinary research programs and build the research infrastructure in academic institutions led to the development and release of Funding Opportunity Announcements for ME/CFS Collaborative Research Centers (CRCs) and the subsequent funding of three Centers and an associated data management coordinating center (DMCC). NIH will consider the development of a strategic plan in future years, once ongoing research has brought us closer to a better understanding of where the science is best focused.

2. Given the extremely low funding for ME/CFS when compared to other diseases of a similar severity, burden, and prevalence, why was the funding commitment made by each of the institutes to the newly created Collaborative Research Centers so low? Can you estimate how long it will take to get total NIH funding up to a level that is commensurate with the disease burden?

It is difficult to estimate when funding increases will occur and at what rate since NIH funding increases in a particular area are largely dependent on the number of scientists submitting applications and the meritorious nature of the research as judged by peer review. NIH continues to work to encourage researchers to submit applications using all available NIH mechanisms. NIH also uses targeted Funding Opportunity Announcements (FOAs) for specific research programs, as funds allow, and in 2017, NIH issued FOAs for ME/CFS Collaborative Research Centers (CRCs). NIH worked to develop an appropriate budget for the Centers given scientific opportunity and availability of funds across the NIH institutes and centers. Nine NIH institutes and centers contributed funds to support the three funded CRCs and DMCC, demonstrating the trans-NIH commitment to this research area. The ME/CFS CRS budget is commensurate with the budgets of other similar Center programs. The findings from the CRCs are aimed at providing compelling opportunities for the CRCs and colleagues across the country to submit investigator-initiated grants to expand their efforts into promising avenues of research. Funding for the CRCs and DMCC resulted in a significant increase in overall spending for ME/CFS in FY17. These FY17 NIH funding numbers have not been made public yet but are expected to be released soon.

3. What percentage growth of researchers in the ME/CFS field do you hope to achieve over the next three years through the Collaborative Research Centers, and what additional mechanisms will you be using to attract those researchers?

It is difficult to quantify the projected growth of any scientific field given the inherent nature of scientific research. Research in a field may be boosted by unanticipated or fortuitous findings in that field, or sometimes in a seemingly unrelated area. This often results in an increased interest in the field and an influx of new researchers. NIH is using the CRCs, together with other NIH-funded research, to help encourage significant growth and interest in ME/CFS research. In fact, the number of students and postdocs doing research on ME/CFS has significantly increased at the three funded CRC institutions and NIH hopes that many of these young investigators will continue their career in ME/CFS research. NIH funding is dependent on the number of meritorious applications it receives, and NIH program officials continue to work to attract researchers to this area through talks and grant-writing workshops at relevant scientific meetings. NIH continues to welcome investigator-initiated research proposals in ME/CFS and related areas and will fund meritorious projects based on the outcome of peer review. NIH has a number of career development awards, training grant mechanisms, and other policies to support trainees and early stage investigators. These programs are open to researchers in all areas, including ME/CFS. For example, last year, the National Institute of Neurological Disorders and Stroke funded a pre-doctoral fellowship to a student investigating the neural correlates of fatigue in ME/CFS.

4. Does the NIH plan to utilize investigator-initiated awards, hypothesis-generating research, early stage investigator awards, student loan forgiveness, training programs, or career awards to support these efforts? If not, why not?

All of the funding opportunities indicated in the question are available to researchers currently working in ME/CFS as well as researchers interested in moving into the field. Scientists who wish to apply to NIH for support using one these mechanisms should reach out to the appropriate NIH program official for advice and guidance. NIH continues to make the ME/CFS community aware of the availability of these opportunities through presentations at scientific conferences, stakeholder outreach, and other more informal interactions between NIH program officials and researchers.

5. Does the NIH have plans to support drug trials for ME/CFS? If so, when will these drug trials take place? If not, why not? What are you doing to remove any barriers to ME/CFS drug trials?

As ME/CFS research moves forward to the point of readiness for clinical trials, NIH will support meritorious applications for clinical trials testing drugs or other therapies for ME/CFS. In order to develop therapies appropriate for testing in individuals we first need a better characterization and understanding of the pathophysiology and mechanisms of the disease which then give rise to promising biologic targets for therapy development. NIH encourages applications for research in all of these areas and has funding mechanisms to enable therapy development to the point of FDA application for Investigational New Drug (IND). The recently funded CRCs also are working to develop better diagnostics and ways to characterize patients, studying the mechanisms underlying the disease, and importantly, building the infrastructure in academic institutions to carry out future clinical trials.

Spina Bifida

Roybal-Allard 9: Spina Bifida, the most common, permanently disabling birth defect that is also compatible with life in the United States, affects approximately 1,500 births each year. Spina Bifida is a serious, life-long condition which occurs when the spinal cord fails to close properly during the early stages of pregnancy. About 80% of people with Spina Bifida have the most severe form, myelomeningocele (MMC).

Spina Bifida is a rare disease, impacting less than 200,000 individuals, about half of which are adults. However, a multidisciplinary care team consisting of neurosurgery, neurology, urology, orthopedics, physical medicine and rehabilitation and others is required to manage this complex disorder. And the estimated cost of lifetime care related to Spina Bifida can exceed $1 million. Out-of-pocket costs for direct medical care for children born with MMC are 13 times more than children born without MMC. These additional costs continue into adulthood, when individuals with MMC pay 7 times more in medical cost than those without MMC.

The last significant research from NIH is the Management of the Myleomeningocele Study (MOMS), which looked at the outcomes related to fetal surgery. Given the complexity and cost associated with care of individuals with Spina Bifida, the funds currently dedicated for this sentential condition are inadequate.

Questions:

1. Given that Spina Bifida is a lifelong multi-discliplinary disorder, does NIH have a strategic plan across institutes to address Spina Bifida? If so, please provide a copy of the plan.

2. Since about half of the individuals with Spina Bifida are adults, and the MOMs study relates to children, what plans does NIH have to address care in adults?

3. As a result of the Genitourinary Conditions meeting at NIH in 2015, a paper was published, "Research Needs for Effective Transition in Lifelong Care of Congenital Genitourinary Conditions: A Workshop Sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases". In this paper, research and knowledge gaps were idenfied. What plans are in place to address these gaps?

4. With more people with Spina Bifida are reaching old age, what is being done to address aging with this multidisciplinary condition?

Answer: National Institute of Health (NIH) Institutes and Centers continue to collaborate on research efforts related to spina bifida. The *Eunice Kennedy Shriver* National Institutes of Child Health and Human Development (NICHD) continues to actively support research on Spina Bifida (SB). Through its efforts and those of others, the prevalence rate of SB has declined 31 percent from 1995 to 2006; this translates into 1,000 fewer babies born with a neural tube defect each year. The original NICHD-funded Management of Myelomeningocele (MOM) study reported that surgically correcting the spinal defect while the fetus was still in the womb greatly reduced the need to divert fluid away from the ventricles to relieve hydrocephalus, improving

health and mobility outcomes. The recently-completed "MOMS 2" study, co-funded by NICHD and the National Institute of Neurological Disorders and Stroke (NINDS), followed children in the original MOMS study to school age to assess health and mental health outcomes as well as capacity to live more independently and function more safely and appropriately in daily life, compared with those treated with surgery after birth. The follow-up study is determining the effects of prenatal repair on adaptive behavior, cognitive and motor function, brain morphology and microstructure, urologic health, and other aspects at school age. Initial results suggest the fetal surgery improves long-term functional outcome, with the majority of children able to successfully complete daily tasks. In addition, long-term ambulatory status is improved.

Even with the significant decrease in children born with a neural tube defect each year, there are still over 150,000 individuals with SB living in the United States, about half of whom are adults. Common manifestations of SB include motor and sensory neurological deficits, neurogenic bladder and bowel, spasticity, and pressure ulcers. A multidisciplinary care team consisting of neurosurgery, neurology, urology, orthopedics, physical medicine and rehabilitation and others is required to manage this complex disorder. A NICHD-funded study of patterns of fat accumulation in children with myelomeningocele (the most severe form of SB) detected a pattern that correlated with an increased risk of developing type 2 diabetes. This finding could alert doctors to the importance of tailoring their care of young patients with SB to reduce muscle-related fat and thus reduce diabetes risk. Research in NICHD's intramural branch is looking at how nutritional and other interventions might prevent neural tube defects such as SB. Recent advances in genomics and computational genetics, together with the creation of genetic mouse models, offer unique opportunities to examine the genetic components of SB. For example, a NICHD-supported study is performing exome sequencing to identify unique variations in genes and pathways influencing myelomeningocele susceptibility to facilitate improved diagnostics and treatment.

Considering the condition's complexity and issues associated with aging with SB, self-management and self-reporting is critical; yet, this approach has received little attention. NICHD recently funded a skin care self-management study to address the chronic skin conditions such as wounds on lower extremities experienced by individuals with SB. Investigators developed a mobile health (mHealth) system for supporting self-care and management of skin problems, called SkinCare, which was shown to be capable of supporting self-care and adherence to regimen, monitoring adherence, and supporting clinician engagement with patients. In addition, the NICHD is currently funding a Small Business Technology Transfer (STTR) application that is developing assistive software to help developmentally disabled youth, including those with SB, provide valid healthcare assessment self-reports. The institute also supports the Gait and Clinical Movement Analysis Society annual meeting, which is aimed at bringing scientists together who are working on improving ambulation and quality of life for children and adults with neuromuscular disorders, including those with SB.

Several of the NIH Institutes and Centers fund research on SB. For example, the National Institute of Nursing Research (together with the Office of the NIH Director) is funding a study whose goal is to identify targets for effective self-management, adherence and health care interventions for youth with SB. Focusing on self-management in late adolescence and young

adulthood will allow for an examination of the transition from pediatric to adult health care. The National Institute of Diabetes and Digestive and Kidney Diseases has long supported research efforts on congenital genitourinary conditions, recently holding a meeting in February 2018, entitled "Individualizing Treatment for Urinary Incontinence—Evolving Research Questions into Research Plans." The focus of the meeting was to develop an interdisciplinary research plan for individualizing treatment for urinary incontinence.

NINDS funds research projects aimed at the understanding and improving treatments for hydrocephalus, which often affects people with SB. Shunts to divert excess cerebrospinal fluid are the primary treatment for hydrocephalus, but complications due to shunt malfunction, obstruction, or infection are common. Investigators are working to understand and prevention such complications, to develop less invasive ways to monitor hydrocephalus and shunt function, and to develop and test potential alternatives to shunt treatment. NINDS also supports research relevant to understanding and treating neurogenic bladder in SB, including efforts to develop a drug to induce urine voiding as an alternative to catheterization, a low oxygen breathing therapy to improve urinary tract function and a surgical method to restore neural connectivity to the bladder and urethral sphincter.

THURSDAY, APRIL 12, 2018.

INVESTMENTS IN OUR HEALTH WORKFORCE AND RURAL COMMUNITIES

WITNESSES

TOM MORRIS, ASSOCIATE ADMINISTRATOR FOR RURAL HEALTH POLICY, HEALTH RESOURCES AND SERVICES ADMINISTRATION

LUIS PADILLA, M.D., ASSOCIATE ADMINISTRATOR FOR HEALTH WORKFORCE, HEALTH RESOURCES AND SERVICES ADMINISTRATION

OPENING STATEMENT BY MR. COLE

Mr. COLE. Good morning. It is my pleasure to welcome our witnesses today to the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies to discuss investments in our health workforce programs and initiatives targeting rural communities. We look forward to their testimonies.

Ninety-seven percent of the Nation's land area is classified as rural, but this area houses less than 20 percent of the Nation's population. Americans living in rural areas are at a greater risk of dying from heart disease, cancer, and stroke than their urban counterparts. Age-adjusted death rates for unintentional injuries are 50 percent higher in rural than urban populations.

Rural areas often have less access to the range of healthcare providers and services when compared to their urban counterparts. Acknowledging this disparity, the subcommittee has supported increases for several rural health programs. Ensuring small rural hospitals can keep their doors open and, where possible, supporting residency programs is critical to improving the health of rural communities.

Rural areas struggle to attract and retain providers, compounding the effects felt from the Nation's primary healthcare workforce shortage. By some estimates, the United States could face a shortage of almost 100,000 physicians by 2025. Not only do we face a shortage in the total number of providers, but we struggle to recruit and train physicians from our local communities. Currently, one in four practicing physicians come from outside the United States.

These figures signal a missed opportunity to attract young individuals to a growing sector of the economy. Moreover, the shortage of health professionals is felt most acutely in geographic areas with the greatest need, such as rural communities and tribal populations. Increasing opportunities for people to become healthcare professionals is a vital component to addressing the high demand for jobs in the health sector.

Today, we look forward to hearing from our witnesses about what Health Resources and Services Administration is doing to ad-

dress the shortage of providers in rural areas, to help rural counties hardest hit by the opioid epidemic recover, and to support rural hospitals from closure. We also look forward to hearing about the workforce investments across the training continuum and how these programs place practitioners in the communities most in need.

We hope to learn more about how we can target our Federal investments to maximize the impact on rural populations and improve access to care for those in other underserved areas.

Today, I am pleased to welcome the following witnesses. Tom Morris is the Associate Administrator for Rural Health Policy at HRSA. Mr. Morris coordinates analysis and response to policy issues affecting rural America, particularly the impact of Medicare and Medicaid regulations on the rural health workforce and service delivery. He oversees nearly 40 grant programs that focus on building rural healthcare capacity at the State and community level.

Dr. Luis Padilla serves as the Associate Administrator of Health Workforce and the Director of the National Health Service Corps for HRSA. With total budgetary resources of over $1,000,000,000 supporting more than 40 programs, the Bureau of Health Workforce seeks to improve access to quality healthcare through a well-trained and well-distributed 21st century workforce. Dr. Padilla coordinates programs that support the healthcare workforce, including support for the more than 10,000 National Health Corps Service clinicians providing care nationwide.

As a reminder to the subcommittee, the Members, and our witnesses, we will abide by the 5-minute rule. The chair will probably be a little more flexible today than normally, and the witnesses will certainly have adequate time to present their testimony, and Members technically have 5 minutes to ask questions. I look forward to hearing from the witnesses.

And with that, I would like to yield to my good friend the ranking member, the gentlelady from Connecticut.

OPENING STATEMENT BY MS. DELAURO

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

And let me welcome Dr. Padilla and also Mr. Morris, and thank you for being here to talk about today Federal investments in what are two incredibly important areas, so critically important areas, our health workforce and our rural communities.

Dr. Padilla, in your testimony, you noted that there are more than 72 million people who live in areas with too few primary care health professionals, more than 54 million with too few dentists, more than 111 million with too few mental health services. I believe the figures are staggering. The United States is the wealthiest nation in the world. Hundreds of million people who can't get the care that they need, that is unacceptable.

In the recently enacted 2018 omnibus, we try to address many of these shortages. The 2018 Labor, HHS, Education bill included an additional $222,000,000 for HRSA's health workforce programs, an increase of more than 25 percent over the previous year, including a total increase of $52,000,000 for health workforce training programs to address the shortage of access to behavioral healthcare services particularly in rural and medically underserved areas.

We also included an additional $135,000,000 for rural health programs. It was an increase of 86 percent over the previous year. And let me just state for the record that I am so supportive of these programs, but there is no healthcare provider in my district, the Third District of Connecticut, for a rural health grant at HRSA. These programs are so necessary, and I am proud to have fought for the funding increases. They are important, and they are desperately needed.

So, today, I would like to hear what actions the administration is taking with that funding to help those families who are in need. I especially want to hear about what the administration is doing to combat the opioid epidemic. Millions of Americans are struggling. It is painfully clear that the opioid epidemic is not just a rural problem.

Last year, my State of Connecticut tragically lost more than 1,000 people to accidental drug overdoses, 190 percent increase since 2012. All other drug overdose deaths were at a 5-year low. In January and February of this year, there were an average of 156 visits to the emergency room for suspected overdoses per week.

So, critical that we provide support for inpatient/outpatient treatment, recovery support services, peer support, targeted case management. I just reintroduced the Access to Substance Abuse Treatment Act, which would provide $1,000,000,000 a year to support community clinics, expand access to treatment for individuals with a history of substance abuse.

Congress also made a substantial investment to address the opioid crisis. The 2018 omnibus boosted spending on opioid-related activities by more than $3,000,000,000, and that includes increases for the NIH for research, state grants for prevention, treatment, prescription drug monitoring, and the training of a healthcare workforce. For example, we provided a $105,000,000 increase for the National Health Service Corps, which will help expand substance abuse treatment.

We are very serious about helping those who are suffering from this terrible crisis, but I really do want to ask the question about the administration and their seriousness with regard to this effort. We have allocated billions of dollars. There are a number of agencies working on all of this, and we are all standing at the front of the line to do this. We want to solve this problem.

How is the administration coordinating it all? Who is focusing full time on this to take a look at what are the services being that we are engaged in, and where are we not providing enough resources? Is there duplication here?

And my understanding is that the White House has put Kellyanne Conway in charge of the national opioid response effort. And you know, a good person. She is a pollster. I have an affinity for people who are in that business. My husband is a pollster. [Laughter.]

Ms. DELAURO. But her primary experience is public relations, as far as I understand it. You know, it is about the credentialing for someone who is dealing with what is labeled a public health emergency and a healthcare crisis. So I ask the question of why don't we have a health expert in charge of what is a monumental effort here?

So, and when I look at the 2019 budget request from the administration, I am looking at, you know, a request that would eviscerate many of the programs that you need to be able to combat the crisis.

I would also note that rural communities, many of those suffering from opioid addiction, would have been covered under the Affordable Care's expansion of Medicaid. There are a number of Republican-led States who have chosen not to expand Medicaid. They declined. They forced rural Americans to go to the very community health centers and getting the services from the healthcare programs that are now being looked at in terms of being unraveled.

So it is kind of a one-two punch. You know, you are hurting people while they are down, and you know, I find that not defensible. So the President's budget would cut funding for HRSA's health workforce programs by nearly—by two-thirds, $1,000,000,000 in total. In addition, the President's budget would cut funding for rural health programs by more than $200,000,000, 75 percent cut.

You eliminate funding for 17 health programs. Your two offices—scholarships for disadvantaged students, primary care training, advanced education nursing, nursing working diversity, and you know the list as well as I do.

One of the other things, and the chairman has heard me say this yesterday, I am really stunned about this notion that we are going to backtrack on the budget agreement that we all agreed to on a bipartisan basis. And according to the press, the President is negotiating with our House Republican leader Kevin McCarthy on a plan to rescind tens of billions of dollars from the recently enacted bipartisan omnibus.

I said yesterday at the hearing if there is this proposal to rescind, so many of the investments that were made in that agreement, it would eliminate those investments. It would abandon our communities, rural and urban. And I believe you will have bipartisan opposition to move against those investments for our communities. We need to build on, not cut down to help communities get the healthcare and the treatment that they need.

So I am hoping to hear from all of you about the efforts. You know, millions of Americans need better access to healthcare services. They can't wait. Their kids can't wait. Our communities can't wait. So we need to be at it, and I know that is what your goal and that is what your mission is.

So I thank you for being here. Looking forward to your testimony and also to our discussion.

Many thanks.

Mr. COLE. Before we turn to our witnesses, just for the record, I remind my friend that I, too, was a pollster before I was in Congress. So we are capable of extraordinary things. [Laughter.]

Ms. DELAURO. Oh, my God. All right. Hear, hear.

Mr. COLE. But with that, I do want to give our witnesses an opportunity to make whatever opening statements they care to for the record. So if we could, Mr. Morris, we will start with you, and then, Dr. Padilla, we will go to you.

OPENING STATEMENT OF MR. MORRIS

Mr. MORRIS. Chairman Cole and Ranking Member DeLauro and members of the subcommittee, thank you for the opportunity to testify today on behalf of the Health Resources and Services Administration and the Federal Office of Rural Health Policy.

We are pleased to discuss with you our investments to support the rural health infrastructure, our response to the opioid epidemic, and the work we have underway to address workforce challenges. I also want to thank you for the recently passed Consolidated Appropriations Act of 2018 and the resources it provides.

HRSA is the primary Federal agency charged with improving access to healthcare for vulnerable populations. My office serves as the focal point for rural health within the Department of Health and Human Services. We are charged in Section 711 of the Social Security Act with advising the HHS Secretary on the effects of policies and programs on rural communities. And in addition to that, we also administer a range of grant programs that support rural communities and capacity building.

Rural hospitals play a critical role in ensuring access to care, and they are often the locus for healthcare services in a rural community, along with community health centers and rural health clinics and a host of other providers. Also, telehealth plays an increasingly important role in ensuring access to care for more specialized services that might not be available locally. HRSA plays a lead role within HHS for leveraging this technology on behalf of rural and underserved communities.

Now while rural hospitals are an important part of the rural healthcare infrastructure, they face some challenges. We have seen since 2010 more than 80 rural hospitals have either closed or ceased operations, and this is an issue we are tracking closely. And we are working to target our grants and our resources to help those communities that are either at risk of losing their hospital or those communities where perhaps the hospital has been lost and what they can do to ensure access to services after that.

Through our Rural Health Research Center Grant Program, we are trying to better understand the driving factors behind these closures, and they are mixed. There is a very challenging payer mix, heavily dependent on Medicare and Medicaid. We know that there is declining population in some rural communities, and we also have declining inpatient admissions, which makes it very hard sometimes to keep the doors open.

So we continue to work with rural communities and leverage our existing grant programs—the Rural Hospital Flexibility Program, the Rural Health Outreach Program, the Telehealth Network Grant Program—all of which provide resources for rural communities to enhance access to care, to improve quality, and to address some of the financial factors they are facing.

You mentioned opioids, and rural communities continue to face significant challenges in this area in addressing the epidemic. Research from the Centers for Disease Control and Prevention show that while the drug use rate is lower in rural areas than urban areas, from 2006 to 2015, the rural overdose death rate has been higher than in urban areas. The fiscal year 2018 appropriation for

our office includes $100,000,000 for the Rural Community Opioid Response Initiative, and this directs HRSA to award grants to high-risk rural communities, and we are hard at work on this effort.

It includes a focus on the 220 vulnerable counties that were identified by research by the CDC that were particularly at risk for epidemics related to drug use, linking to HIV and also hepatitis C. As part of our initiative with the Rural Community Opioid Response, the National Health Service Corps has been allocated up to $30,000,000 to support loan repayment for clinicians in these areas. We plan to leverage all the HRSA programs to try to bring to bear all of our expertise in addressing the opioid crisis in rural communities as part of this effort.

In terms of the workforce, rural areas have long faced challenges in terms of training, recruiting, and retaining healthcare professionals in rural communities. This is not a new issue, but there are HRSA programs and resources that can be brought to bear there, and my colleague, Dr. Padilla, will talk more about some of those and go into greater detail.

What I can tell you is that we know that training more folks from rural areas, training clinicians in rural areas can lead them to staying in rural communities, and so we are pleased to see the money that was allocated for the Rural Residency Training Grant Program. We have had some work in the past working with rural training tracks. We know that if you are a physician and you do your residency in a rural training track, you are twice as likely to then practice in a rural community, compared to somebody in a regular urban-based family medicine training program.

So with the funds that were appropriated to us for the $15,000,000 for the rural residency planning, we will be able to create new residency programs in rural communities, link them to graduate medical education support through Medicare and Medicaid and through general revenues at the State level, and perhaps even private funding. And then each year, those residencies will be able to train a new cohort of physicians that are more likely to practice in rural areas.

So thank you for the opportunity to discuss rural health issues with you and your support of HRSA and the Federal Office of Rural Health Policy, and I look forward to answering any questions you might have.

[The information follows:]

Statement by

Thomas Morris

Associate Administrator, Federal Office of Rural Health Policy

Health Resources and Services Administration
U.S. Department of Health and Human Services

Before the
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
U.S. House of Representatives

Washington, D.C.
April 12, 2018

Chairman Cole, Ranking Member DeLauro, and members of the subcommittee, thank you for the opportunity to testify today on behalf of the Health Resources and Services Administration (HRSA) and the Federal Office of Rural Health Policy (FORHP). I am pleased to discuss with you our investments in rural health and initiatives to support infrastructure in rural communities, our response on the opioid epidemic, and our plans to grow the rural workforce.

To begin, I want to thank members of this Subcommittee and your colleagues in the House of Representatives and the Senate for the bipartisan, bicameral efforts in passing the Consolidated Appropriations Act, 2018 and the Bipartisan Budget Act. The funding and initiatives included as part of those Acts will provide rural communities valuable resources and support in their efforts to improve access to health care for rural individuals.

HRSA is the primary Federal agency charged with improving access to health care services for people who are medically underserved because of their economic circumstances, geographic isolation, or serious chronic disease. FORHP serves as a focal point for rural health activities within the Department of Health and Human Services (HHS). Section 711 of the Social Security Act charges the Director of the Office of Rural Health Policy with advising the Secretary of HHS on the effects of current policies and regulations on rural communities. FORHP ensures that there is a continual focus on improving access to care, ranging from the recruitment and retention of health care professionals to maintaining the economic viability of hospitals and rural health clinics to supporting telehealth and other innovative practices in rural communities.

Support for Rural Hospitals and Rural Health Infrastructure

Rural hospitals play a critical role in the rural health infrastructure, serving as a locus for health care in small communities. They can play a key role in helping to attract and retain health care providers and ensure access to emergency and inpatient medical services. The rural health care delivery system also includes community health centers and Rural Health Clinics, who play a key role in ensuring access to primary care. Over 40 percent of the community health centers nationally are either located in or serve rural populations, and may be the only source of care for behavioral health, substance abuse treatment and oral health.

Telehealth plays an increasingly important role in ensuring access to care for more specialized services that may not be available locally. HRSA plays a lead role in supporting telehealth through a number of its grant programs. The Telehealth Network Grant programs supports the use of telehealth that links specialists with patients in rural and underserved areas. HRSA also administers a national network of Telehealth Resource Centers to help communities that want to start new telehealth projects or expand existing efforts to other clinical areas. HRSA also funds two Telehealth Centers for Excellence to test out new approaches for how to best leverage this technology to not only expand access but enhance health care outcomes. The agency also is working to address policy barriers such as cross-state licensure for telehealth clinicians who often practice across state lines. HRSA's licensure and portability program is working with physician and psychology boards to look at ways to reduce the burden for telehealth clinicians who have to apply for licensure in multiple states.

While rural hospitals are an essential part of the rural health infrastructure, they continue to face ongoing challenges. There are efforts across HHS to enhance rural hospitals' financial viability and rural residents' access to hospital services. Section 711 of the Social Security Act also charges the Director of the Office of Rural Health Policy with advising the Secretary on the effects of proposed changes in the programs related to the financial viability of small rural hospitals, and the ability of rural communities to attract and retain physicians and other health professionals.

HRSA meets this charge by monitoring the environment for rural hospitals through the Rural Health Research Center grant program, which focuses a significant part of its efforts on assessing hospital finance, quality and access to care. This research has shown that there are a number of financial driving factors affecting rural hospital viability. These facilities tend to have low patient volume, paired with high fixed costs. Rural hospitals, like all hospitals, are also seeing declining inpatient admissions, compounded by declining rural populations in many rural communities that can make it challenging for a rural hospital to remain financially viable. These facilities also have a payer mix that is heavily dependent on public payers like Medicare and Medicaid with a smaller share of privately insured patients relative to urban hospitals. Our research shows that rural hospitals often have lower operating margins, less cash on hand and limited ability to invest in capital infrastructure. There is also ongoing market consolidation with rural hospitals becoming part of larger regional systems, some of which may seek to centralize some services. All of these factors have created a challenging environment for rural hospitals and the communities they serve.

In addition to the financial factors facing rural hospitals, it is important to consider the populations that these facilities are serving. Many rural communities have higher rates of chronic disease, higher rates of poverty, higher rates of patients who are dually eligible for Medicare and Medicaid, lower life expectancy, higher mortality rates, and higher rates of avoidable excess death.[1,2,3,4]

While the challenges facing rural hospitals are complicated, there are a number of efforts aimed at supporting rural hospitals. Over the past 25 years, Congress has created a number of special payment classifications and adjustments to assist rural hospitals. This includes payment designations such as Critical Access Hospital (CAH; N: 1,343), Sole Community Hospital (N: 337 with 299 located in rural), Medicare Dependent Hospital (N: 154) and Rural Referral Center (N: 187), which all can play a key role in ensuring financial viability. Congress has also created the Medicare Disproportionate Share Hospital and low-volume hospital adjustments that are also critically important to many rural hospitals. A significant number of CAHs and other rural hospitals also benefit from participating in the 340B Drug Pricing Program.

---

[1] Meit, M., Knudson, A., Gilbert, T., Tzy-Chyi Yu, A., Tanenbaum, E., Ormson, E., Ten Broeck, S., Bayne, A., Popat, S. National Opinion Research Center. "The 2014 Update of the Rural Urban Chartbook." October, 2014. https://ruralhealth.und.edu/projects/health-reform-policy-research-center/pdf/2014-rural-urban-chartbook-update.pdf

[2] Freeman et al. "The 21st Century Rural Hospital: A Chart Book." North Carolina Rural Health Research Center. March 2015. http://www.shepscenter.unc.edu/wp-content/uploads/2015/02/21stCenturyRuralHospitalsChartBook.pdf

[3] "Health Care Spending and the Medicare Program: A Data Book." Medicare Payment Advisory Commission. June 2017. http://www.medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf

[4] CDC Data Visualization Website (https://www.cdc.gov/nchs/data-visualization/potentially-excess-deaths/)

While these protections are critically important to ensure access to care for essential services in rural communities, challenges remain. More than 80 rural hospitals have either closed or ceased offering inpatient services since 2010, though the pace of these closures has slowed in the past year. Our research shows that many more rural hospitals are at varying degrees of financial distress.

Across HRSA and HHS, we are seeking ways to use existing programs and authorities to address the needs of rural hospitals. We are collaborating with the Centers for Medicare and Medicaid Services' Innovation Center (CMMI) in its administration of several rural demonstrations projects. This includes the Rural Community Hospital Demonstration, the Frontier Community Health Integration Project and the Pennsylvania Rural Health Model. CMMI has also seen strong rural participation in broader demonstrations such as the Accountable Care Organization Investment Model and the State Innovation Models. Lessons learned from all of these demonstrations can inform future policy developments for enhancing access to care in rural communities.

HRSA supports rural and Critical Access Hospitals (CAHs) through a number of grant programs. In FY 2017, under the Medicare Rural Hospital Flexibility Grant (Flex) Program, HRSA invested $24 million in state Flex programs to work with CAHs to improve quality, financial performance, and integration of emergency medical services. HRSA's Medicare Beneficiary Quality Improvement Program encourages voluntary reporting and support for CAH quality improvement activities. From 2009 to 2016, the percentage of CAHs reporting Hospital Consumer Assessment of Healthcare Providers and Systems surveys increased from 35.4 percent

to 81.2 percent.[5] This is significant because unlike other hospitals, CAHs are not required to submit quality measure data to Medicare. We are also seeing improved quality scores and enhanced financial performance for CAHs that take part in Flex program activities.[6,7]

The Small Hospital program provides $15 million a year to assist rural hospitals with fewer than 50 beds to prepare for value-based purchasing, participation in Accountable Care Organizations or other shared savings programs. These funds can also assist small rural hospitals on billing issues such as compliance with ICD-10 standards.

We also know that rural communities and their hospitals in some areas such as the Mississippi Delta region face unique challenges that call for a more targeted approach. We are using funding provided by Congress in FY 2017 and FY 2018 to provide hospitals and communities in the Delta region with more targeted technical assistance to improve health care delivery.

In FY 2016 and FY 2017, HRSA awarded a total of 11 Rural Health Network Development Planning grants to communities that were addressing hospital closures or mitigating the loss of services due to hospitals facing financial distress. Rural communities frequently lack the resources and infrastructure to evaluate community needs and develop local and regional plans for access to care after a hospital closure. This funding can help these communities strategically

[5] Lahr et al. "Patients' Experiences in CAHs: HCAHPS Results, 2016." Flex Monitoring Team. December 2017. http://www.flexmonitoring.org/wp-content/uploads/2017/12/DSR24.pdf
[6] Swenson, T., Casey M. "MBQIP Quality Measure Trends, 2011-2016." Flex Monitoring Team. November 2016. http://www.flexmonitoring.org/wp-content/uploads/2016/12/DSR20.pdf
[7] Whitaker et al. "Impact of Financial and Operational Interventions Funded by the Flex Program." Flex Monitoring Team. November 2015. http://www.flexmonitoring.org/wp-content/uploads/2015/11/PB41.pdf

plan for the continued provision of care.

The Rural Opioids Communities Initiative

Rural communities continue to face significant challenges in responding to the opioid epidemic. According to the Centers for Disease Control and Prevention (CDC), while the rate of drug use is lower in rural areas than in urban areas, the fatal overdose rate in rural areas continues to rise. From 2006 to 2015, the most recent year included in the review, the rural overdose death rate has been higher than the urban rate.[8] In FY 2016, five out of the top 10 states with the highest overdose mortality rates were majority rural states (WV, NH, OH, ME and KY). Rural communities also face challenges in recruiting and retaining providers with the necessary training and education to treat individuals with opioid use disorder. More than half of rural counties nationally (60.1 percent) still lack a physician with a Drug Enforcement Agency waiver to prescribe buprenorphine.[9]

The FY 2018 appropriation includes $100 million for a new Rural Communities Opioid Response program, directing HRSA to support treatment for and prevention of substance use disorders, with a focus on the 220 vulnerable counties identified by the CDC, which ranked each county's vulnerability to an outbreak of HIV and Hepatitis-C. That analysis took a number of

[8] Preventing Opioid Overdoses among Rural Americans. Centers for Disease Control. March 2018. https://www.cdc.gov/ruralhealth/drug-overdose/pdf/Policy-Brief_Opioiod-Overdoses-H.pdf

[9] Holly et al. "Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder." WWAMI Rural Health Research Center. August 2017. http://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC5505456&blobtype=pdf

factors into consideration, including drug overdose deaths, opioid sales, unemployment, and per capita income.[10] We will leverage all of our HRSA partners in this effort.

The program will focus on the areas of prevention, treatment, and recovery of substance-use disorders, including the opportunity to improve access to and increase the recruitment of new substance-use disorder providers. HRSA also hopes to build sustainable treatment resources, increase use of telehealth, and build strong community partnerships. Communities will also be strongly encouraged to learn about and to leverage and coordinate with other local, state and federal opioid resources such as the funds provided through the 21st Century Cures Act (P.L. 114-146).

Rural Workforce and Rural Physician Residency Programs

Maintaining the healthcare workforce is fundamental to providing healthcare quality and access in rural areas. Rural areas have historically faced challenges attracting and retaining physicians and other providers. Data from HRSA's Area Health Resource File shows that while urban areas have 7.9 physicians per 10,000 residents, that ratio drops to 5.4 in rural areas. [11] HRSA data also shows that 59 percent of the Primary Care Health Professional Shortage Areas are in rural

[10] Van Handel, M., Rose, C., Hallisey, E., Kolling, J. Zibbell, J., Lewis, B., Bohm, M., Jones, C., Flanagan, B., Siddiqi, A., Iqbal, K., Dent, A., Mermin, J., McCray, E., Ward, J., Brooks, J. The Journal of Acquired Immune Deficiency Syndrome. "County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections among Persons who Inject Drugs, United States. Nov. 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/

[11] US Department of Health and Human Services, Health Resources and Services Administration. Area Health Resource File. HRSA Data Ware House. 2018. The AHRF data includes county, state, and national-level files in eight broad areas: Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions Training, Hospital Utilization, Hospital Expenditures, and Environment. https://datawarehouse.hrsa.gov/topics/ahrf.aspx

areas.[12] Additionally, while physician residency training has been heavily urban, there are new models such as Rural Training Tracks (RTTs) and the Teaching Health Centers, of which 21 percent are rural areas, that have emerged that focus on community-based residency training in rural areas.

In FY 2016, HRSA completed a small pilot program to provide technical assistance to communities interested in creating RTTs. This model allows a medical resident to spend one-year in an urban location and then two years in a rural community. A University of Washington study funded by HRSA shows that residents in these programs are twice as likely to practice in rural communities.[13] Through the RTT pilot program, the number of rural training tracks increased from 23 to 41 over the course of program. Through that work, we also learned about the challenges of creating rural residencies. For example, working through the accreditation process requires a high degree of time and effort that can be a challenge for small rural hospitals and organizations.

The Consolidated Appropriations Act, 2018 provides a way to build on our past efforts at supporting rural residency training by providing $15 million for a new Rural Residency Program

[12] US Department of Health and Human Services, Health Resources Services Administration, *Designated Health Professional Shortage Areas Statistics*, HRSA Data Ware House. 2018. Available at *https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false*

[13] Patterson DG, Schmitz D, Longenecker R, Andrilla CHA. "Family medicine Rural Training Track residencies: 2008-2015 graduate outcomes." Seattle, WA: WWAMI Rural Health Research Center, University of Washington. Feb 2016. http://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2016/02/RTT_Grad_Outcomes_PB_2016.pdf

to expand the number of rural residency training programs. The program will focus on developing programs that are sustainable beyond the Federal grant funding.

Conclusion

Thank you again for the opportunity to discuss these rural health issues with you today and for your support of HRSA's work through the Federal Office of Rural Health Policy to improve access in rural communities across the country. I would be pleased to answer any questions you may have.

Mr. COLE. Thank you very much.

Dr. Padilla, we would love to have your opening statement now.

OPENING STATEMENT OF DR. PADILLA

Dr. PADILLA. Thank you for the opportunity to testify today here on behalf of the Health Resources and Services Administration, HRSA, and the Bureau of Health Workforce on the topic of health workforce programs and rural healthcare delivery. I, too, would like to thank you for the recently passed Consolidated Appropriations Act of 2018.

Ensuring access to care in rural and underserved areas is a key goal for HRSA. HRSA's Bureau of Health Workforce works to improve the health of underserved and rural populations by strengthening the health workforce and connecting skilled professionals to communities in need.

In fact, in the last academic year, HRSA's health professions programs trained over 525,000 future and current healthcare providers across a wide array of fields. Not only are HRSA's health workforce programs training a broad range of clinicians, the majority of those trained are from rural or disadvantaged backgrounds, which is strongly associated with an individual's choice to practice in underserved areas.

HRSA helps to improve access to quality healthcare in rural communities through a variety of programs, and I think you have mentioned a few, including loan repayment and scholarship programs, graduate medical education, and health workforce training programs that aim to strengthen and expand primary care and behavioral health training.

The National Health Service Corps, which is a key HRSA program, supports loan repayment and scholarships for primary care providers, with around one-third of the participants serving in rural areas. In exchange for practicing in underserved communities, clinicians receive an incentive of repayment of educational loans, and students may receive scholarship and financial support while in school. I am a recipient of one of those as a National Health Service Corp scholar, former scholar.

The National Health Service Corps offers—the Nurse Corps Program offers nurse loan repayment and nurse student book scholarship in exchange for service commitment in communities with inadequate access to care. Last year, there were over 1,900 nurses and nurse faculty serving at facilities experiencing a critical shortage of nurses, and 18 percent of those were serving in rural areas.

In fiscal year 2018, as you mentioned, HRSA received $105,000,000 for the National Health Service Corps to expand and improve access to quality opioid and substance use disorder treatment in rural and underserved areas nationwide. HRSA also supports graduate medical education, training through the Teaching Health Center Graduate Medical Education Program, and the Children's Hospital Graduate Medical Education Program.

The THCGME program increases the number of primary care providers in rural and underserved communities by taking the resident training out of traditional academic settings and putting it in community-based settings where they are likely to go back and practice. HRSA's health workforce training programs also aim to

strengthen and expand primary care and behavioral health training, as well as to remove barriers for students from disadvantaged backgrounds who would wish to enter in the health professions.

And you mentioned our Scholarships for Disadvantaged Student Program, which provides funding for health professional and nursing schools to award scholarships to students from disadvantaged backgrounds. Our area health education centers support interdisciplinary education and training, with 53 percent of those clinical training sites in medically underserved communities and 50 percent in rural areas.

Our Primary Care Training and Enhancement Program also supports training for future healthcare professionals, including training in rural and underserved communities for physician and physician assistant trainees. Our Behavioral Health Workforce Education and Training Program supports a wide array of behavioral health providers, with a goal of expanding access to treatment and services, particularly in the rural and medically underserved areas.

In our most recent academic year, BHWET supported training for over 3,800 individuals who provided over 1 million hours of behavioral health service to individuals across the country. In fiscal year 2018, HRSA received, and you mentioned, an additional $25,000,000 for this program to expand behavioral health workforce to address the prevention and treatment of substance abuse disorders, which will allow us to expand the BHWET activities into additional rural and underserved areas across the country.

Collectively, HRSA's workforce programs emphasize the education and training of the next generation of primary care providers with a focus on training providers in community-based settings where individuals typically receive their care. HRSA's programs strengthen the primary care training infrastructure, provide incentives for students to choose primary care, and support the recruitment of providers to communities with the greatest need.

Thank you again for the opportunity to highlight some of HRSA's programs, and I look forward to answering all your questions.

[The information follows:]

Statement by

Dr. Luis Padilla

Associate Administrator, Bureau of Health Workforce

Health Resources and Services Administration

U.S. Department of Health and Human Services

Before the
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
U.S. House of Representatives

Washington, D.C.
April 12, 2018

Chairman Cole, Ranking Member DeLauro, and members of the subcommittee, thank you for the opportunity to testify today on behalf of the Health Resources and Services Administration (HRSA) and the Bureau of Health Workforce on the topics of health workforce programs and rural health care delivery.

Echoing the sentiments of my colleague, Tom Morris, I want to thank members of this Committee and your colleagues the House of Representatives and the Senate for the bipartisan, bicameral efforts you undertook in passing the Consolidated Appropriations Act, 2018, and the Bipartisan Budget Act of 2018.

Today, I would like to give you an overview of a few of HRSA's health workforce training programs and their impact on rural and underserved communities.

Ensuring access to care in rural and underserved areas is a key goal for HRSA. As of September 2017, more than 72 million people live in primary care health professional shortage areas (also known as HPSAs), more than 54 million people live in dental HPSAs, and more than 111 million people live in mental health HPSAs, and many of these individuals live in areas identified as having all three types of shortages. HRSA's Bureau of Health Workforce works to improve the health of underserved and rural populations by strengthening the health workforce and connecting skilled professionals to communities in need. In fact, in the last academic year, HRSA's health professions programs trained over 525,000 current and future health care providers across a wide array of fields including medicine, nursing, behavioral health, dentistry, and public health. Not only are HRSA's health workforce programs training a broad range of

clinicians, 70 percent of those trained are from a rural or disadvantaged background, which is strongly associated with an individual's choice to go on to practice in an underserved area upon completion of training.

The National Health Service Corps and NURSE Corps are two critical programs offering workforce solutions to primary health care challenges in rural and underserved communities. In exchange for practicing in underserved communities, clinicians working at eligible health care sites may receive an additional incentive of repayment of educational loans and students may receive scholarships and financial support while in school. Through this partnership with communities, HRSA's loan repayment and scholarship programs improve access to care by increasing the number of providers in the communities with the greatest needs across the Nation.

To that end, the National Health Service Corps recruits and helps retain primary care, dental, and mental health clinicians to provide primary health services in HPSAs across the Nation. As of September 2017, the National Health Service Corps had over 10,200 clinicians providing care to over 10.7 million patients nationwide with at least one National Health Service Corps clinician in every state and territory. These clinicians have a lasting impact on their communities in that 93 percent continue to serve beyond their services commitment. Of those currently serving, more than 34 percent are in rural areas.

Similarly, the NURSE Corps offers nurses and nursing students loan repayment and scholarships in exchange for a service commitment in communities with inadequate access to care. Last year, there were over 1,900 nurses and nurse faculty serving at a facility experiencing a critical

shortage of nurses—18 percent of whom were serving in rural areas.

In FY 2018, HRSA received $105 million for the National Health Service Corps to expand and improve access to quality opioid and substance use disorder treatment in rural and underserved areas nationwide.

In addition to loan repayment and scholarship programs, HRSA supports graduate medical education, including the Teaching Health Center Graduate Medical Education Program, which increases the number of providers in rural and underserved communities by taking resident training out of the traditional academic medical center setting and locating it in community-based clinics such as community health centers. Currently the program supports the training of 732 residents in 57 primary care residency programs, 21 percent of which are located in rural communities. The Bipartisan Budget Act of 2018 included $126.5 million for the Teaching Health Center Graduate Medical Education Program in FY 2018 and FY 2019. HRSA recently made awards to the existing Teaching Health Center recipients to support a per resident amount of $150,000 for Academic Year 2017-2018.

In FY 2018, HRSA also received funding to support the Children's Hospitals Graduate Medical Education Payment Program. These 58 Children's Hospital Graduate Medical Education funded hospitals train 48 percent of all general pediatrics residents and 53 percent of all pediatric subspecialty residents and fellows annually in the United States. The FY 2019 Budget proposes to consolidate and reform Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospitals Graduate Medical Education program into a new single

grant program. As part of this proposal, children's hospitals would eligible for mandatory funding from this new program.

HRSA also administers health workforce training programs that aim to strengthen and expand primary care and behavioral health training, as well as to provide opportunities for students from disadvantaged backgrounds to enter the health professions. As an example, the Scholarships for Disadvantaged Students Program provides funding for health professional and nursing schools to award scholarships to students from disadvantaged backgrounds pursuing degrees, reducing the financial barrier to education. In the most recent academic year, the Scholarship for Disadvantaged Students Program provided scholarships to more than 2,800 students, nearly 22 percent of whom reported coming from rural backgrounds. Located in almost every state, Area Health Education Centers (AHECs) support interdisciplinary education and training, with 63 percent of clinical training sites in medically-underserved communities and 42 percent in rural areas. In the most recent academic year, 43 percent of AHEC students reported having a rural background. HRSA's Primary Care Training and Enhancement program also supports training for future health care professionals, including training in rural and underserved communities for physician and physician assistant trainees.

HRSA invests in training in behavioral health and substance use disorder services through the Behavioral Health Workforce Education and Training Program (or BHWET), which supports a wide array of behavioral health providers with the goal of expanding access to treatment and services, particularly in rural and medically underserved communities. In the most recent academic year, the BHWET Program supported training for more than 3,800 individuals who

provided over 1 million hours of behavioral health services to individuals. In FY 2018, HRSA received an increase of $25 million to expand training for the behavioral health workforce to address the prevention and treatment of substance use disorders, which will allow us to expand the BHWET Program into additional rural and underserved communities nationwide.

Conclusion

Collectively, HRSA's workforce programs emphasize the education and training of the next generation of primary care providers with a focus on training providers in community-based settings where most people receive their health care. These programs are able to train providers ready to respond to current needs, such as the opioid crisis. HRSA programs strengthen the primary care training infrastructure, provide incentives for students to choose primary care, and support the recruitment of providers to communities with the greatest needs. HRSA will continue to make the recruitment, training, and retention of primary care professionals a priority to meet the health needs of Americans.

Thank you again for providing me the opportunity to share HRSA's primary care workforce priorities with you today. I am pleased to respond to your questions.

PROVIDERS IN RURAL COMMUNITIES

Mr. COLE. Thank you again for being here and, frankly, thank both of you for what you do.

I have a district that is largely rural, and so these problems that you each offered testimony on are very real. I see them over and over, and I spend quite a bit of time on Native American communities across the country, and I don't know of a more underserved area than some of our reservation population.

So with that in mind—I am going to start with you, if I may, Dr. Padilla—could you tell us what provider specialties are most needed in rural communities?

Dr. PADILLA. Thank you, Chairman.

I think that is a very important question. I would like to step back and highlight some of HRSA's most recent projection reports.

We estimate that by 2025, we are going to have an undersupply, and I think in your opening remarks, you mentioned an undersupply of 100,000 physicians. When you break that out by discipline, we are projecting that by 2025, we are going to have over 23,000 shortage of primary care providers. So that is a critical need for rural areas that desperately need access to quality primary care.

On the behavioral health front, our recent projection report estimates that we are going to have a wide array of disciplines, including behavioral health, mental/behavioral health specialists, substance abuse counselors, and others that are facing shortfalls throughout the country. In excess—in some of those disciplines, in excess of 10,000 FTEs nationwide.

In terms of oral health, which is also another critical need in rural communities, recent evidence shows that oral health is strongly linked to life span. And what we are seeing in rural populations, influencing life span as well. What we see in terms of projections is an undersupply of dental and dental hygienists across the country, in excess of 15,000 FTEs nationwide.

I think I would highlight those three as very pressing needs in rural communities across the country.

RURAL RESIDENCY PROGRAMS

Mr. COLE. I certainly know that is true. Our colleague, Dr. Simpson, who normally would be here but is out for medical reasons this week, is a practicing dentist. Every place we go on a reservation, he gets a job offer. You know, please come back here and go to work when you are done in Congress. So I have seen it firsthand.

Obviously, a practicing physician in these remote areas is a challenging situation. I mean, clinicians can often feel isolated, overwhelmed, unequipped to handle the unique aspects of rural medicine. What are we doing to encourage—and we know you have got a lot of programs. But what are we actually doing to encourage medical schools in the respective States to include rural rotation, to establish rural residency programs? In other words, to get some help at the State level so they are encouraging their medical professionals as they are training them to perhaps consider locating in some of these areas?

Dr. PADILLA. Certainly, I think HRSA has a number of activities underway, but I would also like to highlight what I think has been mentioned before, which is starting with rural communities and what is needed there. And then building from that in terms of the practice and what is available there, and then the academic support that those practices would require. And then, ultimately, the network and the environment. And I think those factors hamper our ability to drive health professionals in those areas.

So in terms of the community and what we are trying to do, we highlight—I would highlight our Primary Care Training and Enhancement Program, which 30 percent of those students that are supported in that program have an opportunity to train in rural areas. I think this is important because, as was mentioned earlier, evidence shows that the more that we can longitudinally expose students and trainees and residents in those areas, the more likely they are to practice there.

I would also highlight our Teaching Health Center GME Program, which I know in your State we do have one, and then one that is administered through the Choctaw Nation. It is critically important that we further those, build the capacity of those programs because we know and where we have the ability to track those individuals beyond their residency completion, within a 1,500 mile radius, they end up working there.

So further along the pipeline and continuum in health professions training, the more exposure they get, the more likely they are to practice there. And we see this as a result in our National Health Service Corps program, where over a third of our clinicians are practicing in the rural areas. And the majority of those stay several years beyond their obligation.

So those are some of the ongoing programs that we are administering that highlight the need and advance more health professionals going into those rural areas.

Mr. COLE. I appreciate your efforts in that regard and that very important, again, that quite often we can recruit from these populations themselves. They are just much more likely, obviously, to stay there longer than the discharge of financial obligation or fill a sense of social need.

Just in the spirit of trying to stay within my own time, let us move along. I won't try and cram a question in the last 20 seconds. So we will turn to my good friend, the gentlelady from Connecticut.

BEHAVIORAL HEALTH WORKFORCE EXPANSION

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

And just a couple points before I ask my question is I applaud the efforts that you are talking about with regard to nursing programs, but I also comment I am looking at where we have in all of these programs about a $166,000,000 cut to the nursing programs, Title VIII. The only program that has been funded is the Nursing Education Loan Repayment and Scholarships. All the others are gone. They are eliminated. And you also made reference to oral health training, eliminated.

So I hear you, but you know, we all do. But if these are priorities, they should be priorities, and that ought to be reflected in a budget document.

But let me move to something that you have been talking about is what happens in communities with—this is opioid addiction. I sat down last month with addiction experts, law enforcement officials, those recovering from substance abuse disorders at something called the Rushford Center in Middletown, Connecticut. It is a residential facility.

What impressed me there was these are folks who were talking about what is needed on the ground. That is what they talked to me about. Better care coordination. Expanded recovery support services like recovery coaches affiliated with hospitals, and there are not the resources available for all the hospitals to be able to do this.

Increased peer support. I met with a recovering addict who stated just how confusing and frustrating it is to connect with services for someone who is battling addiction. So I think this would be a great focus to look at our communities and see where the shortfalls are. Obviously, we have NIH doing research. We want to continue doing all of that.

But what are the services? How can they be centralized so that someone can call a 211 number and be able to access health because they are on the long path to recovery. Where do they get transportation facilities to get to that appointment to get methadone or whatever else they need? Because if they don't go, then we know what the result is.

We provided in the omnibus increased funding for Behavioral Health Workforce Education and Training Program, $25,000,000, total of $75,000,000. How do we expand behavioral health workforce across all levels, paraprofessionals, substance abuse workers, social service aides, peer paraprofessionals?

And these are, oftentimes, people who don't have a master's degree or a doctoral-level education. So talk to me about your efforts to expand this workforce and your willingness to be able to look on the ground and try to provide the wraparound services that are critical, in my view, to being able to succeed in the future.

Dr. PADILLA. I will begin by saying that I understand and certainly view the over a decade I spent in the community health center addressing these issues in an urban environment, certainly not in the rural area, many of my patients who were suffering from substance abuse and addiction and the pressing need to have care coordination, effective team models, recovery services, referral services is something I learned over that 12-year period.

In terms of what we are doing, and you have mentioned the additional funding we received through the Behavioral Health Workforce Education and Training Program, which does support professionals and paraprofessionals, including community health workers. And the last academic year, it was over 900 paraprofessionals that graduated. It is important for us to leverage that program.

And again, as I mentioned in my opening remarks, our focus is on community-based training as much as possible, wherever we have the ability to coordinate and establish relationships with communities in terms of where that care is being delivered, the academic institutions that are supporting the training of those students, and healthcare delivery. So I think that is critically important, and we are appreciative of the funding that was received

there, and that is what we intend to do is to focus that program on that care coordination.

ADDICTION RECOVERY COACHES

Ms. DELAURO. This notion of—not notion, this idea of recovery coaches attached to hospitals, what is your view of that?

Dr. PADILLA. I would have to get back to see—with you on whether or not the Behavioral Health Workforce Education and Training Program supports recovery coaches. Certainly, it might be in the realm of paraprofessionals, but we have heard from stakeholders that that is a critical need, where patients are often lost to recovery when they are referred to other services.

[The information follows:]

Yes, BHWET awardees could propose to support the training of recovery coaches as part of the program's paraprofessional track. HRSA's current BHWET paraprofessional grantees do provide this training to recovery coaches. HRSA received additional funding to expand the mental and behavioral health workforce development programs in the FY 2018 Omnibus Appropriations Act. HRSA is currently exploring options for developing mental and behavioral health paraprofessionals, including recovery coaches, in future funding opportunities.

Ms. DELAURO. And the other thing is putting someone in a police department, like we did with domestic violence referral efforts or rape crisis referral efforts. Somewhere in the same way that right in the PD, when they found someone, they can move them from, you know, Narcan to moving them through a process.

Thank you. Thank you very, very much.

Thank you, Mr. Chairman.

Mr. COLE. Thank you. We next go to my good friend who was actually supposed to sub for me this morning, and I took his moment of glory away, for which I apologize. But it is always good to have my good friend from Tennessee here.

Mr. FLEISCHMANN. Mr. Chairman, thank you for your comments. It is always great to be in your bullpen, sir. Thank you.

RURAL HOSPITAL PAYMENT MODELS

Mr. Morris, Dr. Padilla, thank you so much for being before us today.

I represent the wonderful people of the Third District of Tennessee, and we have some large cities there—Chattanooga, Oak Ridge, great places. But a large part of my district is rural, and many of my counties are rural. And wonderful people, wonderful histories, and you get back into the community, and it is wonderful to see some of the men and women in healthcare who decide to come back and serve these communities. So this is such an acute need, and I appreciate both of you all addressing that.

I have one question. Doctor—or rather, Mr. Morris, recent trends in healthcare have shifted from the traditional fee-for-service model to payments based on the quality of care received, also called value-based purchasing. There has been a shift toward bundled payments for common procedures.

Rural hospitals are excluded from these new payment models or unable to participate due to low patient volumes. How can rural hospitals still participate in payment innovation models and deliv-

ery systems reform, and what can we do through HRSA's programs to support rural hospital participation in new healthcare models?

Thank you.

Mr. MORRIS. Thank you for that question.

I think that the transition to value for all providers is a big adjustment, but I think particularly for rural providers, as you noted, because when rural healthcare is not simply a smaller version of urban healthcare. There are unique differences to it, and you mentioned one of them when you mentioned volume.

And so when you think about some of the models out there like payment bundles, they are definitely designed I think more with an urban focus in mind. But having said that, I think there are other things that are going on that are relevant to rural areas.

And for instance, a lot of the work that is underway around accountable care organizations and shared savings, we are seeing higher rural participation in that. In particular, there is an initiative from our colleagues at Centers for Medicare and Medicaid Services with the ACO investment model. And it was designed I think specifically with rural and low-volume providers in mind, and it provides some upfront capital to those providers so that they can build the infrastructure and then, hopefully, achieve the savings targets that save the Government money and then return some of those savings to them.

And we are seeing much higher rural participation in the ACO investment model. So that is one model that I think has worked very well.

The other thing we are trying to do is just make sure that I think at the heart of all this value transition is the need to be focused on quality and quality measurement, and your district may include a number of small hospitals known as critical access hospitals. And these hospitals are by statute not required to report any of their quality data, unlike other hospitals that are paid under the Prospective Payment System under Medicare.

We have taken our funding through the Rural Hospital Flexibility Grant Program and used it to help them voluntarily report that data and then use it for benchmarking because if you don't know anything about the quality of care you are giving, it harder then to think about where you sit in that value transition. And so we are seeing a much higher percentage of those Community Access Hospitals (CAHs) reporting, and then they are using that data to then benchmark and see where their areas of improvement are.

And in particular, we see that they do better on things like patient satisfaction. And maybe that is a reflection of the fact that care is so local and everybody knows each other, and you are caring for your neighbors, but they outpace urban facilities in that in terms of care. So with that program, but also with some of our outreach funding which goes to small rural communities to try out their ideas, we are seeing folks leverage those dollars to do things like improve discharge planning and make sure that when folks get released from the hospital, they have the right instructions, that there is a system in place to take care of them.

And that is important because if you get a readmission on some procedures, you can get dinged under Medicare. And so I think rural hospitals have found a way to use our grant funding to sort

of think through those transitions of care, which is where it is really important to focus on quality as folks get discharged from the hospital and you don't want them bouncing back and forth into the emergency room.

And so all of those—all the dollars we have that can support that, we are really pushing that to rural hospitals and rural communities as a way to leverage that for this value transition.

Mr. FLEISCHMANN. Thank you. And in my closing seconds, I would also like to share with my colleagues, of my 11 counties, we have had 2 rural hospitals either close or be in danger of closing or closing and reopening and the devastating effects on these communities of when they lose their hospital. First of all, that local hospital is a great source of employment, good-paying jobs and the like. But the ripple effect that they have, EMS having to take someone many, many miles to another healthcare facility.

So I would ask my colleagues to work with me to help strengthen rural hospitals all across America, and I thank you for your service.

Mr. Chairman, I yield back.

Mr. COLE. I thank the gentleman. We will next go to my good friend from Wisconsin, Mr. Pocan.

HEALTH PROFESSIONAL SHORTAGE AREAS

Mr. POCAN. Thank you, Mr. Chairman.

And thank you both for being here.

So I also have a lot of rural areas in my district. Even though Madison, Wisconsin is there, most of the rest of the district is rural. I live in a town of 839 people, no town center. It is a rural town. One of my counties, Lafayette County, is 1 of 2 counties out of 72 in the State that doesn't have a stop-and-go light, with a very large Amish population. So I think I have justified my credentials on the rural front with the district.

We have an issue around rural health workforce shortages. In our State, as you know, there is 18,000 health professional shortage areas in the country. My district has 27. My State has 131. And you know, that means a lot of folks may not have regular access to a health professional.

Our Wisconsin Rural Health Association has brought up something, I just wanted to present the idea to you and just get your feedback, if you could. Because the definition of a health professional shortage area, it takes in consideration if an older physician is there working half or three-quarters time, it doesn't necessarily meet the definition of a health professional shortage area, even though they are not fully—they are technically not really in full practice.

And they have raised the idea of a different threshold, for a population-to-providers definition, maybe a medium definition, something that allows a physician who is ready to retire can flag what they are trying to do so that we can start directing resources or improve recruitment before the fact that they fully leave. And I would just love to have your feedback on that idea or if you are looking at anything or how else we might be able to try to take that in consideration because it happens in a lot of these rural areas.

Dr. PADILLA. In terms of the HPSA designation and the methodology and the threshold, obviously, as you know, those designations

which are deemed to allocate appropriately Federal resources. The threshold and the designation is principally derived by the provider-to-population ratio, and we have heard that in some rural areas and frontier areas where there is a very small population that the thresholds that we have in place have been having some problems. And we are continuing to engage with your Primary Care Office (PCO) and in others to look at that issue. So I would like to take that back to our team and engage with the PCO in your State specifically on that issue.

RURAL BROADBAND ACCESS

Mr. POCAN. Great. No, I would appreciate it. Anything around that front, just as we do have a lot of issues. I think in my district, I have, oh, what is it, seven rural hospitals and five rural clinics out of all that land mass that I have.

Which brings me to my second—well, actually, my first favorite subject is rural broadband, and I am just, you know, wondering as we try to get more resources in the rural areas and we are able to get some money in the omnibus, which we are very appreciative of, but there is still a lot of facilities having difficulty. And I am just wondering if we are seeing this in some of these rural facilities trying to put in telehealth, what you are looking at on that front, if there is anything that we can do to help guide that that you are looking at that you could suggest?

Mr. MORRIS. Yes. Well, the broadband issue is critically important. As we make a push into broader use of electronic health records and telehealth, you need the proper bandwidth to be able to do all those. And while there are some areas where the broadband is affordable, accessible, and robust enough to do that, there are also gaps, as you have noted.

HHS does not have any direct funding to support the broadband, but there are other parts of the Federal Government that do. So we really try to push rural providers to look into the FCC's Rural Healthcare Program. They offer a universal service discount that can cut the rate for broadband, and some of that funding can also be used for deployment.

And then also we coordinate a lot with the U.S. Department of Agriculture and their broadband program. And the omnibus, I think, included some more funding for that. And so there was an Agriculture and Rural Prosperity Task Force that the administration put forth, and broadband was a key part of the findings of that group and how important it was not just for healthcare, but for the vitality of rural communities.

So a lot of what we are doing is dependent on that, and so it is a question of how can we best leverage those programs to make sure that we are targeting those areas that needed broadband capacity.

Mr. POCAN. Just to kind of bring it home a little bit now, and I will end this, Mr. Chairman, is where I live, I get one Mbps of speed. So I pay for a separate satellite. I was fortunate enough to get the half-price sale. I pay $300 a month for 80 measured GBs a month. I am supposed to get 40 GBs for that. An hour on Netflix is 2.5 GBs. So just to give you an idea.

So every month, I literally track where I am at, but for a lot of folks who might need the coverage or these areas where the clinics are, it can be prohibitively expensive because of how the providers charge for this in those rural areas. If you don't have lines coming in or other direct-to-site ways of doing this, it can get really, really expensive. So I just wanted to raise that.

Thank you very much, Mr. Chairman.

Mr. COLE. I thank the gentleman. Next we will go to my good friend, the gentleman from Michigan, Mr. Moolenaar.

RURAL OPIOID RESPONSE PROGRAM

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And I want to thank you both for being here today and your testimony.

And Mr. Morris, as you mentioned, the appropriation fiscal year 2018 included the $100,000,000 for a new Rural Communities Opioid Response Program aimed at the unique issues facing the rural community during the opioid crisis and that focus on 220 counties identified by the CDC as being the most at risk. Three of those counties are in my district—Ogemaw County, Clare, and Roscommon Counties.

As far as we know, there aren't posted guidelines on how to apply for the grants. When could we expect the details of how to apply, who can apply of these grants? When would that be available?

Mr. MORRIS. We are working on the guidance for the grants right now. It is our goal to get it out as soon as possible. I don't have a specific date for you, but we have got the hard edge of the end of the fiscal year. If I could, I will explain a little bit about how we are broadly seeking to structure the program.

So with the $100,000,000, we plan to do 75 planning grants by the end of this fiscal year, and the thought being and I think it was brought up earlier is this is not strictly a health issue. It is a human services issues. It is law enforcement, all these—all these different sectors have to come together to really address this challenge.

The planning grants will be designed to allow that to happen and to provide some resources to communities to think locally about how the opioid crisis plays out in their community. We want to let the community determine what the focus should look like and use the funding to sort of come up with a comprehensive plan.

In the next year, in Fiscal Year 2019, then we plan to do 50 implementation grants. The dollar levels are still being assessed, but they are going to be substantial. And the idea would be that you could then create a plan. You could focus on prevention. You could focus on treatment. Whatever is the significant need in that community, we want to hear from the communities in their application. It might look different in Michigan than it might look in New Hampshire. We also may do some additional planning grants in that year.

And at that point, in Fiscal Year 2019, we will also then have the National Health Service Corps loan repayment, and Dr. Padilla could probably talk a little about how that is going to play out. But the idea being that over the next 5 years, between the combination

of planning grants, implementation grants, and the loan repayment through the National Health Service Corps, we can build an infrastructure that will then be self-sustaining after the Federal funding ends, and that we can have treatment services that will then be there to serve those rural communities.

And we are really encouraging broad-based partnerships and in recognition of the fact that addressing this crisis really requires a range of community partners that cuts across our normal sectors.

Dr. PADILLA. Thank you, Tom.

As Tom stated, in Fiscal Year 2019, we are looking to partner, and we are very appreciative of that opportunity to partner with Tom and his team. So in Fiscal Year 2019, as that planning period ends and the organizations that Tom's office is going to fund begins to identify those clinicians that would be eligible for National Health Service Corps awards, we would begin to incentivize those clinicians to work in those 220 vulnerable counties.

In addition to that, as part of the $105,000,000 that we received, we would then be expanding that nationwide with the remaining resources that were allocated to us. But we anticipate expending that $30,000,000 and beginning that expenditure in fiscal year 2019, and then using the additional funds that we receive to broaden that and expand that to rural and underserved areas to face substance use disorder and opioid issues nationally.

Mr. MOOLENAAR. So if I went to each of these three counties and wanted to tell them, "Here is how you can start the process of preparing, there will be some guidelines eventually posted, but here is what you can do to begin the process of preparing for an application," what—who would you recommend that I meet with, and what steps would you encourage them to take to get the ball rolling?

Mr. MORRIS. We have a notice posted on our website right now with some general information about the grants. So folks, you know, instead of having to call all the time, they can at least see the general parts of it.

We anticipate, if our timeline goes the way we hope it does, that the application guidance would be out in spring, maybe May, June, around that time. And so I would ask—I would suggest they look at the website first, but we are happy to have them call us directly.

The other thing is we are looking for promoting this through a variety of ways. We have reached out to like National Association of Counties, National Governors Association, you know, any stakeholder group that we can find, State Offices of Rural Health. All of those folks, we want to make sure that they can help us promote these resources once the information is out there.

But we are happy to talk individually with those counties, and I would say that for all the members of the subcommittee. We want to make sure people are aware of this funding, how it is structured, and we want to give them, we are hoping to give them 60 days to apply so that they will be able to put together a strong application.

Mr. MOOLENAAR. Okay. Thank you.

Thank you, Mr. Chairman. Right on time.

Mr. COLE. You did. I am very impressed. We will now go to my good friend from Massachusetts, Ms. Clark.

Ms. CLARK. Thank you, Mr. Chairman.

And thank you to the witnesses for being here today and for the work that you do. I am not going to try and establish my rural district credentials, but——

[Laughter.]

SUBSTANCE USE DISORDER WORKFORCE

Ms. CLARK. But we do share something with many rural and certainly Native American communities, which is devastation by the opioid crisis. And one of the things that I have—has come to my attention, as we travel, we talk to families and clinicians and doctors in my—in my district is that there is a significant problem in both rural, suburban, and urban in accessing treatment. Only 1 out of 10 Americans with a substance abuse disorder receive any treatment at all, and we need to change that.

So I have teamed up with our good friend, Chairman Hal Rogers, and we have a bill looking at very specifically how we can encourage those sort of range of professionals who are—who need to be drawn into treatment and working in the substance use disorder field. And it goes from everybody from physicians, nurses, social workers, and specifically includes recovery coaches because we found them to be an integral part of the solution.

We are delighted. This is a student loan repayment up to $250,000 in student loans over 6 years is the maximum, that you can collect that if you work in the treatment area for 6 years. But we are delighted that under the omnibus, there was significant funds, $105,000,000, to the National Health Service Corps.

I wondered, first, what your plans are for that money and how you are going to be looking at that? And I am going to make a shameless plug that you look at our bill as well. Because I think the combination of the spectrum that are covered and the fact that we qualify counties or municipalities if they are in a mental health HPSA or over the national average of fatal overdoses.

And I think it captures not only districts like mine, but also the problem that Congressman Pocan was talking about. Sometimes the levels don't really match. And I think that is not in the omnibus plan for repayment, but I wondered if, in general, you can tell us how you are looking at this issue and see treatment in rural areas and the needs there?

Dr. PADILLA. Why don't I start because I think you have mentioned the National Health Service Corps, and I am aware of the bill that you and Representative Rogers have submitted. We will continue to work with the Department and with you on the technical assistance that we can provide on that bill. I know that our teams have provided technical assistance thus far.

In terms of our plans for the fiscal year 2018 appropriation for the National Service Corps, as I mentioned earlier, focusing on up to $30,000,000 in the 220 vulnerable counties. But the additional $75,000,000 is planned and intended to increase support and awards for clinicians across the country. In the omnibus bill, there was obviously guidance in terms of substance abuse counselors at the master's level, and that is an area where we are going to principally looking at.

And right now, just as stepping back in terms of the National Service Corps and where we are right now, we have over 3,500

mental/behavioral health clinicians currently in the field. And the majority of those are working in rural areas. Actually, almost 40 percent of those. So we do have a significant presence as it is right now with the National Service Corps in rural areas in mental/behavioral health providers.

With that additional funding, we are looking to further incentivize clinicians to work in rural areas, identifying those clinicians through our application process who have the eligibility credential training to provide effective services to those populations in the area of opioid and substance use disorder.

So we intend to use fully that additional funding that we have through the omnibus bill, and then looking in Fiscal Year 2019, plans toward incentivizing those clinicians who are DATA 2000 eligible to administer medication-assisted treatment (MAT). Of the 10,000 National Service Corps clinicians that we have, we estimate that 2 right now currently have a DATA 2000 waiver.

We think that far many of them are eligible for that waiver. We want to encourage those and incentivize those clinicians who currently don't have that waiver who are working—60 percent of those clinicians, those over 10,000 clinicians are working in community health centers. We want to incentivize those clinicians to get that DATA 2000 waiver.

Medical physicians are eligible for that. Nurse practitioners are eligible for that. Physician's assistants are eligible for that DATA 2000 waiver.

Mr. MORRIS. The only thing I would add is that the funds appropriated by Congress for the community health center expansion into medication-assisted treatment have offered that service in community health centers that was not available before that. The epidemic has sort of raised the ability of the community health centers to also, in addition to providing behavioral health, to also add specifically medication-assisted treatment. And roughly 40 percent of the community health centers are located in or serve rural populations. So that is an important part of it.

The other thing we are looking at and we are currently funding three pilot programs looking at can you use telehealth to provide substance abuse treatment? It has not been widely used or studied, but it may offer a possibility where a community can't get that provider, but maybe can link to them.

And then some of the things you mentioned around recovery coaches and I think peer support counselors were raised earlier. Those are all the sort of things that would be funded under the—if the community decided they want to do it, under the Rural Community Opioid Response. It is a noncategorical grant in the sense that we are going to let the communities determine what the approach should be, and if it is those providers, then they can do that. If it is about getting the waiver, they can do it. It really is going to be a community-driven process.

Ms. CLARK. Thank you. I am sorry to ruin the streak that everybody was on. [Laughter.]

Mr. COLE. No, I think that is why—as the chair said, we are going to be pretty generous with time this morning. So——

Ms. CLARK. Yes.

RURAL OPIOID RESPONSE PROGRAMS

Mr. COLE [continuing]. Always happy to extend it when we have got it, and we do today.

I want to go back to this Rural Community Opioid Response issue that you both touched on in different ways, and the ranking member and I had the good fortune this morning to actually have breakfast with the Secretary. And in the course of that, he mentioned the discussion, which I assume relates to this program, about picking out a community or two and literally throwing everything at it, so to speak, to see whether or not we could really move the needle. Is this part of that effort?

Mr. MORRIS. There is a lot of effort going on across HHS, and there is a group that is meeting regularly to try to figure out that we are all coordinating and thinking about that. And that is certainly one of the issues that has been discussed is, is there an ability to sort of really target resources from across the board to a community?

And I think the key, what I can mostly focus on, though, is what we plan to do with the $100,000,000 we have, and I think that that is specifically designed to sort of address that in the sense that it is not focused just on medication-assisted treatment or just on the workforce issue. It can cover all of those things to the extent that the community identifies it.

But the other thing that we are hoping is that with the planning grants that we do this year, it may be that some of those folks come in and do an implementation grant in Fiscal Year 2019, but it may also be that the planning grant is what they needed just to connect all the dots at the State level with the money from the 21st Century Cures Act that is going to the States. A lot of that is how do you best coordinate that and work with the State partners?

There is also philanthropic money going into this, and some States are putting their own revenues toward it. So in a lot of cases, the planning grants may help connect those dots in a way that better provides those services and targets them.

PROMISING OPIOID PROGRAM MODELS

Mr. COLE. Mr. Morris, as you look at this problem—and it is one that vexes us all, and I think we all recognize we are in the beginning phase of trying to come to grips with this—are there different parts of the country or different areas that you see have had more success than others that you think, gosh, here is somebody on their own that has done something really valuable that perhaps we could take and replicate?

Mr. MORRIS. I think we are still in the process of learning that. We are heavily reliant on what we learn from the HRSA regional offices and the HHS regional offices because they are closer to the problem in a lot of ways than we would be here in Washington, D.C. And I am aware of a project that happened out of our Denver regional office, where they went into one county in Utah in particular and tried to bring to bear all of the resources—SAMHSA's resources, HRSA's resources—and they were able to really help the community stitch all that together.

But I think that we are still in the early stages of learning. I mentioned the telehealth pilot. I think that has promise. I think we have to really study it further. But I think we can come back to you with that because I think there are some early lessons learned. I don't have them specifically before me, but I think we can share them with the committee.

[The information follows:]

One of the federally qualified health centers (FQHC) located in West Virginia has an onsite integrated pain management clinic and has integrated with behavioral health and primary care. They have demonstrated a number of outcomes related to opioids specifically and have had over 2,500 patients enter the program since 2013 with over 1,000 current users and zero overdoses since.

There is also another program located in Iowa that has developed an evidence-based program to build youth competencies and prevent risky behaviors, particularly substance abuse. The PROSPER program was implemented in 28 rural communities in Iowa and Pennsylvania and findings have ranged from improved family functioning and parenting, delayed initiations of a variety of substances and reduced conduct behaviors in youth. Youth participating in the program scored lower on a number of negative behavioral outcomes, including drunkenness, cigarette use, marijuana use and use of other illicit substances.

The Federal Region 8 Opioid Misuse Consultation Team members (representing HRSA, SAMHSA, and OASH), consulted with local, county, and state health and human services leadership to address opioid overdose and deaths in Carbon County, UT, which has been identified as one of the 220 rural counties with high vulnerability for an infection disease outbreak due to injection drug use (CDC, 2015). Financial support for the Consultation Team consisted of individual agency travel funds and the Consultation Team then helped the state and county leverage multiple federal funding streams (such as CDC and SAMHSA programs) to support existing networks and enhance collaboration. Initial 6-month summary outcomes included the establishment of an Opioid Council in Carbon County, strengthened partnerships, and the development of strategies addressing community prevention, clinical practice, workforce development, and crisis services. Naloxone distribution in Carbon County led to 15 lives saved in the first 6-months post implementation. There were also a number of lessons learned from this activity including the need for the strategies to address opioid addiction and reduce opioid overdose death to be driven at the local level, the need for State and Federal partnerships to leverage resources and accomplish identified strategies, the critical need for data for rural communities to "tell their story," and the five key areas that rural communities must address: a) Community Prevention, b) Crisis Services, c) Treatment, d) Recovery Support Services/After-Care, and e) Workforce. All local, State, and Federal partners play a role within these areas.

In FY 2015, HRSA funded 18 Rural Opioid Overdose Reversal grant awards to allow rural communities to develop community partnerships, purchase and strategically place naloxone and train licensed healthcare providers, emergency responders, and other community members in its use including recognizing the signs of opioid overdose, and refer individuals with a drug dependency to appropriate substance abuse treatment centers and/or mental health (counseling) centers. Outcomes after one-year demonstrated that over 9,500 naloxone doses were purchased, over 4,500 people were trained in its use, and nearly 400 total attempts to reverse an overdose with a 96% success rate. HRSA has also developed an evidence-based rural prevention and treatment of substance abuse toolkit that consists of evidence-based examples, best practices and resources that can be used by rural organizations to implement substance abuse programs.

Mr. COLE. I would very much appreciate any information you could provide. I mentioned this morning to the Secretary, look, if I just judge by Members, Hal Rogers' district probably knows more about this than anybody else just because he has worked it so long and, I mean, does a national conference. And so there clearly have been some local resources and infrastructure created there that would be, frankly, atypical of most communities, just out of result of his efforts and the focus of that particular district on this problem.

Let me switch pretty radically—no, not switch radically. We should build on this a little bit. Another thing I would hope you would look at, and again, you have some experience in doing this, is as you look at these communities, you would include a diversity of communities. Rural America is obviously every bit as diverse as urban America is. I think particularly my focus on tribal communities, those sorts of things, I would hope that a few of those are also in your models, different kinds, different levels of affluence and what have you, just to see if there are some common things that work everywhere.

Mr. MORRIS. Certainly. I think if you look at the list of the 220 counties that are identified, a number of those are in tribal areas, and I think it does play out differently there than it might play out in the New England area or in the deep South. So we will definitely do that.

I didn't mention it earlier, but as part of the funding, we are going to support a coordinating center that will work with all the planning grantees and the implementation grantees. And we are hopeful through that to really sort of highlight best practices and then learn from each other and really create a learning collaborative that allows people to replicate those models.

Mr. COLE. Again, it would be very helpful to this subcommittee that as you did that, we will try and have you back, but any information that you can share. Because all of us hear about this from our constituents and see it firsthand on a regular basis, and you are both to be commended for your respective agencies for the part they are playing in help with this, begin to grapple with this really horrific problem.

And with that, let me go to my good friend the ranking member for another round of questions.

HHS OPIOID COORDINATION

Ms. DELAURO. Thank you, Mr. Chairman.

Just a very quick question before a couple of others. And we did talk to the Secretary about this this morning. Is there someone who is overseeing all of the various agencies that are dealing with this problem?

And we have provided a fair amount of money here to various, and I think you have the bulk of the responsibility. But we have got SAMHSA, CDC, HRSA, ACF, NIH, et cetera. And the Secretary talked about someone in his shop, but who is overall coordinating that effort of seeing who is doing what and organizing the——

Mr. MORRIS. Yes, ma'am. The coordinator for HHS is the Assistant Secretary for Health, the ASH, and that is Assistant Secretary Giroir. And so he is coordinating all of the——

Ms. DELAURO. Yes. That is the person that we should touch base with who kind of has oversight——

Mr. MORRIS. Yes, ma'am.

Ms. DELAURO [continuing]. Of what is happening for all of the efforts that are under your jurisdiction?

Mr. MORRIS. Correct.

MEDICAID AND ADDICTION TREATMENT

Ms. DELAURO. Okay. All right. That is fine. Good for us to know.

Let me ask a couple of questions with regard to or question with regard to Medicaid. I think one of the things we saw when there were the deliberations around the Affordable Care Act that Medicaid emerged as a—as quite frankly, in my view, a hero in terms of a program because it dealt with disabled adults, children, obviously seniors as well. But also we found out that it is really people who are opioid addicted, et cetera, that Medicaid was a very, very big part of their ability to get and access treatment and get the treatment that was needed. I think you all concur with that effort.

We have got a whole number of States who have decided that they were not going to expand the Medicaid. So, and in my view, we are looking at States that are rendering those who are suffering from addiction and the need, they are hostage really to their geography. One of the pieces that this group that I met with earlier this year at the Rushford Center talked to me about was that there was a shortage of Medicaid providers in order to be—address this issue.

The other piece of this is that in the budget, there is the support for the Graham-Cassidy-Heller-Johnson repeal of the Affordable Care Act. That would cut traditional Medicaid by $175,000,000,000. Thirty-two million people lose their healthcare coverage. The plan includes a block grant, the Federal funding for the ACA Medicaid expansion, converts the rest of Medicaid to a per capita cap.

This would force Governors and legislators to choose who deserves to have health coverage and what services and supports should get covered. If we think the amount of opioid deaths are unacceptable now, I think we will just see a real increase in this without Medicaid expansion and without the opportunity to look at treatment through Medicaid.

If these efforts go forward, where would individuals go for their care? Especially those who are in medically underserved areas, how could it be covered, and what are, you know, your views about the—the budget calls for a $1,400,000,000 cut to the Medicaid program. How do you grapple with that in terms of your overall look at treatment for the populations that you are responsible for?

Mr. MORRIS. Medicaid falls under the Centers for Medicare and Medicaid Services. I would probably have to defer to our colleagues there on that.

Ms. DELAURO. You are the recipients of this. If you want to deal with treatment and people who are going to need treatment, and when you go to Hal Rogers' community or Congresswoman Clark's community, where are people getting the treatment? I think you all need to think about this very, very carefully before we have an ideological response to what has proven to be a central part of a social safety net with regard to healthcare in this country, proven by the debate and the discussion of the Affordable Care Act.

Love you, Mr. Morris. Not an adequate response, from my point of view. But you know, we will take it from there.

I don't know if you want to say anything, Mr. Padilla? Dr. Padilla.

Dr. PADILLA. I think I would concur with Tom on that. I would just add that the health profession shortage designation activity does fall under my purview in terms of designating health profession shortage areas across the country. We take into account as an assessment of that score the population that a provider sees, including the population below a certain threshold of poverty.

We realize that within the National Health Service Corps, which is driven by the health profession scores, a number of those organizations, those sites where the National Health Service Corps clinicians serve do receive Medicaid in the community health centers and others, including Medicare. As part of our program and what drives those clinicians into those areas is HPSA scores, which take into account the percent of poverty that that population currently suffers from.

Ms. DELAURO. Mm-hmm. Once again, I would just say—my time has well expired—the professionals in the field who come together say we do not have adequate Medicare/Medicaid providers to deal with the scope and depth of the crisis. We have just designated this as a national healthcare crisis.

Thank you, Mr. Chairman.

Mr. COLE. Thank you. And I probably ought to take this opportunity to advise the committee Dr. Padilla is actually taking the day off from grand jury duty so he could be here to testify. So I am tempted to ask you which experience is worse or better. [Laughter.]

Mr. COLE. But we are delighted to have you here, regardless.

Dr. PADILLA. And yesterday, I had a dental procedure. So which one?

Mr. COLE. Well, you are well prepared for the hearing then.

Dr. PADILLA. Which one?

Mr. COLE. But again, very good to have you here. I will next—we are all shuttling back and forth. We have a lot of hearings going today. And so our friend Dr. Harris has now been able to join us, and I want to recognize him for any questions he cares to ask.

340B PROGRAM

Mr. HARRIS. Yes, thank you very much. And I apologize, Mr. Chairman. We have Customs and Border Patrol across the hall. You can imagine, a little hot button issue.

But this, of course, a very important topic, what we are discussing here. Let me ask just two areas. One has to do with HRSA and the 340B program, and you may or may not know the answer. You can get back to me about it.

But the GAO and the HHS Office of Inspector General have issued several specific recommendations to HRSA, such as clarifying the definition of a 340B patient, more closely scrutinizing how private hospitals become eligible for 340B, that would improve the 340B program integrity because, you know, we have the impression that this is an important program, but that some hospitals

game the system a little bit. So what actions is HRSA taking toward implementing those specific recommendations, if you know?

[The information follows:]

In their 2011 report, the GAO recommended that HRSA clarify hospital eligibility requirements and the definition of a 340B patient. The FY 2019 President's Budget includes a proposal to provide HRSA comprehensive regulatory authority over all aspects of the 340B Program, including patient and hospital eligibility.

Mr. MORRIS. Yes. I would have to get back to you about the specifics of that. It is with our colleagues that actually run the program. I can speak to the role that it plays in rural communities and the providers it affects, but not to the specific definition of patients, some of the broader policy issues that I think Congress has been debating over the past year.

RECRUITMENT AND RETENTION OF RURAL PHYSICIANS

Mr. HARRIS. Okay, yeah. No, I would appreciate that because, again, we know the program is important, especially important in rural areas. But we also know that some institutions are taking advantage of it, and you know, and that always diverts resources from where they should be.

The second one is important as I go, and I represent a rural district. We have difficulties in, as you know, of course, recruiting physicians to rural areas. But we also have to retain physicians in areas. That is one of the important things. And when we get them there, we would like to keep there as well.

And physicians, as you know, increasingly face greater administrative burdens. There is no question about it. Whether it is prior authorization, electronic health records, which is a huge issue in rural communities, you know, quality reporting measures, the need to report Federal regulations, Federal reporting, all the things that make people not want to practice medicine in general, especially in a small rural practice.

Some studies indicate that a primary care physician is spending 2 hours of administrative work for every hour of direct clinical care. That is probably not much of an exaggeration if you actually talk about patient contact time. Many physicians spend a lot more now on administrative work, whether that is entering an electronic health record on a computer or whatever.

These burdens are obviously amplified in small practices that lack administrative staff. You know, you work at a hospital, part of a large group. They hire scribes. They hire all that to help you with that.

What is HRSA doing specifically to work with other HHS partners and agencies to reduce the burden on these smaller rural practices that would allow us to retain, you know, the docs who decide that they are going to practice in a rural or have practiced for years? Are there efforts in that toward—so we not only recruit people there, but the people who are there, we keep them going in practice longer.

You know, when people reach—I am 61 now. When people reach their sixties as docs now, they are just like, you know, I have had a good run at it. But in the old days, people would stay until they are 70, 75 in a community. What can you do about that, or what have you been doing?

Mr. MORRIS. Well, those are issues we hear a lot about, no doubt, and we hear them from across the country. And they do affect recruitment and retention, and so they are a real concern. There is an ongoing effort within the Department to look at administrative burden, and I think if you look at what we have seen in our analysis of the Quality Payment Program, raising the threshold to make sure that small practices aren't overburdened by this. So that was one effort, to reduce that sort of burden.

I think that you are right. The days of a solo or two-person practice being able to handle that are quite challenging. We have some community-based funding where we support networks of care in rural communities, and the idea behind all of it is you lack economies of scale in these small areas. If there were practices that wanted to come in and if their overall goal was to do a better job retaining the folks we have, the one way we can do that is by spreading the administrative burden across five or six practices, maybe hiring one practice manager to do all of them. We have funding that can do that.

We probably could do more to promote that as a possible way to do the funding. So that is one thing we could do through sort of our promotion of the grants. But there are resources to address that.

Also in the rulemaking process, we are charged in our statute with reviewing all the Medicare and other regulations that come to the Department, and often we are looking at it from an administrative burden standpoint. We don't win every one of those battles, but we do always raise it because it is an ongoing concern.

Mr. HARRIS. Well, thank you. Thank you very much again for—you know, for being the voice of physicians and healthcare providers in rural areas like my district.

And thank you, Mr. Chairman. I yield back.

Mr. COLE. Certainly. Thank you.

I will next go to my good friend again from Massachusetts for another round.

INTEGRATING CLINICIANS WITH LAW ENFORCEMENT

Ms. CLARK. Thank you, Mr. Chairman.

A very specific question. Last week, I got to meet with the police chief in Arlington, Massachusetts, Chief Ryan, who has embedded clinicians into his police force to deal with a host of issues. And I wondered if under the grant program that you are putting out to these 220 vulnerable counties, would that be an acceptable use of the grant funding for—for the recipients of those grants to use clinicians along with their police?

Mr. MORRIS. In terms of the funding, yes, that would be——

Ms. CLARK. Okay.

Mr. MORRIS. They could do that. We modeled this after a grant program we are currently administering, the Rural Health Opioid Grant Program, in which we really wanted to let the communities come and identify the solutions that were unique to them.

So if a community decided what we want to do is need to embed a couple clinicians in with law enforcement or we need to do better diversion from the jails being the treatment system——

Ms. CLARK. Right.

Mr. MORRIS [continuing]. Instead of the clinical system. We hope the grantees will come in and rethink all of those pathways. I can't speak to whether they would qualify for a National Service Corps loan repayment or not.

Dr. PADILLA. I think whether or not they qualify for the National Health Service Corps depend on, again, I think you mentioned earlier whether or not they are in HPSA areas, where are they spending their clinical time? And I think you have a very strong interest in expanding that, and we look forward to working with you on that.

The way the current National Service Corps program works is it is primarily driven by health profession shortage area and whether or not those clinicians are in those designated areas. So it would depend.

PRIMARY CARE INFRASTRUCTURE

Ms. CLARK. Okay, great. And just as a sort of general, you talked before about primary care, and I know that is a focus, trying to encourage and build robust primary care in all areas of the country, but specifically in rural areas. And as we see with opioids, you know, this is a chronic disease and needs to be treated as such.

And if we look across the spectrum of public health, looking at Alzheimer's and the breakthroughs that we are seeing, the likely first treatments that we are going to have are going to be for people who are perhaps asymptomatic. It is going to be at the early end of those diseases and progression, which is going to bring more of a focus onto primary care, early detection, managing substance abuse disorder as a chronic disease, and how can we help you? What further resources or changes can we make to help you build the primary care infrastructure in this country?

Dr. PADILLA. Well, obviously, we agree with the focus on primary care, but also with supporting those paraprofessionals and other professionals that are part of that comprehensive team. Our focus, in terms of health workforce, is not just training those clinicians in community-based areas, but also assuring that they are trained in areas that are really leveraging interprofessional and interdisciplinary care so they are accustomed to providing that type of delivery.

The substance abuse disorder and opioid crisis that is occurring right now is going to require that kind of delivery of care. It is unlikely to be a sole primary care provider in a single area that is going to address a complex issue like that. So towards that end, our Behavioral Health Workforce Education and Training Program is going to be a pivotal program for us to support those efforts, professionals and paraprofessionals as was mentioned earlier, community health workers, and others that help coordinate the care among these different facilities that patients often go to.

Our PCTE program as well, focusing on training those medical trainees and physician assistant trainees in familiarizing themselves with the complex care of a population that has multiple needs in terms of substance use disorder. To that end, we provided supplemental funding for our Primary Care Training and Enhancement (PCTE) program to address MAT within the curriculums of those schools that we support.

And again, we are looking forward to working with Tom and his team on the rural residency planning and development program. That is another program that is going to help to increase the number of residency slots that the aim is to increase the number of primary care providers that will go into those rural areas. So we are looking forward to working with Tom and his team on that.

Mr. MORRIS. I guess the only thing I would add is through our grants, one of the things that we hope folks will emphasize is what you just pointed out, which is seeing it more as a chronic disease. And part of it is breaking down the stigma——

Ms. CLARK. Right.

Mr. MORRIS [continuing]. Of having Opioid Use Disorder (OUD), and so, you know, hopefully, we will see applicants that will try different approaches to that. And then, combined with what Dr. Padilla said, you will develop a system of care that really moves them through, you know, to treatment and success with it.

Ms. CLARK. Yes. And I would—just to end on more of following up on what my colleague from Connecticut said that, of course, all of this needs funding, and Medicaid is the key. It is how most Americans access treatment in this country, and I understand you are in a political position here with your testimony. But we need your advocacy and we need your experience in rural America, and how we build good access to medical treatment for every American needs your point of view and your experience because this is critical, and we can tip the balance.

And our rural hospitals, our rural healthcare, those hospitals are not only access to healthcare, they are employers and major employers in rural areas. And this is a system that doesn't work if we dramatically cut Medicare and Medicaid, and we need your voices in that as well.

Thank you very much.

Mr. COLE. We will now go to my good friend from Alabama, who also finds herself with the challenge of shuttling between multiple committees this morning. But the gentlelady is recognized for whatever questions she cares to pose to our witnesses.

RURAL HOSPITAL CLOSURES

Mrs. ROBY. Thank you, Mr. Chairman.

And thank you both for being here today, and I appreciate you recognizing that we are all running in a lot of different directions. I thank you for your patience as well, as Members have come in and out, I am sure.

A few weeks ago, I had the opportunity here with my colleagues to speak to Secretary Azar about rural healthcare, and I hear some of my colleagues have already asked about this question, but specifically as it relates to hospital closures in rural communities. And so I was pleased to hear the Secretary's commitment to pursuing a solution that addresses this imminent problem facing our country and disproportionately affecting Americans living in rural areas.

So my home State of Alabama has seen 5 rural hospitals close their doors over the past 8 years, and since 2005, 120 rural hospitals have gone out of business across the country. This certainly has not gone unnoticed. As you can imagine, the impact is detrimental to patients who live in these rural communities, as they are

often forced to travel more than 30 miles—in some cases a lot more than that—to access care, including elderly patients and those with chronic health conditions.

So, Mr. Morris, you acknowledged in your opening statement that rural hospitals play a critical role in our healthcare infrastructure, and they also face difficult operational challenges. This is clear as hospitals located in rural areas across the country have been closing their doors at alarming rates and much more frequently than in urban facilities.

So I have serious, serious concerns about the impact this has on choice and access, two words that I also think you have probably heard this morning, to the care for the Alabamians that I represent. So I want to hear if there are any specific initiatives from where you sit that you are considering to address the needs of rural hospitals and helping prevent more of them closing their doors?

Mr. MORRIS. I share your concern with that. We know that the rural hospital tends to be the focal point for healthcare. In a rural community, it is easier to recruit clinicians if you have a hospital in the community than if you don't. Employers look to communities where there is a hospital and adequate healthcare services. So when a hospital closes, that creates a range of challenges for a rural community.

In terms of what we are doing to try to address it, I think I would place that on two levels. First—well, three levels, really. First, we got to understand what is going on. So we have a Rural Research Center Grant Program, and one of our rural research centers, the University of North Carolina, has focused on this issue almost exclusively, and they have identified the closures and also some of the driving factors behind it.

And also identified risk factors for existing hospitals so that we have a better picture of how many have closed, but how many more are financially at risk? And I think you have to understand that context before you can go to solution.

In terms of the solutions, I think they start on two levels. The first is what can we do to help the hospitals that are still open and get them so they are not in a vulnerable state? And the primary ways we are doing that is with our grant programs. We have the Rural Hospital Flexibility Grants, which work with the critical access hospitals. Those are the smallest of small rural hospitals, 25 beds or less. And so we want to focus on with them is making sure that they are providing good quality and that we can benchmark that quality and given them the resources to be able to show that.

But then also on the financial side, it was brought up earlier that administrative burden can be a challenge for these facilities. Whereas large systems can constantly upgrade their billing and their coding to make sure they are not leaving any money at the door, sometimes that is a struggle for rural hospitals.

And so with our Flex program, we are seeing the hospitals that take part in that funding, their quality scores go up, and we see an association between improved financial performance and the hospitals that take part in some of the coding and billing training, updating their charge masters, all the things you need to do to make sure you are billing appropriately. And so if you can provide

good quality care and if you can improve your financial bottom line, you are less at risk for closure.

Now there are communities where even if you do all that, you may have lost population, and it is just the economy of scale just doesn't work. Nationwide, we have seen declining inpatient admissions. That number is even more dramatic in rural communities.

And so one of the challenges for those facilities is if you can't have a full service hospital, what can you have? And so we have had—we have network planning grants that go out each year, and we have made a nod in the guidance each year. We are particularly interested in applications that focus on rural hospital closure or communities at risk of closure.

And so we funded 11 grants in the last 2 years to help those communities bring together the stakeholders and figure out, okay, what do we need to do to keep the hospital open? Or if the hospital is going to close, can we partner with a nearby regional system? Can we expand our EMS? Are there other things we can do to maintain an adequate level of access in those communities?

Beyond the grants, we also realized that there is a lot of technical assistance we could provide. So we have a particular program in the Delta region, and Alabama has some counties that are eligible for that, that we are going to pick like six hospitals a year and go in there and do some intensive technical assistance not only with the hospital, but also with the other providers, home health physicians, look at how telehealth can be brought to bear, with the idea of being particularly in the Delta region they face some really tough, challenging demographics. So we have that in place, too.

And then you have another program, the Small Rural Hospital Transition Program, that is similarly structured, and it looks at hospitals and communities of persistent poverty and tries to provide targeted technical assistance to those that need more than we can provide through our grant programs.

The other lever we have is telehealth may be part of the solution. It is not the solution of closing a rural hospital. But it can be part of a strategy to sort of maintain access in a rural community, and so we operate both grant programs and technical assistance programs that work at that.

The other part I guess I would add is that when we review the regulations each year for how Medicare pays hospitals, we do keep an eye towards how does this affect rural communities? And we will raise those concerns in our regulatory process to make sure that if we have the legislative authority, similar to what you heard from Secretary Azar, that we take that into account in the rulemaking process.

Mrs. ROBY. Mr. Chairman, I am well over my time, but I would just like to end by saying that I would like to make sure that we have really strong lines of communication through your office to make sure that our rural hospitals and their administrators have access, know where to find this information so that they can then take advantage of these programs that already exist, and so I look forward to working with you on that.

And Mr. Chairman, thank you very much.

Mr. COLE. You are most welcome. We are being very generous on time this morning.

Mrs. ROBY. That is good. I was a bad example. [Laughter.]

MENTAL HEALTH PROFESSIONALS

Mr. COLE. Now, now. Now I said that was announced earlier we were going to be very flexible with the clock, and then much to my surprise, everybody behaved for most of the hearing. That almost never happens around here.

I have just got one quick question, and I know my friend, I think, still had another one or two she would like to ask. So we will do that, and then we will probably close the hearing at that point. And again, I always allow my friend to make whatever comment she cares to make at the conclusion, and I will do the same.

But you actually mentioned this, Dr. Padilla, in your opening testimony about when you identified some of the areas of critical shortage, and you talked about mental healthcare—psychologists, psychiatrists—and we know that literally 90 percent of those two professions work in metropolitan areas.

And one of our colleagues here, who is actually much more knowledgeable than me about mental health made the point recently when we were looking at different program—it was actually last year, looking at different programs, and he said, your whole problem is supply. Don't worry about too much else until you get an adequate number out there, and what you get is people competing for healthcare professionals because there just simply aren't enough in the areas that are less attractive in particular from a lifestyle standpoint and get left behind.

I know we made an effort in the omnibus to try and put some resources toward that particular challenge. What are the sorts of things that you are doing that you think will help us draw more mental health professionals into, again, our more rural areas or other ways in which, you know, we can provide those communities with better access than they have had so far?

Dr. PADILLA. Thank you, Mr. Chairman.

And I mentioned before in terms of, and you are right, the critical shortage that we have in mental/behavioral health clinicians across the country, and I would highlight again the Behavioral Health Workforce Education and Training Program has a wide range of behavioral health disciplines within that program.

Currently, 20 percent of those trainees have trainee sites in rural areas. With the additional funding that we have received, we are going to try to leverage that again nationwide, and it is important to note that the focus that we are particularly paying attention to is how can we get those trainees, that partnership between. And Tom mentioned it earlier, that partnership is really important for us as well from a workforce perspective.

That community-based organization, that rural community, an academic partnership. It may not be that we have a Behavioral Health Workforce Education and Training grantee in every single rural area, but regionally, we are looking at where can we leverage those partnerships?

Training is occurring in those academic organizations, but they also have requirements of clerkships, internships, preceptships, and we want to leverage those programs to have as many contact hours in those community-based areas or those rural and under-

served areas. So I would highlight the Behavioral Health Workforce Education and Training Program.

That is on the training side. And then when you go to the service side really look towards what we are doing with the National Health Service Corps and the additional funding that we are going to leverage to incentivize those clinicians who are graduating from those eligible disciplines that are graduating from those programs to go and work, if they are not already working there, or be eligible for those awards so that when they do go work there, there is a retention aspect.

Because we know that once you are in the National Health Service Corps, over 90 percent of those clinicians stay up to 2 years beyond their obligation. So it is not only a recruitment arm, but a retention arm, as well.

Mr. COLE. That is great. With that, let me just go to my friend for whatever questions she cares to pose.

RANKING MEMBER DELAURO'S CLOSING REMARKS

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

Just a couple of points, and my colleague Congresswoman Clark talked about primary care. But there again, there is almost a $50,000,000 cut in primary care training, and I know you are aware of that. But we are very aware of that as well, if that is a direction of focus.

The other, I would ask you if it is—I know those 220 counties can utilize the resources for the kind of embedding in police departments that Congresswoman Clark talked about as well. But I go back to a program that is actually at DOJ, which was the community policing and police where they are the first responders and can identify kids who are at risk for violence or are victims of violence, et cetera, and they have a way of working with the police departments to do this.

And beyond the 220 counties, I think if we are thinking strategically about where we can move quickly, first responders are there. Whether they are now in our firehouses or whether they are in our police departments, they are on the scene. And so if we have a way of being able to get folks access to treatment and care as quickly as possible, just find that for me because I am technologically challenged.

This is about maternal healthcare shortage areas. You have got these 7,000 primary healthcare professional shortage areas. I don't know if you all want to think about it and you get back to me, there is no such designation as a—as I understand it, for a maternal healthcare effort, and we are looking at higher rates of maternal mortality today in the United States. It has doubled, you know, in the last several years. So would you be supportive of an additional maternal health designation as a sub-designation of primary care HPSAs?

So last thing I would just say to you, and thank you, Mr. Chairman. This is just released. Kaiser Family Foundation. And non-elderly adults with opioid addiction covered by Medicaid were twice as likely as those with private insurance or the uninsured to have received treatment in 2016.

I know it is in potentially another jurisdiction, but we cannot be siloed in this effort to cope with this national emergency. It is a very poignant article. You, me, we need to heed this as we move forward. Otherwise, we are flying in the blind and not being able to provide adequate service.

Thank you for what you do, and thank you this morning.

Thank you, Mr. Chairman.

CHAIRMAN COLE'S CLOSING REMARKS

Mr. COLE. I want to thank the gentlelady for persevering with me from the beginning to the end. She is always here.

But I also want to add a word of thanks again to our witnesses. Look, this is an interesting panel that we have here, or an interesting hearing and interesting committee. But you know, we quite often are looking at something like the NIH or whatever, and the room is packed and everything.

But what you guys do are really the nuts and bolts of real healthcare for the average Americans and certainly for areas that are underserved and very challenged, and we just want you to know how much we appreciate your work professionally and what you do and what an enormous difference I see it making in the lives of Americans that perhaps aren't fortunate enough to have the level of service that others take for granted.

And so your work is extraordinarily valuable to us and deeply valuable to the American people. So, again, we thank you, and we thank you for leaving the grand jury testimony, Dr. Padilla, to come in and get grilled a little bit, and we thank you for enlightening us.

With that, with my good friend's consent, we will go ahead and adjourn the hearing. So we are closed.

Thank you.

House Appropriations Committee

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Budget Hearing: Investing in our Health Workforce and Rural Communities

Thursday, April 12, 2018

[Questions for the record submitted by Chairman Tom Cole]

CHIEF DENTAL OFFICER

Mr. Cole: I am pleased to see progress on the integration of oral health into HRSA's programs. My expectation of the Chief Dental Officer function is to lead efforts at all stages including, design, planning, Budget request, and implementation of HRSA's programs to ensure the importance of oral health literacy is emphasized. As you continue to build on this work, please describe some of the efforts you expect to undertake in the next year to further integrate the importance of oral health with your programs?

Dr. Padilla: Acknowledging the critical part that oral health plays in health outcomes, HRSA continues to integrate oral health in our health workforce programs. The Chief Dental Officer at HRSA is responsible for coordinating oral health activities across all HRSA programs; counseling program officials throughout HRSA on the recruitment, assignment, deployment, retention, and career development of dentists and other oral health professionals within the agency; and advising HRSA oral health investments throughout the various oral health programs in the agency.

In addition, HRSA's Bureau of Health Workforce (BHW) invests in Oral Health Training Programs to increase access to high-quality dental health services in rural and other underserved communities by increasing the number of oral health care providers working in underserved areas and improving training programs for these providers. For FY 2018, HRSA was appropriated over $40 million in oral health workforce training activities, including Training in General, Pediatric, and Public Health Dentistry and Dental Hygiene Programs; the Dental Faculty Loan Repayment Program; the Primary Care Medicine and Dentistry Career Development Program; and Grants to States to Support Oral Health Workforce Activities.

- The Training in General, Pediatric, and Public Health Dentistry and Dental Hygiene Programs seeks to increase the number of dental students, residents, practicing dentists, dental faculty, dental hygienists, or other approved primary care dental trainees qualified to practice in general, pediatric and dental public health fields. In Academic Year 2016-2017, grantees of these programs trained 5,291 dental and dental hygiene students in pre-doctoral training degree programs; 460 dental residents and fellows in advanced primary care dental residency and fellowship training programs; and 1180 dental faculty members in faculty development activities.

- The Dental Faculty Loan Repayment Program seeks to increase the number of dental and dental hygiene faculty in the workforce by assisting dental and dental hygiene training programs attract and retain dental and dental hygiene faculty through loan repayment and help fund development program to provide continuing education opportunities. In Academic Year 2016-2017, the Dental Faculty Development and Loan Repayment Program provided a median loan repayment of $12,526 to 14 dentists serving as teaching faculty.

- The Grants to States to Support Oral Health Workforce Activities seeks to enhance dental workforce planning and development through the support of innovative programs. The program focuses on supporting new projects including integrating oral and primary care medical delivery systems and supporting oral health providers who practice in advanced roles specifically designed to improve oral health access. In Academic Year 2016-2017, grantees established 6 new oral health facilities for children with unmet needs in dental HPSAs, and expanded 24 oral health facilities in dental HPSAs to provide education, prevention, and restoration services to 99,581 patients. Grantees also supported four tele-dentistry facilities; replaced 26 water fluoridation systems to provide optimally fluoridated water to 2,691,366 individuals; provided dental sealants to 31,273 children; provided topical fluoride to 85,383 individuals; provided diagnostic or preventive dental services to 85,764 persons; and oral health education to 170,931 persons.

Mr. Morris: FORHP continues to invest in oral health activities in rural communities, many of which integrate oral health into primary care. In FY 2017, over $2 million was invested in rural communities to focus on outreach and education on oral health issues and FORHP anticipates making new oral health awards through the Outreach program in FY 2018. Nearly $5 million was invested through the Rural Network Development Program to utilize a network approach to provide innovative solutions to oral healthcare needs. Both of these program continue to support innovative approaches that includes the use of telehealth, school-based clinics, and mobile dental clinics to increase access to and quality of oral health services. Telehealth may play a valuable role in increasing access to oral health services and through FORHP's Telehealth Network Program. In FY 2017, more than $3 million was awarded to eleven grantees to demonstrate how telehealth networks can improve access to health care services and support health care providers in rural and underserved communities. These grants will continue in FY 2018. Finally, HRSA has invested in the development of an evidence-based oral health toolkit, which provides rural communities an opportunity to learn about models that have worked in rural and implement some of the strategies as they implement similar services. This can be found on the Rural Health Information Hub (RHIHub).

HEALTH PROFESSIONAL SHORTAGE AREAS

Mr. Cole: Please describe the process for determining a health professional shortage area? What factors are taken into the determination? Who collects the data? How often is the data updated? Can you provide some online resources for me to learn more?

Dr. Padilla: Health Professional Shortage Areas (HPSAs) are used to identify areas, populations groups, or facilities within the United States that are experiencing a shortage of health care professionals. HPSAs are statutorily required to be annually reviewed and revised as necessary after initial designation.

As part of HRSA's cooperative agreement with the State Primary Care Offices (PCOs), the State PCOs conduct needs assessment in their states, and submit designation applications to HRSA. Communities or facilities that wish to become designated as a HPSA may submit data to their State PCO. HRSA reviews the HPSA applications submitted by the State PCOs, and—if they meet the designation eligibility criteria for the type of HPSA the application is for—designates a HPSA. It should be noted that some HPSAs must be applied for, and some facilities are automatically designated by statute. For more information about shortage designation, please visit: https://bhw.hrsa.gov/shortage-designation. For more information about HPSAs, please visit: https://bhw.hrsa.gov/shortage-designation/hpsas.

TRIBAL COORDINATION

Mr. Cole: Including the unique interests of Tribal populations is critical when determining how to address health workforce shortages in rural areas. Can you describe your efforts at Tribal consultation when designing your grant proposals for fiscal year 2018? Please include specific programs that will be designated to target Tribal areas specifically.

Mr. Morris: HRSA leadership actively participates on the Secretary's Tribal Advisory Committee, as well as the Interdepartmental Council on Native American Affairs and its various sub-groups, to strengthen its relationship with American Indian (AI)/Native American (NA) communities. While none of HRSA's health workforce and rural health programs are statutorily designated to support Tribal populations exclusively, HRSA is aware of the significant health care challenges in many tribal communities.

HRSA supports Tribal populations through the various grant programs administered within the Federal Office of Rural Health Policy (FORHP). Currently, FORHP is investing approximately $5.7 million in funding across 24 Native American grantees with common social and economic challenges, including geographic isolation, lack of economic opportunity, and health care provider shortages. Funding supports increased access and quality of healthcare for tribal communities. In addition to providing funding opportunities that support tribal communities, FORHP has also conducted outreach activities that include quarterly tribal calls with grantees and other tribal stakeholders. These calls provide an opportunity for tribal organizations to network, share resources, and discuss public health challenges and potential resolutions. Topics covered during the past year have included: behavioral health and opioid use, care coordination, creating partnerships, implementation of telehealth programs, and information on upcoming FORHP funding opportunities. Participants have included members of the Ute Mountain Tribe, Yellowhawk Tribal Health Center, Santee Sioux Tribe, Toiyabe Indian Health Project, Inc., Eastern Aleutian Tribe, and Navajo Nation.

FORHP's Office of the Advancement for Telehealth will be providing outreach to tribal communities through coordination with HRSA Region 9, the Indian Health Service, and two HRSA-funded Telehealth Resource Centers to develop a webinar titled "Telemedicine 101 for Tribal Organizations" scheduled for May 22, 2018. This will provide information targeted to meet the needs for tribal organizations on the implementation and practice of telehealth.

FORHP also works to ensure that that rural specific information including funding opportunity announcement, that tribes may be eligible for is included in the Secretary's Tribal Advisory Committee report and the Annual Budget Consultation. Finally, FORHP will conduct a webinar for Tribal populations for the upcoming FY 2018 opioid announcement and other opportunities in FY 2019.

Dr. Padilla: HRSA provides targeted assistance to Tribal populations. The Health Workforce Connector provides a free, online recruitment resource where all NHSC and NURSE Corps-approved sites can post job vacancies connecting tribal sites to primary care professionals seeking employment throughout the United States. HRSA provides targeted guidance to Tribes on the benefits of using the Connector to market their clinic to recruit providers. HRSA is also conducting a grant-writing training targeted towards Tribal communities in October 2018. This training will discuss best practices and lessons learned from successful HRSA tribal grantees.

GRADUATE PSYCHOLOGY EDUCATION PROGRAM

Mr. Cole: Dr. Padilla, as you know the omnibus for fiscal year 2018 provided a substantial increase for the Graduate Psychology Education Program and other training activities targeted to the mental and behavioral health workforce. Can you give us an update on the status of the grant announcement for the graduate psychology education program?

Dr. Padilla: The current Graduate Psychology Education (GPE) grantees are in their third and final year of funding. With the additional funds, HRSA is developing funding opportunities that will expand upon the current mental and behavioral health workforce development programs, including GPE and the Behavioral Health Workforce Education and Training grants.

HIV & HEPATITIS C INCREASES DUE TO INJECTION DRUG USE

Mr. Cole: The opioid epidemic is rampant in our nation's rural communities and has resulted in too many lives lost, and has strained already underfunded public health programs. Rates of hepatitis C are increasing among the young adult populations in the Midwest, Appalachia, and elsewhere. While our nation has made progress in combatting HIV infection associated with injection drug use, the CDC has recently released data that there are now increases in new HIV infections associated with injection drug use among young people, those living in rural areas, the Midwest and the West.

How is HRSA responding to infections associated with drug use in rural areas? Are you increasing testing, education, and prevention programs in rural areas?

Mr. Morris: The FY 2018 appropriation provided $100 million to support treatment for and prevention of substance abuse disorder, including opioid abuse. The program will focus on high-risk rural communities across the U.S., including the 220 counties potentially vulnerable to HIV and Hepatitis C (HCV) infections among people with injection drug use as identified by CDC's 2015 analysis[1], , and other. The program will allow communities to implement programs that focus on the testing, education and prevention of HIV and HCV associated through opioid use, among other things. Additionally, as directed by the FY 2018 HRSA appropriation, HRSA will make up to $30 million in loan repayment awards through the National Health Service Corps program, in coordination with the Rural Communities

[1] Van Handel MM et al, "County-level vulnerability assessment for rapid dissemination of HIV or HCV infections among persons who inject drugs, United States," J Acquir Immune Defic Syndr (2016): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; See also Centers for Disease Control and Prevention, "Managing HIV and Hepatitis C Outbreaks Among People Who Inject Drugs," March 2018, https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-guide.pdf.

Opioid Response program, to increase the number of substance use disorder providers serving in these areas.

[The following questions were submitted to be answered for the record by Herrera Beutler]

Questions for the record from Ms. Herrera Beutler to Tom Morris, Associate Administrator for Rural Health Policy, HRSA and Luis Padilla, MD, Associate Administrator for Health Workforce, HRSA

RURAL HEALTH CHALLENGES AND ACCESS TO PRIMARY CARE.

Ms. Herrera Beutler: Rural health care challenges hits home for individuals and families in my district. Dwindling health insurance options in the individual market have been a troubling trend under Obamacare in communities like Klickitat County, WA, where residents were in danger of not having a single insurer to choose from in the individual market. I pushed for an immediate solution, but it took an 11th hour fix from Washington state's insurance commissioner to resolve this crisis. As we continue to work on these broader issues, the work that you do to support the hospitals, clinics, and providers who choose to serve in remote areas is critical to providing access to life-saving care for countless people.

Access to primary care presents specific challenges in medically underserved communities. I've spoken with rural hospitals and clinics in Southwest Washington who have had positions now vacant for years. What is HRSA doing to incentivize for providers to work in underserved areas?

Mr. Morris: HRSA has a number of activities targeting the recruitment and retention of health care providers in rural areas. HRSA funds the National Rural Recruitment and Retention Network (3RNet). In FY 2016, 3RNET activities resulted in 2,974 new candidate registrations to search for rural health care employment; 6,085 new rural job opportunity postings; and 1,984 provider placements with an estimated economic impact of $1.9 billion. HRSA also funded the Rural Training Track Technical Assistance (RTT-TA) Demonstration Program, in FY 2013-2016. The purpose of the RTT-TA program was to support the training of physicians in rural-focused allopathic and osteopathic physician family medicine residency training programs, as well as to provide technical assistance where appropriate to increase the number of family medicine resident trainees in RTTs. In the first year of the RTT program, 35 medical resident trainees were supported. In the second year, 60 medical resident trainees were supported. The third and final year of the grant program 39 medical resident trainees were supported. The funding also resulted in an increase from 23 to 41 rural training tracks over the course of the three-year program.

Looking ahead, the Consolidated Appropriations Act of 2018 provided $15 million to expand the number of rural residency training programs, and support the planning and development costs accrued while achieving program accreditation. This program will provide support to rural hospitals, medical schools and community-based ambulatory settings.

Dr. Padilla: HRSA's NURSE Corps and the National Health Service Corps (NHSC) are among the key programs to incentivize providers to practice in rural areas. NURSE Corps works to alleviate the critical shortage of nurses in high need areas across the U.S., including rural areas. The FY 2019 President's Budget requests $83.1 million for the NURSE Corps Program, which will fund an estimated 202

scholarship (new and continuation) and 1,015 loan repayment (new and continuation) awards. As of September 30, 2017, about one in five NURSE Corps clinicians serve in rural areas.

NHSC serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved and rural areas where shortages of health care professionals exist. While 18 percent of the U.S. population is rural, almost 37 percent of NHSC clinicians are serving in rural areas. The NHSC Loan Repayment Program (LRP) modified telehealth requirements this past year in order to provide clinicians with additional flexibility to better serve patients in rural and frontier areas. The program no longer places a cap on the percentage of time that clinicians may spend on telehealth.

In FY 2018, the NHSC will build on this flexibility and more directly target investments in rural areas. HRSA was appropriated $105 million to expand and improve access to quality opioid and substance use disorder treatment in rural and underserved areas nationwide. HRSA will make up to $30 million in loan repayment awards in coordination with the Rural Communities Opioid Response initiative within the Federal Office of Rural Health Policy and $75 million to expand access to substance use disorder services across the Nation.

SCHOOL-BASED MENTAL HEALTH PROGRAMS

Ms. Herrera Beutler: I recently hosted an open discussion with Southwest Washington superintendents and law enforcement on school safety and mental health challenges. We discussed the particular challenges in rural school districts who lack resources for mental and behavioral health.

What programs under HRSA do you believe are most successful in meeting the needs of schools and rural communities who are on the front lines of this issue?

Can you elaborate on any school-based mental health programs that were included in the FY19 Budget request?

Mr. Morris: HRSA continues to prioritize mental health in school-based settings. Currently, HRSA is investing $5.3 million in the School-Based Telehealth Network Grant Program where 85 percent of the grantees included a behavioral health component in their work plan. One awardee, the Sunnyside Community Hospital Association, located in Sunnyside, Washington, received grant funds to coordinate care for rural students in the Lower Yakima Valley and is currently working to get the telehealth services up and running successfully in the school-based clinics. In FY 2018, HRSA anticipates making up to 14 awards through the Evidence-Based Tele-Behavioral Health Network Grant Program, which will be a three-year program and has a specific focus on providing behavioral health services in rural communities. Other current investments addressing mental and behavioral health in rural schools include our community-based programs. Due to the broad nature of the Rural Healthcare Services Outreach Grants, rural communities have the ability to identify their particular need and develop their project to address that need. Currently, nearly $1.5 million is invested in rural communities to focus on school based mental health.

In addition, HRSA supports school-based health centers (SBHCs) under the Health Center Program. SBHCs provide a variety of comprehensive primary health services to children and adolescents, including primary care, mental health, substance abuse, dental services, case management, nutrition education, health education, and health promotion. SBHCs emphasize age appropriate services with a particular

focus on prevention, early intervention, and risk reduction. In FY 2019, HRSA plans to award approximately $10 million to support an estimated 100 School-Based Health Center Capital one-time grants to increase access to mental health, substance abuse, and childhood obesity-related services in SBHCs, by funding minor alteration/renovation (A/R) projects and/or purchase of moveable equipment, including telehealth equipment. HRSA expects to make FY 2019 SBHCC grant awards on or about February 1, 2019.

CRITICAL ACCESS HOSPITAL REIMBURSEMENT

Ms. Herrera Beutler: Ocean Beach Hospital in Pacific County, WA is a great example of small community hospitals in rural areas that are designated as critical access hospitals to ensure Americans living in remote areas have local access to life-saving emergency treatment and other medical care.

What is HRSA doing to ensure funding is preserved for these vital rural hospitals and the communities they serve?

Mr. Morris: In FY 2018, there are two programs within HRSA's FORHP that support hospitals directly, the Medicare Rural Hospital Flexibility Grant (Flex) and the Small Rural Hospital Improvement Program (SHIP). The Flex Program invests nearly $24 million to support Critical Access Hospitals (CAHs) to promote quality and performance improvement including, integrating emergency medical services into health care systems, incorporating population health, fostering innovative models of health care.

SHIP funds state governments to support rural hospitals with 49 beds or fewer. Funding helps small hospitals with technology equipment and training to assist the transition to measuring quality outcomes and the new value-based payment programs.

Our Rural Health Outreach funding provides flexibility for communities to apply for funds to ensure that access to services are maintained in rural areas. Within the last two years, HRSA has awarded eleven network grants to communities that were addressing hospital closures or mitigating the loss of services.

PREGNANCY AND TELEMEDICINE IN RURAL AREAS

Ms. Herrera Beutler: Maternal-fetal medicine doctors, cardiologists and other specialists who can treat pregnant women at risk normally don't practice in small towns. Given the rising rates of maternal mortality and severe maternal morbidity, what is HRSA doing to explore the use of telemedicine for high-risk pregnant women who live in remote areas?

Mr. Morris: In rural and remote areas, HRSA's FORHP has been monitoring the rates of maternal morbidity and mortality, as well as rural hospital closures which compound the issues surrounding access to pre-natal and OB care in rural communities. As with many other health care services, telehealth provides an opportunity to increase access to services that might not otherwise be available in rural. HRSA is also aware that rural hospitals are less likely than urban hospitals to have operational telehealth implementations in obstetrics, gynecology, NICU, and/or pediatrics (2.5% vs. 3.8%).[1]

[1] Ward, MM, et al."Extent of Telehealth Use in Rural and Urban Hospitals." RUPRI Center for Rural Health Policy Analysis. 2014. Accessed at: https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2014/Telehealth%20Utilization.pdf

HRSA has been involved with stakeholders on this issue. For instance, the HRSA-funded rural health research center at the University of Minnesota has conducted numerous studies on the loss of OB services in rural areas, and while the research does not specifically focus on the use of telemedicine in the context of rural maternity care access, discussions around the barriers to and cost of telemedicine as a solution have come up. This topic is also one that the HRSA-funded Heartland Telehealth Resource Center has engaged in planning time and providing expertise to interested groups around both high-risk OB ECHO and neonatal abstinence syndrome ECHO.

Due to the broad nature of the Rural Healthcare Services Outreach Grants, rural communities have the ability to identify their particular need and develop their project to address that need, which may include access to services for pregnant women. HRSA will also continue to explore the use of telehealth to address access to care for high-risk pregnant women who live in rural areas.

HRSA's Maternal and Child Health Bureau focuses more broadly on issues related to maternal mortality and infant mortality, working closely with state partners through the Maternal and Child Health Title V program. Additionally, in FY 2018, MCHB will launch the Improving Remote Monitoring of Pregnancy Challenge, a competition that will award $375,000 in prizes to support the development and testing of tech innovations to improve the ability of prenatal care providers to monitor the health and wellbeing of pregnant women, while helping pregnant women to monitor their own health and make informed decisions about care.

CHILDREN'S HOSPITALS GRADUATE MEDICAL EDUCATION (CHGME) PAYMENT PROGRAM

Ms. Herrera Beutler: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program supports training throughout the nation, including multiple rural sites in Washington state. CHGME helps boost the workforce in rural areas, because where physicians train or do rotations can often be where they choose to practice medicine.

What are HRSA's plans for this program as it relates to establishing a pipeline for pediatrics in rural communities?

Dr. Padilla: The FY 2019 Budget proposes to better focus Federal spending on training GME by consolidating spending that is currently in the Medicare, Medicaid, and Children's Hospital GME Payment Program into a new Federal grant program. In an effort to improve the distribution of specialties in health care, to address health care professional shortage areas, and to incentivize better training of professionals, funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages. Children's hospitals would remain eligible for funding.

The FY 2019 Budget also prioritizes health workforce programs that require service commitments in underserved areas and that are providing direct patient care to communities in need. Two of these programs, the National Health Service Corps (NHSC) and Teaching Health Center GME (THCGME), play a key role in training the primary care workforce, including pediatric specialties. The NHSC serves as a vitally important recruitment tool for community health centers and other health care entities nationwide operating in underserved areas where shortages of health care professionals exist. In FY 2017, the NHSC had over 490 pediatricians, pediatric dentist, and pediatric nurse practitioners and physician assistants providing health care services in NHSC approved sites and 20 percent of NHSC clinicians are primary care physicians. In addition, the THCGME program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs. Three of the 57 THCs are pediatric residencies.

[Questions submitted by Ranking Member Rosa DeLauro]

GRADUATE PSYCHOLOGY EDUCATION PROGRAM

Ms. DeLauro: The Graduate Psychology Education (GPE) Program trains new psychologists at the beginning of their careers to work in integrated care teams with underserved populations. In my district, GPE grantees have done tremendous work to increase the competency of providers to address children's mental health, including children exposed to trauma and violence. And the data show that the program has been highly effective in keeping its graduates working in those underserved areas.

In fact, HRSA data show that last year, 84 percent of graduates reported that they intended to work or pursue further training in underserved communities. And 87 percent of funded GPE training sites were located in underserved communities, with 74 percent of them being primary care settings.

Dr. Padilla, what plans does HRSA have to build on the GPE program to leverage additional funds provided for fiscal year 2018? Do you have a strategy to broaden the GPE program's reach across the country?

How will HRSA balance the need to expand training for treating opioid use disorders with the training needed to address ongoing unmet mental and behavioral health needs of vulnerable populations, including children and adolescents?

Dr. Padilla: The current Graduate Psychology Education grantees are in their third and final year of funding. With the additional funds, HRSA is developing funding opportunities that will expand upon the current mental and behavioral health workforce development programs, including GPE and the Behavioral Health Workforce Education and Training grants.

[Questions submitted by Rep. Roybal-Allard]

GERIATRIC HEALTH CARE PROVIDERS

Associate Administrator for Health Workforce Dr. Padilla

We are all very familiar with the aging of the boomer generations and the severe shortage of health care professionals trained in geriatrics. In 2016 there were less than 7000 geriatricians in the United States, significantly below the 20,000 needed to serve our current senior population.

By 2030, 20% of the population will be over the age of 65, totaling more than 70 million people. At that point it is estimated that we will need an additional 3.5 million health care professionals and direct-care workers to care for us all as we age. With only 3% of medical students taking even one class in geriatrics, and less than 4% of social workers and 1% of RNs specializing or certified in geriatrics, it is a formidable goal to reach. The Geriatric Workforce Enhancement Program is the only federal program focused on addressing this crisis, and yet your Budget eliminates it.

Questions:

Ms. Roybal-Allard: What is the value to our health care system of geriatric health providers in terms of providing quality, cost effective care?

Dr. Padilla: HRSA is committed to supporting comprehensive and high quality health care for older Americans. Achieving such care is dependent on the availability of a well-distributed, well-trained group of providers focused on the needs of our aging population. Geriatricians are medical doctors who specialize in evaluating and managing the unique health care needs and treatment preferences of individuals ages 65 and older. In FY 2017, HRSA published the National and Regional Projections of Supply and Demand for Geriatricians: 2013-2025, which projects a national shortage of 26,980 FTEs in 2025.

Ms. Roybal-Allard: How will HRSA address the needs of an aging population within your proposed Budget for FY19?

Dr. Padilla: The FY 2019 Budget prioritizes access to care by providing funding for health workforce activities that provide scholarships and loan repayment to clinicians in exchange for their service in underserved communities across the Nation. The Budget also funds primary care graduate medical education; while these residents and fellows are being trained, they provide direct care to patients in primary care settings and in medically underserved communities.

The NHSC serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved areas where shortages of health care professionals exist. In FY 2017, the NHSC had over 10,000 clinicians providing health care services in NHSC-approved sites.

In addition, the Teaching Health Center Medical Education (THCGME) program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs, including a geriatrics residency program.

PRIMARY CARE HEALTH PROFESSIONAL SHORTAGE AREAS

Associate Administrator for Health Workforce Dr. Padilla

Currently there are more than 18,000 Health Professional Shortage Areas in the U.S. This includes more than 5,000 mental health, nearly 6,000 dental health, and over 7,000 primary care shortage areas.

HRSA's Title VII health professions training programs are an invaluable tool for recruiting, training and retaining minority healthcare professionals, and have dramatically improved the health of underserved populations. However, the HHS Budget proposal cuts two-thirds of the health professions training Budget, and completely eliminates 15 health workforce programs, including all Training for Diversity, Primary Care Medicine, Preventive Medicine, and Oral Health Training programs.

Questions:

Ms. Roybal-Allard: At a time of growing provider shortages in primary care, how does HHS envision compensating for the cut and the future loss of direct care delivery capacity it would imply? Studies have consistently shown the value of comprehensive primary care to improve health outcomes and reduce systemic costs. In the absence of a sufficient primary care workforce, how does the administration plan to mitigate future unnecessary costs for patients as well as public and private payers?

Dr. Padilla: The FY 2019 Budget prioritizes access to care by providing funding for health workforce activities that provide scholarships and loan repayment to clinicians in exchange for their service in underserved communities across the Nation. The Budget also funds primary care graduate medical education; while these residents and fellows are being trained, they provide direct care to patients in primary care settings and in medically underserved communities.

The National Health Service Corps (NHSC) serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved areas where shortages of health care professionals exist. In FY 2017, the NHSC had over 10,000 clinicians providing health care services in NHSC-approved sites. In addition, the Teaching Health Center Graduate Medical Education (THCGME) program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs.

Ms. Roybal-Allard: Significant numbers of individuals suffering from opioid use disorder receive access to treatment solely through their primary care provider. By eliminating funding for the Training in Primary Care Medicine line, how does the administration plan to operationalize a long-term opioid epidemic response with a diminished primary care workforce?

Dr. Padilla: In the Consolidated Appropriations Act of 2018, HRSA received $105 million to expand the National Health Service Corps and improve access to quality opioid and substance use disorder

treatment in rural and underserved areas nationwide. HRSA will make up to $30 million in loan repayment awards in coordination with the Rural Communities Opioid Response initiative and $75 million to expand access to substance use disorder services across the Nation.

In FY 2019, the NHSC will award enhanced loan repayment to physicians, nurse practitioners and physician assistants (with a specialty in psychiatry) who have DATA 2000 waivers. As of September 2017, only two of the over 10,000 NHSC clinicians have DATA 2000 waivers. HRSA anticipates the incentive awards would:

- Encourage behavioral health clinicians to obtain a DATA 2000 waiver;
- Increase participation in NHSC LRP by DATA 2000 waiver clinicians who can be placed in at-risk communities, and give NHSC-approved sites an added incentive to support their recruitment of behavioral health clinicians who are well-positioned to address the need for medication-assisted treatment. The Department is also assessing other changes in NHSC that can help address the opioid epidemic.

TRAINING THE NEXT GENERATION OF PROVIDERS

Associate Administrator for Health Workforce Dr. Padilla

Some of the Title VII and VIII Health Professions cuts proposed in the administration's FY 19 Budget proposal are explained as an effort to refocus the agency's programs on "direct services."

Questions:

Ms. Roybal-Allard: Dr. Padilla, would you agree that workforce training programs contribute to developing the next generation of health professionals who will provide direct services?

Ms. Roybal-Allard: How would HRSA's health workforce bureau continue its success in training the next generation of health professionals without this funding?

Dr. Padilla: The FY 2019 Budget prioritizes health workforce programs that require service commitments in underserved areas and maintains funding for the National Center for Health Workforce Analysis, a national resource for health workforce research, information, and data. The Budget also proposes to better focus Federal spending on GME by consolidating spending that is currently in the Medicare, Medicaid, and Children's Hospital GME Payment Program into a new capped Federal grant program. In an effort to improve the distribution of specialties in health care, to address health care professional shortage areas, and to incentive better training of professionals, funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages.

The National Health Service Corps (NHSC) and Teaching Health Center GME (THCGME) programs also will continue to address health professions shortages. Specifically, the THCGME program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs. In addition, NHSC serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved areas where shortages of health care professionals exist. In FY 2017, the NHSC had over 10,000 clinicians providing health care services in NHSC-approved sites. The Consolidated Appropriations Act of 2018

included an additional $105 million to the NHSC to expand the delivery of substance use disorder treatment services in rural and underserved communities. HRSA will make up to $30 million in loan repayment awards in coordination with the Rural Communities Opioid Response initiative and $75 million to expand access to substance use disorder services across the Nation.

PEDIATRIC DENTAL RESIDENCY PROGRAMS

Associate Administrator for Health Workforce Dr. Padilla

Since 2000 Title VII has supported over 60 pediatric dental residency programs in underserved areas that provide a significant amount of care to populations most in need. Yet the need is so much greater. Last year 40% of all applicants to pediatric dental residencies were turned away due to lack of training slots.

Question:

Ms. Roybal-Allard: How will you ensure dental health equity for the 6000 dental shortage areas in this country when you are cutting the only program to fund pediatric dentistry residencies?

Dr. Padilla: The President's FY 2019 Budget prioritized funding for scholarship and loan repayment programs, such as the National Health Service Corps (NHSC), in exchange for service in areas of the United States where there is a shortage of health professionals. The NHSC Students to Service Loan Repayment Program (S2S LRP) specifically targets dentists and provides up to $120,000 to DDS or DMD students in their final year of school in return for a commitment to provide primary health care full time for at least 3 years at an approved NHSC site in a Health Professional Shortage Area of greatest need.

Overall, the NHSC is currently supporting 1,298 dentists practicing in underserved communities, 37 of whom are pediatric dentists. In addition, the NHSC supports participants to provide clinical education to students and residents up to 8 hours per week or up to 20 hours per week if the teaching takes place in a HRSA-funded Teaching Health Center.

TITLE VII TRAINING FOR DIVERSITY

Associate Administrator for Health Workforce Dr. Padilla

As is the case with most Title VII workforce development programs, the Budget also proposes the elimination of the Training for Diversity line. The Institute of Medicine identified that increasing healthcare workforce diversity is an effective method in narrowing the racial and ethnic disparities gap. Yet, minority populations make up 10% of the healthcare workforce despite representing 25% of the total US population.

To provide a more specific example, 5% of medical school graduates are Hispanic or Latino, but Hispanics and Latinos make up 17.8% of the population. Equally, 39% of full-time faculty at universities are female but only 4% of full-time faculty identify as Black or African American, Latino or Hispanic, Native American or Alaska Native, or Native Hawaiian or Pacific Islander females. Elimination of the Training for Diversity will only perpetuate our alarming lack of diversity within the healthcare workforce and limit our efforts in addressing health disparities.

Questions:

Ms. Roybal-Allard: How does HHS propose to address the stagnant or falling numbers of diverse students entering the health professions?

Dr. Padilla: HRSA's health profession training programs have helped create a pipeline of diverse primary care professionals, who are more likely to practice in the nation's most underserved areas. The National Health Service Corps (NHSC) and the NURSE Corps loan repayment and scholarship programs improve the health of the nation's underserved by recruiting health care providers to Health Professional Shortage Areas (HPSAs), which are areas of the country having shortages of primary medical care, dental, or mental health providers. These programs also tend to attract higher percentages of health professions students and clinicians who are minorities and from rural and disadvantaged backgrounds than in the health workforce. Specifically, programs focused on students include:

- ***NHSC Scholarship Program (SP):*** The NHSC SP provides financial support through scholarships, including tuition, other reasonable education expenses, and a monthly living stipend to health professions students committed to providing primary care in underserved communities of greatest need. Awards are targeted to individuals who demonstrate characteristics that are indicative of success in a career in primary care in underserved communities. The NHSC SP provides a supply of clinicians who will be available over the next one to eight years, depending on the length of their education and training programs. Upon completion of training, NHSC scholars become salaried employees of NHSC-approved sites in underserved communities.
- ***NHSC Students to Service (S2S) Loan Repayment Program (LRP):*** The NHSC S2S LRP provides loan repayment assistance of up to $120,000 to allopathic and osteopathic medical students and dental students in their last year of school in return for a commitment to provide primary health care in rural and urban HPSAs of greatest need for three years. This program was established with the goal to double the number of physicians in the NHSC pipeline and was expanded to dentists in FY 2017.
- ***The NURSE Corps Scholarship Program (SP):*** NURSE Corps SP which began in 2002, awards scholarships to individuals who are enrolled or accepted for enrollment in an accredited school of nursing in exchange for a service commitment of at least two years in a Critical Shortage Facility (CSF) after graduation. The NURSE Corps SP awards reduce the financial barrier to nursing education for all levels of professional nursing students and increase the pipeline of nurses who will serve in CSFs.

Ms. Roybal-Allard: How will HHS meet the growing demands of our minority communities in the years to come?

Dr. Padilla: The NHSC and the NURSE Corps loan repayment and scholarship programs improve the health of the nation's underserved by recruiting health care providers to Health Professional Shortage Areas (HPSAs), which are areas of the country having shortages of primary medical care, dental, or mental health providers. These programs also tend to attract higher percentages of health professions students and clinicians who are minorities and from rural and disadvantaged backgrounds than in the health workforce.

Under the NHSC program, minorities represent approximately 37% of the FY 2017 NHSC field strength and half of the FY 2017 NHSC pipeline (students presently in health professions programs). Under the NURSE Corps program, minorities represent approximately 31% of the FY 2017 NURSE Corps field strength and approximately 52% of the FY 2017 NURSE Corps pipeline.

Ms. Roybal-Allard: The Centers of Excellence and Area Health Education Centers received modest increases in the FY18 Omnibus. Can you provide us with an overview on how the Bureau of Health Workforce will utilize these investments in our districts to prepare health professionals to work with underserved, diverse, and rural communities?

Dr. Padilla: At this time, HRSA's BHW is still planning and determining how to best utilize funding from the FY 2018 Consolidated Appropriations Act for both the Centers of Excellence and Area Health Education Centers programs.

AREA HEALTH EDUCATION CENTERS

Associate Administrator for Health Workforce Dr. Padilla

Area Health Education Centers, eliminated in the President's Title VII Budget cuts, have served as crucibles for innovation in health professions education as well as a successful mechanism to direct students to rural and underserved areas once they enter practice. Health profession programs rely upon AHECs to mitigate the crisis in clinical training site availability.

Question:

Ms. Roybal-Allard: Beyond programs like the National Health Service Corps, how will the administration compensate for this cut to avoid creating additional barriers to care in rural areas?

Dr. Padilla: HRSA's NURSE Corps and National Health Service Corps (NHSC) are among the key programs to incentivize providers to practice in rural areas. NURSE Corps works to alleviate the critical shortage of nurses in high need areas across the U.S., including rural areas. NURSE Corps allows nurses to not only be located in federally qualified health centers and inpatient facilities, such as Public and Private nonprofit hospitals, but also long term facilities, residential nursing homes and hospice programs, which benefit smaller rural communities. The FY 2019 President's Budget requests $83.1 million for the NURSE Corps Program, which will fund an estimated 202 scholarship (new and continuation) and 1,015 loan repayment (new and continuation) awards. As of September 30, 2017, about one in five NURSE Corps clinicians serve in rural areas.

NHSC serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved and rural areas where shortages of health care professionals exist. In FY 2017, roughly one-third (34 percent) of NHSC clinicians are serving at rural sites and almost half (45%) of approved NHSC Sites are rural as of September 30, 2017.

The Teaching Health Center GME (THCGME) programs will also continue to address the physician shortage and was funded in the recently enacted Bipartisan Budget Act of 2018 (P.L. 115-123). Specifically, the THCGME program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs. Three of the 57 THCs are pediatric residencies and 12 THCs are located in rural communities.

NURSING WORKFORCE PROGRAMS

Associate Administrator for Health Workforce Dr. Padilla

We recognize the value of the nursing pipeline and were pleased to provide additional funding for the Title VIII Nursing Workforce Development programs in the FY 2018 omnibus. However, we also are aware that there are currently 7,167 primary care Health Professional Shortage Areas in this country impacting over 84 million Americans. And the Bureau of Labor Statistics projects that by 2026 there will be over 438,000 new positions needing to be filled (15% increase) for nurses, and an additional 64,000 positions (31% growth) for APRNs.

Questions:

Ms. Roybal-Allard: What is HRSA currently doing to help ensure we have a highly-educated registered nurse and advanced practice registered nurse workforce to provide care in rural and underserved regions of the country?

Dr. Padilla: Currently, HRSA operates several nurse-focused programs that ensure we have a highly-educated registered and advanced practice registered nurse workforce to provide care in rural and underserved regions of the country.

NURSE Corps awards scholarships and loan repayment to nurses, nursing students, and nurse faculty. Specifically, the NURSE Corps Loan Repayment Program enables registered nurses, advanced practice registered nurses, and nurse faculty to pay off a portion of their student debt in exchange for two years of full-time service in a Critical Shortage Facility (CSF). A CSF is a public or private nonprofit health care facility located in, designated as, or serving a Health Professional Service Area – an area with shortages of primary care or mental health professionals. The NURSE Corps Scholarship Program provide scholarships and monthly stipend to associate, bachelor, and graduate nursing students in exchange for a minimum two-year full-time service commitment (or part-time equivalent), at an eligible health care facility. In fiscal year 2017, NURSE Corps had over 1900 nurses fulfilling their service obligation in underserved communities across the nation. As of September 30, 2017, about one in five NURSE Corps clinicians serve in rural areas.

The National Health Service Corps provides scholarships and loan repayment to nurse practitioners and other advanced practice nurses in exchange for a two-year service comment in a health professional shortage area.

The Nurse Anesthetists Traineeship (NAT) Program educates registered nurses to become nurse anesthetists. Nearly 63 percent of trainees intended to seek employment or further education in Medical Underserved Communities following program completion. Additionally, training sites commonly served older adults (92 percent), the chronically ill (88 percent), and adolescents (87 percent).

The Advanced Nursing Education Workforce Program (ANEW) supports innovative academic-practice partnerships to prepare primary care advanced practice registered nursing students to practice in rural and underserved settings through academic and clinical training. The partnerships support traineeships as well as infrastructure funds to schools of nursing and their practice partners who deliver longitudinal primary care clinical training experiences with rural and/or underserved

populations for selected advanced nursing education students in primary care nurse practitioner, primary care clinical nurse specialist, and/or nurse-midwife programs. ANEW also helps facilitate program graduates' employment in those settings.

The Nurse Faculty Loan Program (NFLP) funds participating schools to operate a loan fund to assist registered nurses in completing their graduate education to become qualified nurse faculty. The program also offers partial loan forgiveness of up to 85 percent of the loan amount over four years to borrowers who graduate and serve full-time as nursing faculty in any accredited school of nursing. The NFLP student trainees were enrolled in a variety of degree programs all of which included a nurse educator component. Nearly 20 percent of students reported being from a rural background.

Ms. Roybal-Allard: How does HRSA intend to improve the pipeline and patient care with the additional support provided in the FY18 Omnibus?

Dr. Padilla: At this time, HRSA's BHW is still planning and determining how to best utilize funding from the FY 2018 Consolidated Appropriations Act.

Ms. Roybal-Allard: How would continuing to grow funding for Title VIII help address these current and projected shortages and the needs of our nation's patients?

Dr. Padilla: HRSA's National Center for Health Workforce Analysis projects that in 2025 there will be a shortage of 23,640 primary care physicians at the national level. With delivery system changes and the full utilization of nurse practitioners and physician assistants, the national shortage can be effectively mitigated. However, at the regional and local levels, there are areas that have and will continue to have primary care provider shortages. HRSA's NURSE Corps program, funded through Title VIII, has a direct impact on underserved communities by having nurses, including advanced practice nurses, practice in Critical Shortage Facilities in health professional shortage areas in exchange for loan repayment or scholarships. Investments in this program allow HRSA to provide awards to individuals serving underserved communities.

MATERNITY CARE SHORTAGE AREAS

Associate Administrator for Health Workforce Dr. Padilla

There are more than 18,000 health professional shortage areas (HPSAs) across the nation – more than 7,000 of which are primary care HPSAs. However, despite the unique health care needs required of maternal care, we do not know how many maternal health HPSAs there are because there is no such designation.

Question:

Ms. Roybal-Allard: Would you be supportive of a maternal health designation as a sub-designation of primary care HPSAs?

Dr. Padilla: HRSA would welcome additional dialogue with you to determine how best to address Congress's concerns regarding the availability of maternity care in underserved areas.

AUTISM SPECTRUM DISORDERS

Associate Administrator for Health Workforce Dr. Padilla

According to the Centers for Disease Control and Prevention, approximately 1 in 68 children have been diagnosed with autism, and the needs of these families are enormous. In 2006, the Combating Autism Act amended the Public Health Service (PHS) Act to add an emphasis on the early identification, diagnosis and treatment of children an Autism Spectrum Disorder (ASD) diagnosis. This law, which was reauthorized in 2011 and again in 2014 increased investments across HHS to address the growing needs of individuals with ASD and families, including training for pediatrician and other health professionals to be able to correctly diagnose or rule out autism as early as possible. Unfortunately, the President's Budget proposes NO funding for the Autism CARES Act workforce programs.

Question:

Ms. Roybal-Allard: How will HRSA ensure that our Primary Care Workforce is sufficiently prepared to correctly diagnose or rule out autism spectrum disorders without these designated funds?

Dr. Padilla: The FY 2019 Budget prioritizes funding for targeted workforce programs, including those that train pediatricians. For example, the Budget proposes to better focus Federal spending on Graduate Medical Education (GME) by consolidating spending in the Medicare, Medicaid, and the Children's Hospital GME (CHGME) Payment Program into a new capped Federal grant program. In an effort to improve the distribution of specialties in health care, to address health care professional shortage areas, and to incentivize better training of professionals, funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages. Children's hospitals would remain eligible for funding. In FY 2017, 58 children's hospitals received CHGME funding. During Academic Year 2016-2017, the most recent year for which FTE information was reported, CHGME hospitals trained 7,164 resident full-time equivalents (FTEs). Among these FTEs, 41 percent were pediatric residents, 33 percent were pediatric subspecialty residents, and 26 percent were residents training in other primary disciplines such as family medicine.

The FY 2019 Budget also continues to prioritize health workforce programs that require service commitments in underserved areas and that are providing direct patient care to communities in need. Specifically, the National Health Service Corps (NHSC) serves as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved areas where shortages of health care professionals exist. In FY 2017, the NHSC had over 490 pediatricians, pediatric dentist, and pediatric nurse practitioners and physician assistants providing health care services in NHSC approved sites and 20 percent of NHSC clinicians are primary care physicians. In addition, the Teaching Health Center GME (THCGME) program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, THCGME supports the training of 732 residents in 57 primary care residency programs. Three of the 75 THCs are pediatric residencies.

WEDNESDAY, APRIL 18, 2018.

HEALTH AND HUMAN SERVICES BIODEFENSE ACTIVITIES

WITNESSES

ROBERT KADLEC, M.D., MTM&H, M.S., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

STEPHEN REDD, M.D., DIRECTOR, OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. COLE. Good morning. It is my pleasure to welcome you to the Subcommittee on Labor, Health and Human Services, and Education appropriations to discuss biodefense activities in the Department of Health and Human Services.

Over the past several decades, the frequency and diversity of disease outbreaks has increased across the world. Events such as the Ebola outbreak in 2013, the Zika outbreak in 2016 are just two examples of reemerging infectious diseases that required a quick, sustained international approach to contain and eventually stop.

These outbreaks remind us of the need for surveillance to detect outbreaks as soon as possible, training and resources to prepare to respond to such emergencies, research to develop vaccines and treatments, and the infrastructure to stockpile or quickly produce and distribute these countermeasures.

The threats America faces are not limited to those that are naturally occurring. There are some state actors who seek to harm Americans, have demonstrated the ability to use chemical and other unconventional weapons abroad, and we know that many either already have the ability or are developing the ability to biological, radiological, and nuclear weapons to harm us.

I am proud that Congress was able to expand its investment in Health and Human Services biodefense and public health emergency preparedness programs in fiscal year 2018 omnibus. The omnibus provided a $200,000,000 increase for the procurement of promising medical countermeasures in Project BioShield, a $178,000,000 increase to prepare for pandemic influenza outbreak, a $3,000,000,000 for the National Institutes of Health, which includes expanded support for research on biodefense and emerging infectious diseases, and additional funding for cooperative agreements to improve the capacity of state and local health departments and hospitals to prepare for public health emergencies.

Now while I realize that your fiscal year 2019 budget request was submitted before Congress completed the fiscal year 2018 om-

nibus, I am still concerned that the administration's budget request for biodefense activities is inadequate to address the gaps in the country's preparedness for future health emergencies.

I look forward to hearing about how Health and Human Services is making use of the significant new investments in fiscal year 2018, as well as how HHS will focus resources on its top priorities in the upcoming fiscal year.

Today's panel includes three witnesses actually that are old friends. First, Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response at HHS. Next is Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. Finally, we have Dr. Stephen Redd, the Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention.

Before I remind everybody about the 5-minute clock, although this looks like we are going to be able to move expeditiously, I just want to say for the record, I think this may be the most important hearing we have, actually, this year in many ways. And we always have a lot of good ones.

I think we are at an inflection point, personally, where a lot of good work has been done over a lot of years, but we really need to develop a national consensus that this is an important investment that needs to be done on a sustained basis. And we need to think of ways that we can strengthen the structures and, frankly, just institutionalize the response to both pandemics and the danger that we face of a bioterrorist event. And I am particularly proud of this subcommittee and the full committee and the Congress, honestly, for being willing to step up this last year in the omnibus and make some really critical investment.

But we know money is not the only answer. We know it is part of the answer. So we will really be looking to you for advice as to how we create the structures to use the resources that we have and sustain that investment over time, what it really will require so that we don't relapse and we don't make this sort of a one year, we had had a really great year sort of thing, but that we begin to build up the capabilities that we have we know to respond to the things we know that are ahead of us.

The biosphere will keep throwing us things that are unpredictable and that we don't anticipate. And frankly, obviously, adversaries potentially could do the same thing. So really look at this as really as much a defense hearing as I do traditional Labor, HHS hearing, and we appreciate, again, the work all three of you have already done in this area. I read the testimony very carefully last night, and I look forward, again, to your sage advice.

So as a reminder to the subcommittee, again, we will abide by the 5-minute rule. But before we begin, I would like to yield the floor to my good friend, who is acting in the ranking member's stead today, the gentlelady from California.

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

And welcome to our panelists. Thank you for being here to discuss the Department's activities to protect our Nation from biological threats that occur naturally or are developed intentionally by people who want to do us harm.

Today's witnesses lead the agencies responsible for advanced research and development of medical countermeasures to respond to these threats. They are also in charge of coordinating the Federal response to public health emergencies, working in cooperation with hospitals, State health departments, and public health labs.

Four years ago, when the Ebola epidemic was raging through West Africa, we were reminded that we were not fully prepared for a serious public health threat. We had no vaccine, and many parts of the country were unprepared to handle a patient infected with such a deadly pathogen.

In Dallas, two nurses were exposed to Ebola, and there were only a few facilities in the country willing to accept them. One of the nurses was transferred to NIH's clinical center, where she was treated by one of today's panelists, Dr. Fauci. And to Dr. Fauci, let me again say thank you for what you did.

Ultimately, Congress passed $5,400,000,000 in emergency spending to respond to the Ebola crisis. Much of that was dedicated to advanced research and development of vaccines, therapeutics, and diagnostics. The funding was also used to improve our emergency preparedness and response networks, including the development of a regional system of infectious disease treatment units.

Sadly, more than 11,000 people in West Africa died before the outbreak was brought under control. We were very fortunate that only a limited number of cases came to the U.S., but I think we can all agree it is better to invest in advance so we are better prepared to deal with a threat when it arrives.

There is clearly a wide spectrum of threats that confront us. I imagine our panelists could give us an extensive list of chemical, biological, radiological, or nuclear threats that keep them awake at night. Just last week, we were shocked to learn that Bashar al-Assad once again attacked his own people with chemical weapons. And we continue to be confronted by new naturally occurring threats such as MERS-CoV, Zika, and the possibility of pandemic flu, among others.

In the fiscal year 2018 omnibus, we made it a priority to invest in biodefense and preparedness by providing large increases to NIAID, Project BioShield, BARDA, and the Strategic National Stockpile. But biodefense involves much more than simply developing and stockpiling vaccines, therapeutics, and diagnostics. We also need enough well-trained epidemiologists and health professionals to identify, investigate, and track disease outbreaks. We need enough laboratory capacity to analyze large volumes of samples and determine what pathogens are involved. We need effective plans and enough supplies and personnel to efficiently distribute and dispense vaccines and treatments. And we need the surge capacity in hospitals and other facilities to take care of large numbers of seriously ill patients.

All this work needs to be done through partnerships between Federal agencies like the CDC, State and local health departments, and the medical and first responder communities. So while the omnibus provided modest increases for CDC and ASPR grants to States and hospital coalitions, I think it is worth discussing whether we have moved too far in the direction of drug development at the expense of other public health preparedness activities.

There are many important topics to discuss. NIH and BARDA have medical countermeasures in the pipeline. The administration has proposed shifting control of the Strategic National Stockpile from CDC to ASPR, and the administration has discussed a plan for a new regional disaster health response system, just to name a few.

I am also interested in hearing about ongoing efforts in Puerto Rico, which continues to recover from last September's devastating hurricanes. The remaining emergency funding provided in the Ebola supplemental will be fully exhausted next year, which means we need to discuss the best way to maintain and strengthen our investments in the Global Health Security Agenda. So today, I look forward to a discussion of both the achievements of the biodefense programs and the challenges we face ahead.

Thank you again for joining us, and I look forward to your testimony.

Mr. COLE. I thank the gentlelady. And if we can, we will go now to our witnesses for whatever opening statements they care to make.

And Dr. Kadlec, we would start with you, if we may?

Dr. KADLEC. Thank you, Chairman Cole, Ranking Member Roybal-Allard, and members of the subcommittee.

I am Dr. Bob Kadlec, the ASPR at HHS, and I am also accompanied by my BARDA Director, Rick Bright, behind me.

On behalf of the Secretary, I am responsible for leading the medical and public health preparedness and response activities within HHS and across the Federal interagency in support of State, local, and tribal authorities during a public health emergency or a Stafford Act disaster. This is referred to as Emergency Support Function Number 8 of the National Response Framework.

I just want to say thank you for your recent support and funding that you provided to ASPR, including the $80,000,000 for the hurricane supplemental, as well as the increase in $459,000,000 in the omnibus, the 2018 omnibus appropriations bill.

This morning, I will briefly touch on the 21st century health threat environment and the role of ASPR and two key ASPR priorities, the medical countermeasure enterprise and the healthcare readiness piece. Before I took this position, I served as the Deputy Staff Director on the Senate Select Committee on Intelligence, where I was immersed in the intelligence describing the challenges and the threats confronting our Nation. Quite frankly, I slept like a baby. I woke up every 2 hours screaming.

It is from this experience that I fully understand the role of the ASPR is a supporting one of the Constitution's fundamental provisions, providing for the common defense to protect America, American people, and our homeland and our way of life from threats foreign and domestic, as ASPR's mission is to save lives and protect Americans from 21st century health threats, and those threats have changed significantly since the origin of ASPR nearly a decade ago. And I am happy to further that conversation in the appropriate classified setting.

As illustrated in slide 2, there are multiple deliberate and natural health security threats confronting America. This includes natural disease outbreaks with pandemic potential, as well as se-

vere weather events. We still have serious gaps in the availability of medical countermeasures and capabilities to address the range of threats.

As ASPR, I have four key priorities highlighted on slide 3. First, provide strong leadership. Second, create the—seek the creation of a regional disaster health response system. Third, advance an innovative medical countermeasure enterprise. And fourth, advocate for the sustainment of robust and reliable public health security capabilities, primarily through the Centers for Disease Control.

For medical countermeasures, ASPR oversees the advanced research, development, and procurement of these products through BARDA and Project BioShield. Medical countermeasures are vaccines, medicines, diagnostics, and devices to protect Americans from health security threats. These products often have little commercial value or market value and take 8 to 10 years to develop.

On slide 4, you can see a visual depiction of the HHS medical countermeasure development pathway. This successful enterprise is built on strong public-private partnerships that has resulted in 35 FDA approvals in just 12 years. First, DHS identifies agents that present a material threat to our national security. Next, NIH, DOD, and industry both support early-stage research. We are dependent upon their early successes to advance those candidate products.

Promising product candidates go to advanced development, and BARDA partners with companies to scale manufacturing, conduct human and animal trials, and prepare products for stockpiling and FDA approval. Next, we purchase promising product candidates through Project BioShield for the Strategic National Stockpile. When these products are fully approved by the FDA, future purchases are done through the Strategic National Stockpile. Finally, we are intent to basically—to quickly distribute and dispense lifesaving products in the stockpile in times of crisis.

One of ASPR's other core responsibilities is ensuring health readiness to respond to emergencies and disasters. During the last hurricane season, ASPR worked closely with State, territorial health officials to provide medical care through our National Disaster Medical System teams and other resources. Through this experience, we learned that HHS ASPR need to improve our internal capabilities, as well as enhance our support for the healthcare infrastructure across the country.

As with medical countermeasures, the Nation's healthcare delivery infrastructure is mostly a private sector enterprise. We must better leverage existing programs, such as the Hospital Preparedness Program, to create a more coherent, comprehensive, and capable regional system to respond to current and future threats. I call this the foundation of a regional disaster response system.

In closing, ASPR looks forward to working closely with you to protect the Nation from 21st century health security threats. Thank you for your bipartisan commitment to this national security imperative, and I am happy to answer any questions you may have.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

"FY 2019 Budget Health and Human Services: Biodefense Activities"

Testimony before the

House Committee on Appropriations

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Robert Kadlec, M.D., MTM&H, M.S.

Assistant Secretary for Preparedness and Response, HHS

April 18, 2018

Good morning Chairman Cole, Ranking Member DeLauro and Members of the Subcommittee. I am Dr. Robert Kadlec, the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS). Thank you for the opportunity to testify before you today to discuss the state of our nation's preparedness for 21st century health security threats, including biological incidents, and HHS's plans for FY 2018 and beyond.

Before assuming this role, I served as the Deputy Staff Director for the Senate Select Committee on Intelligence, where I was immersed in understanding 21st century threats. For decades before that, I worked in various government capacities focused on biodefense and national security, including more than twenty years in the United States Air Force as an officer and physician, and as Special Advisor for Counter Proliferation Policy within the Office of the Secretary of Defense during 9/11 and the 2001 anthrax attacks. I also served two tours of duty at the White House Homeland Security Council, including as Special Assistant to President Bush for Biodefense Policy from 2007 to 2009. I am proud to have played a part in drafting the original legislation that established ASPR when, during the 109th Congress, I was Staff Director of the Senate HELP Committee's Subcommittee on Bioterrorism and Public Health Preparedness.

Readiness for 21st Century Health Security Threats: A National Security Imperative

The Constitution states that one of the federal government's fundamental responsibilities is to provide for the common defense—to protect the American people, our homeland, and our way of life. The strength of our nation's public health and medical infrastructure, and the capabilities necessary to quickly mobilize a coordinated national response to emergencies and disasters, are foundational for the quality of life of our citizens and vital to our national security. Threats facing the United States during the 21st century are increasingly complex and dangerous. Therefore, improving national readiness and response capabilities for 21st century health security threats is a national security imperative.

Additionally, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola, and SARS. We are currently monitoring potential emerging infectious diseases that could cause a pandemic, such as the H7N9 influenza strain circulating in China. This year marks the 100-year anniversary of the 1918 influenza pandemic, which killed more people than World War I. During that pandemic, more than 25 percent of the U.S. population became sick and 675,000 Americans, many of them young, healthy adults, died from the highly virulent influenza virus. Finally, we face extreme weather events, such as the recent 2017 hurricane season in which Hurricanes Harvey, Irma, and Maria caused an unprecedented amount of damage and destruction, reminding us of the awesome destructive power of nature.

These are threats that most people would rather not think about. However, when natural disasters, disease outbreaks, or attacks occur, the people expect our government to be ready to respond to save lives. Since September 11, 2001, the nation has made great progress in building our defenses to protect America from health security threats; however, we still have much to do.

Assistant Secretary for Preparedness and Response (ASPR)

ASPR's mission is to save lives and protect Americans from 21st century health security threats. On behalf of the Secretary of HHS, ASPR leads public health and medical preparedness for, response to, and recovery from, disasters and public health emergencies, in accordance with the National Response Framework (NRF) (Emergency Support Function (ESF) No. 8, Public Health and Medical Services), as well as the National Disaster Recovery Framework (Health and Social Services Recovery Support Function). ASPR also supports HHS's role in the delivery of mass care and human services in emergencies (NRF ESF No. 6).

When ASPR was established by Congress a decade ago in the Pandemic and All-Hazards Preparedness Act (PAHPA), the law's objective was to create "unity of command" by consolidating Federal civilian public health and medical preparedness and response functions under the ASPR. This approach was modeled on the Goldwater-Nichols Act that created the Department of Defense combatant commands; the impetus was the disorganized and fragmented response to Hurricane Katrina in 2005.

ASPR coordinates across HHS and the Federal interagency to support state, local, territorial, and tribal health partners in preparing for and responding to emergencies and disasters. In partnership with HHS agencies, ASPR works to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for Federal responses to public health emergencies. ASPR supports readiness at the state and local level by coordinating Federal grants and cooperative agreements, such as the Hospital Preparedness Program (HPP) and the Medical Reserve Corps (MRC), and carrying out drills and operational exercises. ASPR also oversees advanced research, development, and procurement of medical countermeasures (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies), and coordinates the stockpiling of such countermeasures. As such, ASPR manages the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise.

Currently, ASPR has four key priorities for building readiness and response capabilities for 21st century health security threats:

- First, provide strong leadership, including clear policy direction, improved threat awareness, and secure adequate resources.
- Second, seek the creation of a "regional disaster health response system" by better leveraging and enhancing existing programs—such as HPP and NDMS—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery.
- Third, advocate for the sustainment of robust and reliable public health security capabilities. For ASPR to accomplish its mission, CDC, and other partners need support to quickly detect and diagnose infectious diseases and other threats. This is critical to rapidly and effectively dispensing medical countermeasures in an emergency.

- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on additional authorities provided in the 21st Century Cures Act, as well as advances in biotechnology and science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, and supplies to respond to emerging disease outbreaks, pandemics, and chemical, biological, radiological and nuclear incidents and attacks.

Two areas of progress and opportunities ASPR would like to highlight are our medical countermeasures enterprise and our healthcare readiness capacity.

Medical Countermeasures Enterprise

Congress established BARDA to speed up the availability of medical countermeasures by bridging the so called "valley of death" in late-stage development where many countermeasures for health security threats historically languished or failed. By using flexible, nimble authorities, multiyear advanced funding, strong public-private partnerships, and cutting-edge expertise, BARDA has successfully pushed innovative medical countermeasures, such as vaccines, drugs, and diagnostics, through advanced development, to stockpiling and FDA approval or licensing.

In the last decade, BARDA's strong partnerships with biotechnology and pharmaceutical companies, the National Institutes of Health, and other HHS components, have led to 35 FDA approvals for 31 unique medical countermeasures addressing chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging and re-emerging infectious diseases. This is a staggering accomplishment in just 12 years. BARDA has supported the development of 27 medical countermeasures against Department of Homeland Security- (DHS) identified national security threats through Project BioShield, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events. Fourteen of these products have been placed in the Strategic National Stockpile and are ready to be used in an emergency, and seven have achieved FDA approval. BARDA also has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza. Because of this progress, more medical countermeasures than ever before are eligible to be acquired for the SNS, thereby creating new challenges in terms of acquiring and maintaining sufficient quantities of medical countermeasures to address the requirements for identified threats.

ASPR would like to thank this committee for its support for BARDA, Project BioShield, and pandemic influenza medical countermeasures. The Consolidated Appropriations Act of 2018 includes $710 million for Project BioShield, an increase of more than $200 million over FY 2017, for the initial procurement of medical countermeasures against DHS-identified national security threats, including CBRN agents. This funding will enable BARDA to continue to fill remaining gaps in our nation's preparedness for CBRN threats by transitioning products from advanced development to initial procurement and stockpiling. The Administration supports a 10-year advance appropriation for Project BioShield, an approach which will help incentivize private industry to dedicate resources to developing medical countermeasures to meet the

government's national security requirements. Without this "guaranteed market", companies can be reluctant to incur the opportunity costs required to focus on a limited government market that may not materialize when product development is complete.

The committee also included $537 million, an increase of $26 million, to support BARDA's advanced research and development of medical countermeasures. This additional funding will enable BARDA to implement new authorities provided in the 21st Century Cures Act, without detracting from continued investments in CBRN medical countermeasures. The Medical Countermeasure Innovation Partner authority focuses on driving public and private investment in medical countermeasure innovation by investing in disruptive technologies with the potential to make far-reaching impacts in both national security and commercial medical products.

This committee also included $610 million, an increase of $35 million, for the Strategic National Stockpile (SNS) currently managed by the CDC. The SNS is the Nation's largest repository of life-saving medical countermeasures and medical supplies intended to support state and local emergency needs. The FY 2019 President's Budget reflects the Administration's decision to shift oversight and operational control of the SNS from CDC to ASPR. This move will more fully integrate the SNS with other public health and medical preparedness and response capabilities under ASPR, improve the efficiency of emergency responses, strengthen and streamline the medical countermeasures enterprise, and leverage synergies in supply chain logistics. The Department is committed to ensuring a smooth transition of this important national security asset, including no loss in operational capability or degradation of connection with state and local health officials. We look forward to working closely with this committee during this deliberative transition process.

The Consolidated Appropriations Act of 2018 also includes $250 million, an increase of $193 million, for Pandemic Influenza preparedness, which has previously been funded through emergency supplemental appropriations bills. This additional funding will support the sustainment of domestic influenza vaccine manufacturing and stockpiling capacity, advanced development of novel influenza vaccines and therapeutics, and international pandemic preparedness activities. It is urgent that the United States continue the development of modern, large-scale, domestic vaccine production. These activities are essential to responding to pandemic threats and are carried out by ASPR, as well as the HHS Office of Global Affairs. As newly evolved strains of drug-resistant influenza viruses emerge that pose a significant threat to public health, as seen with the 2017 H7N9 avian influenza outbreak in China, the Department will put these additional resources to work to ensure we do not lose ground.

Healthcare Readiness to Respond

The 2017 hurricane season highlighted the importance of regional healthcare readiness and medical surge capacity. ASPR led the public health and medical responses to Hurricanes Harvey, Irma, and Maria under the NRF Emergency Support Function No. 8 mission. ASPR worked closely with state and territory health officials in affected areas to augment care with

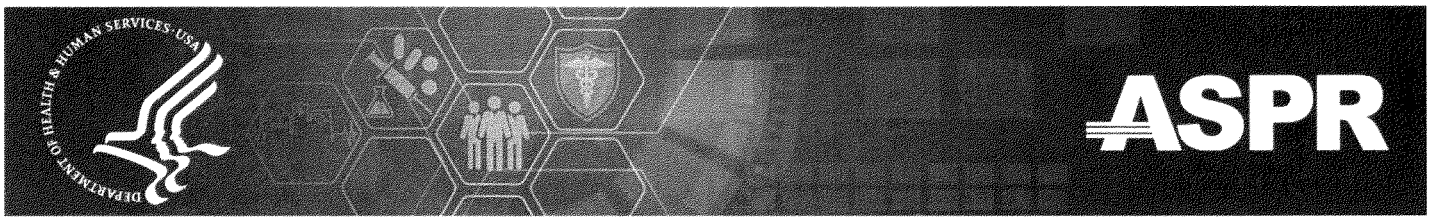
NDMS teams, Public Health Service Commissioned Corps Officers, VA personnel and facility support, and DoD transportation, facilities, and clinicians. Personnel under the supervision of HHS treated over 36,000 patients, and HHS deployed over 4,500 personnel, evacuated nearly 800 patients, awarded over 200 contracts, and provided nearly 950 tons of equipment. Today, HHS continues to support recovery efforts in impacted communities.

During the response, due to the combined efforts of ASPR and the Centers for Medicare & Medicaid Services (CMS), we utilized the innovative HHS emPOWER program to pre-identify at-risk individuals requiring electricity-dependent medical and assistive equipment (e.g., ventilators, oxygen concentrators, feeding machines, intravenous infusion pumps, suction pumps, dialysis machines, wheelchairs). In one instance, ASPR teams, deployed with Urban Search and Rescue teams, used this data to identify every dialysis patients in the U.S. Virgin Islands and evacuate those patients for treatment since the local dialysis centers were destroyed.

Despite our successes, we also learned that HHS and ASPR need to improve our internal capabilities as well as enhance our support for the healthcare infrastructure across the country. As with medical countermeasures, the nation's healthcare delivery infrastructure is mostly a private sector enterprise. We must better leverage and enhance existing Federal programs—such as HPP and NDMS—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery. I call this the foundation of a "regional disaster health response system."

ASPR would like to thank this committee for its support for HPP and NDMS. The Consolidated Appropriations Act of 2018 includes $265 million, an increase of $10 million over FY 2017, for HPP, and more than $57 million, an increase of almost $8 million, for NDMS. This funding will enable ASPR to invest in innovative approaches to building regional health system readiness for complex mass casualty events, and to rebuild NDMS teams and train them to respond to 21st century threats.

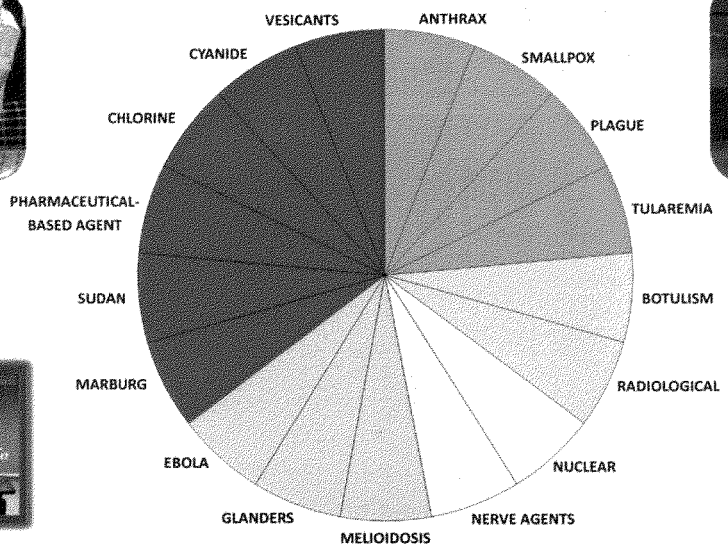
ASPR looks forward to working with this committee in fiscal year 2018 and beyond to protect the nation from 21st century health security threats. I am committing the entire ASPR team's grit, ingenuity, expertise, and perseverance to this mission. Thank you, again, for your bipartisan commitment to this national security imperative, and I look forward to continuing to work together to enhance our nation's health security. I am happy to answer any questions you may have.

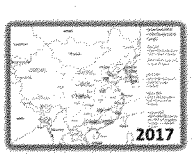


ASPR Role in Biodefense

Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
April 18, 2018

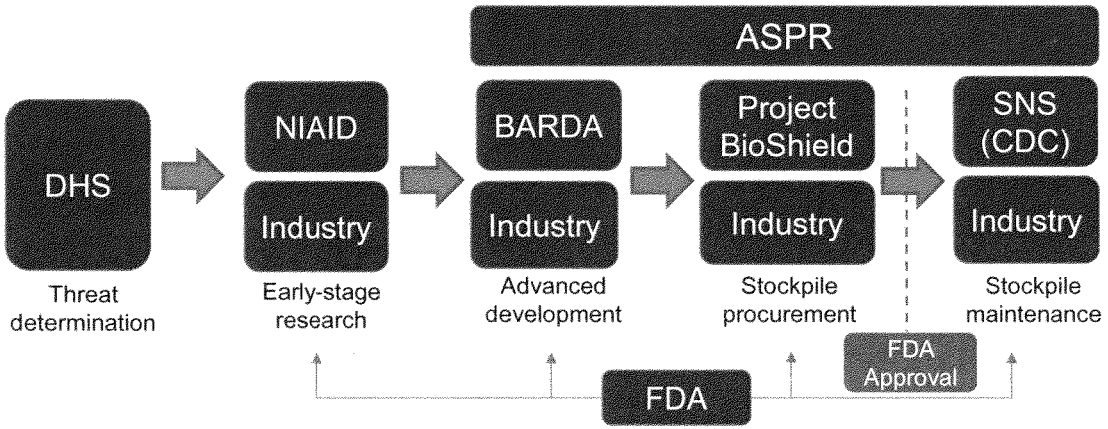
21st Century: An Increasingly Complex & Dangerous World





ASPR Priorities for Building Readiness for 21st Century Threats

HHS Medical Countermeasures Development Pathway



Mr. COLE. Pretty impressive, within 13 seconds of the 5 minutes, and that is perfect. [Laughter.]

Mr. COLE. If we can, now we will go next to an old friend of the subcommittee, Dr. Fauci.

Dr. FAUCI. Thank you very much, Chairman Cole, Ranking Member Roybal-Allard, members of the committee. I appreciate the opportunity to again have the capability here with you to discuss what the role of the NIH, particularly NIAID, is in what we are talking about today.

As you can see from this first slide, and we recall years ago, that relatively soon following the anthrax attacks that we saw in 2001, we immediately, over a period of several months, developed a strategic plan for biodefense research and a research agenda. And to a greater or lesser degree, we have been following that plan over the last 15-plus years.

And what it does is outlines for us the things that the NIH has done in response to a number of threats that go well beyond biodefense, and that is to utilize the research capabilities from a basic, fundamental research standpoint, including clinical research, research resources for our grantees and our contractors. But as you can see from the top of this slide, the three countermeasures that are critical to how we respond to any threats, be they deliberate or natural, and that is the importance of diagnostics and understanding immediately what the threat is.

Because be it a deliberate threat or an emerging infection, not infrequently, if it is brand new, you don't know for a while what you are dealing with. And then once you do know what you are dealing with, you need to understand which in the population are actually afflicted with it, among the other diseases that you get risk to.

Then there is therapeutics, and obviously, one of the most important components, as you just mentioned when we were talking about Ebola, Ms. Roybal-Allard, and how quickly we got a vaccine for Ebola into the field. This was all based on things that had been going on for years.

This map of the United States illustrates the facilities that are necessary to adequately deal with and study the threats that you might have again from a deliberate or from a naturally occurring standpoint. What is seen here in red are the Centers of Excellence for Translational Research, and the yellow are the BSL–4. That is the highest degree of containment. We have four of them in the United States under the auspices of the Federal Government and one private one.

The two intramural are at the research facility in Frederick and at the Rocky Mountain lab in Hamilton, Montana. And the two extramural are in Boston University and the University of Texas Medical Branch. And as you see the other BSL–3 facilities, you are going to hear during the question period, I am sure, of the kinds of achievements that have occurred from the real teamwork between the National Institutes of Health, the CDC, and BARDA—particularly BARDA—in the way they were able to get countermeasures developed and into the stockpile. This is just a brief example of some of the countermeasures that are related to smallpox, anthrax, botulism, and plague.

Now not only biological threats, but there is also the threat of radiological, nuclear, and chemical threats that we need to be concerned about. Again, we have a strategic plan and research agenda for these also.

Very briefly, if you look at things like radiation countermeasures, which we focus on acute radiation sickness, as well as how you can chelate or absorb radionucleotides that might get released into the atmosphere and afflict the population. With regard to chemical countermeasures, I think there is something on that slide, the very last bullet, that is relevant to what is in the news today. It is the chlorine chemical attack to those unfortunate individuals in Syria.

There aren't many countermeasures against that. You saw on television they were wiping the children with water to try and get the chlorine off. But once it gets into the lung, you have to have a way to neutralize that, and we have been working on that with BARDA to have those kind of countermeasures.

And again, it was alluded to in your statement, Ms. Roybal-Allard, and it is true, very much so, that there really isn't much difference about how you respond to a natural threat or a deliberate threat. And this was from Newsday years ago right after anthrax, that the worst bioterrorist may be nature itself.

And in that regard, one example of that is what I testified before this committee literally several days ago, when we were talking about the threat of a flu, particularly a pandemic flu. And we have put together our plan for developing of a universal influenza vaccine, and I want to close with this last slide, which goes way back to 2001, a few months after the anthrax attack when, with my colleagues, I wrote this showing that the clear and present danger of bioterrorism there, and we will be judged very harshly if we don't respond to that.

Thank you.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases Research Addressing Biodefense and Emerging and Re-emerging Infectious Diseases

Testimony before the

House Committee on Appropriations

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Anthony S. Fauci, M.D.

Director of the National Institute of Allergy and Infectious Diseases

April 18, 2018

Mr. Chairman, Ranking Member DeLauro, and members of the Subcommittee, thank you for the opportunity to discuss the research response of the National Institutes of Health (NIH) to potential attacks with chemical and radiological/nuclear agents as well as biological threats, including emerging and re-emerging infectious diseases. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead NIH institute for biodefense research.

The NIH conducts and supports basic and clinical research to better understand the biological effects of, and to develop medical countermeasures (MCMs) for, chemical, biological, and radiological/nuclear threats. Most of this work is conducted by the NIAID at the NIH. NIAID supports basic research on microbiology and immunology as well as applied and clinical research to evaluate candidate MCMs including diagnostics, therapeutics, and vaccines. This strategic effort includes the pursuit of foundational platform approaches that could be used to develop MCMs against multiple threats or pathogens. These platforms include molecular biological technologies for vaccines, targeted antibody therapeutics, and broad-spectrum antibiotics and antivirals.

NIH coordinates its biodefense research with partners in industry, academia, and the Federal Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to ensure that promising countermeasures for biological, chemical, and radiological public health threats can proceed to advanced development. Since fiscal year 2012, NIH has supported the early development of 20 candidate MCMs for high-priority threats, and ultimately transitioned support for those candidate MCMs to the Biomedical Advanced Research and Development Authority (BARDA) for advanced development, with the goal of Food and Drug Administration (FDA) approval, licensure, clearance, or authorization, and for potential inclusion in the Strategic National Stockpile. NIH funding for emerging infectious disease, including biodefense research, was approximately $2.6 billion in FY 2017.

NIH MEDICAL COUNTERMEASURE DEVELOPMENT

Innovative technologies and approaches supported by NIH are enabling the development of new medical countermeasures (MCMs) at an unprecedented pace. High-throughput sequencing and platform-based technologies are facilitating the development and manufacture of MCM candidates to expedite their clinical evaluation. For example, during the Zika virus outbreak in the Americas, NIAID scientists used Zika virus genetic sequence information to develop a vaccine candidate that moved from concept to first-in-human trial in less than four months – likely the shortest development period ever for such a vaccine. The vaccine was developed with a readily deployable DNA vaccine platform that is a form of gene-based immunization previously employed by NIAID to develop a candidate vaccine for West Nile virus. These types of genetic platforms could be used to respond similarly to multiple emerging and re-emerging infectious disease threats.

Other broad-spectrum approaches are being used to advance the development of therapeutics that could be used against multiple pathogens. For example, NIAID has supported development of broad-spectrum antiviral agents such as BCX4430 (galidesivir), which has demonstrated activity against Ebola and other RNA viruses, and broad-spectrum antibacterial products, including a compound with activity against the two different bacteria that cause tularemia and plague.

NIAID continues to explore other inventive approaches to treat or prevent bioterrorism threats. Monoclonal antibodies, which precisely bind to a single target, have been used to treat certain cancers, infectious diseases, and autoimmune diseases. Monoclonal antibodies also have the potential to treat emerging and re-emerging infectious diseases, and as a first line intervention to prevent or slow the progress of infectious disease outbreaks as vaccines are being developed. A notable example is ZMapp™, a cocktail of three monoclonal antibodies targeting Ebola virus. ZMapp™ showed promise as a treatment for Ebola virus disease in an NIAID-supported clinical trial during the 2014-2016 outbreak in West Africa. Another innovative approach specific to vaccine development is the use of adjuvants. Adjuvants are valuable tools that can boost immune responses to otherwise modestly effective vaccines, and potentially can expedite development of vaccines for emerging pandemic threats. NIAID supports programs for discovery and development of adjuvants that have led to 50 novel adjuvants and 18 vaccine clinical trials.

NIAID also has invested in critical infrastructure and research resources to encourage the development and testing of biodefense MCMs. NIAID supports research capacity at high-containment laboratories where dangerous pathogens can be studied safely. In addition, NIAID provides qualified scientists with research resources, including microorganisms, research reagents, and preclinical development services that can fill knowledge gaps. These programs lower the financial risk for potential commercial partners, and expedite the development of MCMs.

These NIH-supported activities are advancing a robust pipeline of candidate MCMs needed to ensure the development of safe and effective products to protect the public health. Notable successes are outlined below.

Ebola. NIAID partnered with the government of Liberia to establish the Liberia-U.S. clinical research partnership known as PREVAIL. This partnership enabled a series of clinical trials, including studies testing several Ebola virus vaccine and therapeutic candidates, among them ZMapp™ and the NIAID-developed cAd3-EBOZ vaccine. Several candidates have transitioned to BARDA for advanced development.

Smallpox. NIAID supported the early-stage development of a novel smallpox vaccine, IMVAMUNE®, and a therapeutic, TPOXX® (tecovirimat), prior to their transition to BARDA for advanced development. IMVAMUNE® was shown to produce a superior immune response compared to the currently licensed smallpox vaccine. TPOXX® currently is under consideration for FDA approval pursuant to the Animal Rule, using pivotal animal model data supported by NIAID.

Anthrax. NIAID supported the preclinical and clinical development of the anthrax countermeasure ANTHIM® (obiltoxaximab), prior to its transition to BARDA for advanced development. ANTHIM® was approved by the FDA in 2016 for the treatment and prevention of inhalational anthrax, the deadliest form of the disease. NIAID also has supported the development of AV7909, a third-generation anthrax vaccine with a dry formulation that is easy

to store and has increased shelf life. AV7909 has been transitioned to BARDA for further development.

Pneumonic Plague. NIAID supported critical animal model studies of ciprofloxacin and levofloxacin for FDA approval, pursuant to the Animal Rule, as treatments for pneumonic plague. In addition, NIAID scientists conduct foundational research on the bacteria that cause plague, and the fleas that transmit them, to understand plague biology and to aid in the design of new MCMs.

Pandemic Influenza. NIAID is partnering with BARDA to support the development of vaccine candidates for influenza strains with the potential to cause a pandemic, including H7N9 avian influenza. NIAID also is working to develop broadly protective, or "universal," influenza vaccines that could protect against multiple strains of seasonal and pandemic influenza. NIAID recently developed a Strategic Plan to guide research efforts focused on the design and development of universal influenza vaccines.

Radiological/Nuclear Threats. NIH investment in radiation/nuclear research revitalized physician training and infrastructure for studying radiation injury and developing effective medical countermeasures. Since 2005, NIAID has transitioned 29 radiation/nuclear countermeasure candidates to BARDA for advanced development. Recent successes include FDA approval of NEUPOGEN® (filgrastim) and Neulasta® (pegfilgrastim) to treat radiological or nuclear injuries. In addition, NIAID is funding animal studies of Nplate® (romiplostim) for acute radiation syndrome for consideration for FDA approval under the Animal Rule.

Chemical Threats. NIAID administers a trans-NIH chemical countermeasures program that supports the development of therapeutics for people exposed to dangerous chemicals, including nerve agents, metabolic poisons, and toxic industrial chemicals. NIH recently transitioned several candidate therapeutics to BARDA for advanced development, including those for nerve agent poisoning (midazolam and galantamine), sulfur mustard exposure (tissue plasminogen activator), and inhalation chlorine exposure (R-107 and GSK2798745).

CONCLUSION

NIAID has moved strategically toward a MCM research paradigm that features broader, more flexible platform technologies. This effort is yielding significant scientific advances that help protect against multiple emerging public health threats, whether man-made or naturally occurring. Together with academia, industry, and PHEMCE partners, NIAID remains committed to meeting public health emergency needs by advancing high-priority research toward development of MCMs for radiological/nuclear, chemical, and biological threats, including emerging and re-emerging infectious diseases.

Hearing of the House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

The Role of the National Institute of Allergy and Infectious Diseases in Research Addressing Biodefense and Emerging Infections

Anthony S. Fauci, M.D.

Director

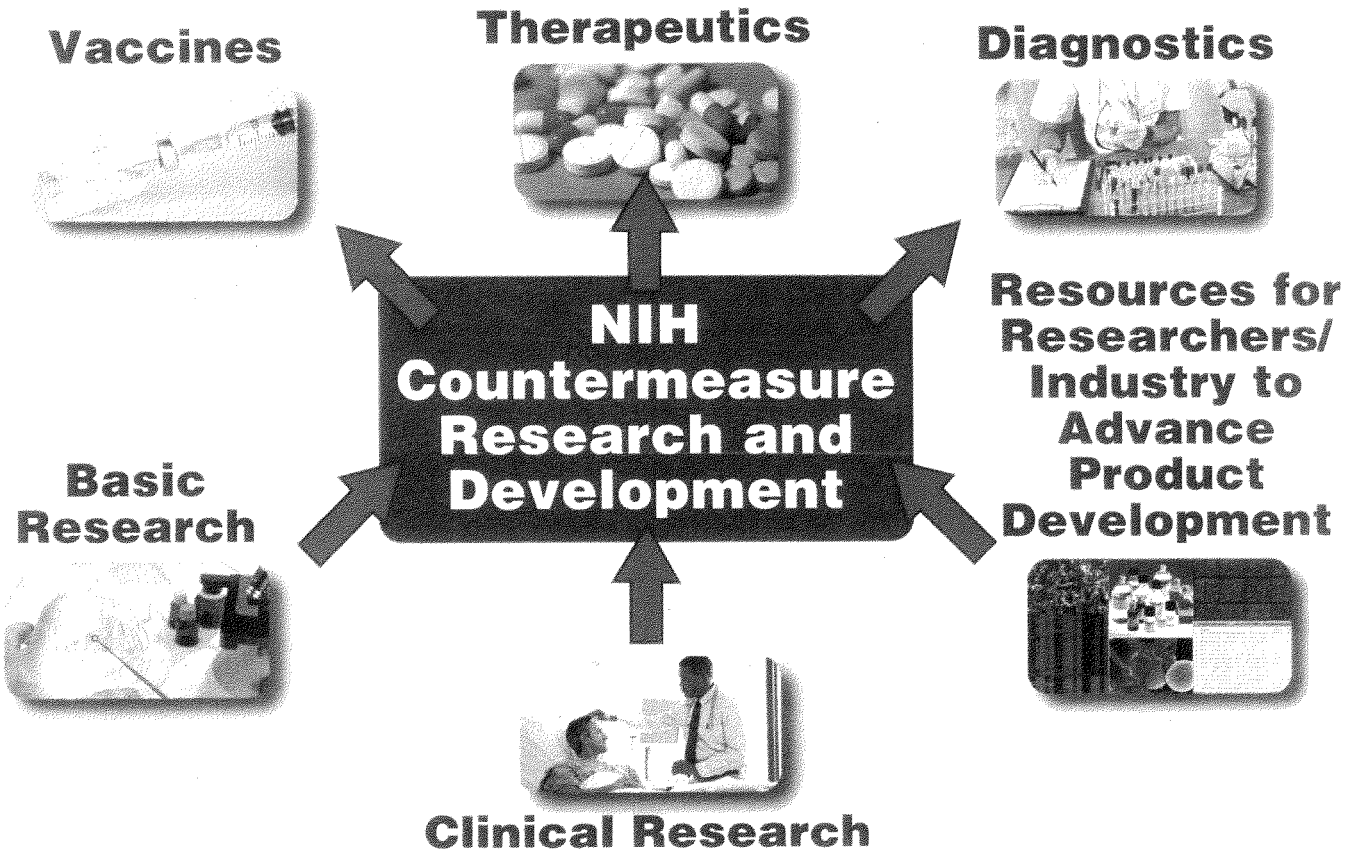
National Institute of Allergy and Infectious Diseases

National Institutes of Health

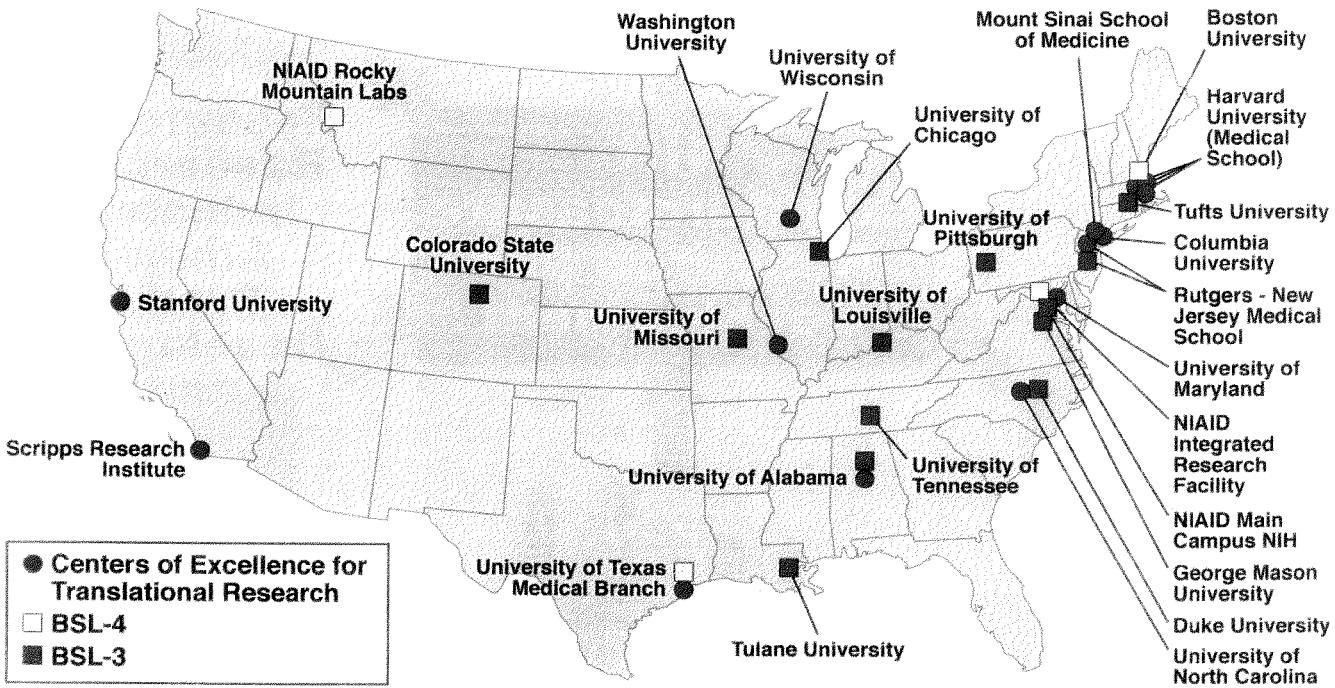
April 18, 2018

National Institute of Allergy and Infectious Diseases

February 2002
NIAID Strategic Plan for Biodefense Research
Responding Through Research
National Institute of Allergy and Infectious Diseases
NATIONAL INSTITUTES OF HEALTH
February 2002
NIAID Biodefense Research Agenda for CDC Category A Agents
Responding Through Research
National Institute of Allergy and Infectious Diseases
NATIONAL INSTITUTES OF HEALTH

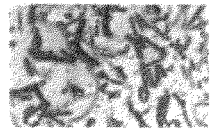
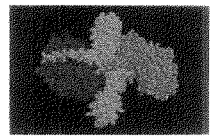
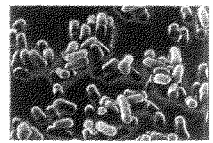
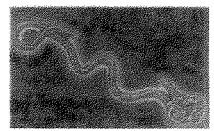

Vaccines
Therapeutics
Diagnostics
NIH Countermeasure Research and Development
Resources for Researchers/ Industry to Advance Product Development
Basic Research
Clinical Research

NIAID-Supported Biodefense Research Infrastructure, 2018



Category A Select Agents: Key Achievements

- **Smallpox**
  - Dryvax; MVA; antivirals
- **Anthrax**
  - Next-generation vaccines; antitoxins
- **Botulinum**
  - Antitoxins; mAbs
- **Plague**
  - Antibiotics
- **Ebola**
  - First human vaccine trials; therapeutics; diagnostics

06.2005

NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Radiological and Nuclear Threats

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases

NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Chemical Threats

Radiological and Chemical Threats: Key Achievements

- Radiation countermeasures for:
  - acute radiation syndrome (ARS)
  - radionuclide decorporation

- Chemical countermeasures for:
  - nerve agent poisoning
  - sulfur mustard exposure
  - inhalation chlorine exposure

Newsday

November 18, 2001

The Worst Bioterrorist May Be Nature Itself

Published online
February 28, 2018

IDSA

hivma
hiv medicine association

The Journal of
Infectious
Diseases

A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases

EJ Erbelding, D Post, E Stemmy, PC Roberts, A Deckhut Augustine, S Ferguson, CI Paules, BS Graham, AS Fauci

Bioterrorism: A Clear and Present Danger

HC Lane, J La Montagne and AS Fauci

Mr. COLE. Thank you very much for your testimony.

And Dr. Redd, I think it is the first time, at least in my tenure, we have had the privilege of having you testify. These guys are old hands at it. They have been invited back. So this is a big test for you. [Laughter.]

Admiral REDD. Appreciate the invitation.

Mr. COLE. But you are recognized for whatever opening remarks you care to make.

Admiral REDD. Thank you.

Chairman Cole, Ranking Member Roybal-Allard, and members of the subcommittee, I am Rear Admiral Stephen Redd, Director of CDC's Office of Public Health Preparedness and Response.

Thanks for the opportunity to testify before you here today to discuss CDC's role in biodefense. I would also first like to express my gratitude for your support of CDC's programs in the fiscal year 2018 omnibus.

CDC provides for health security of the Nation by working to prepare to respond to health threats of all kinds, including chemical, biological, radiological, or nuclear attacks, natural disasters, or outbreaks of emerging diseases. For 75 years, this has been CDC's core mission.

Today, I will highlight two aspects of CDC's work in biodefense, detection and response. And there are three themes that I would like you to appreciate as I give my remarks. Number one, the work CDC does every day in public health lays the foundation for responding to emergencies. Number two, CDC's world-class scientific and medical expertise ensures we are ready to respond to any threat. And number three, our connection to State and local health departments ensures that public health systems function effectively, both day to day and during emergencies.

Let me first talk about our work in detection. CDC has the ability to detect and identify agents causing disease, whether that cause is microbial or exposure to a chemical or radiation. Every year, laboratories from all over the world send hundreds of thousands of specimens to CDC because they know we will be able to identify pathogens other laboratories cannot.

Congress' support of our advanced molecular detection investments allow CDC to detect outbreaks faster before they become widespread. We apply these improvements to dozens of areas, such as food-borne disease, influenza, antimicrobial resistance, and even tuberculosis.

CDC's Laboratory Response Network maintains an integrated scalable, flexible system of 153 Federal, State, and local laboratories. The development of this network has provided a larger capacity to test and report more quickly than was possible before. For example, during the Zika response, CDC and other Laboratory Response Network laboratories processed 207,000 specimens.

Let me turn now to the response function. When there is a health crisis, CDC responds. We are able to rapidly deploy large numbers of scientific and medical experts anywhere in the world. By the end of the 21-month Ebola response, over 2,000 CDC staff had deployed to West Africa, and there are similar numbers in terms of volumes of responders both to Zika and the H1N1 pandemic.

During public health emergencies, CDC communicates both to professional audiences and to the public. During the H1N1 response, CDC held 39 press conferences and 21 telebriefings. During the Zika response, we published 51 morbidity and mortality weekly report scientific articles to ensure that public and professionals had the latest information.

For 75 years, CDC has worked closely with State and local public health departments. For the past 15 years, the Public Health Emergency Preparedness Program has deepened that relationship. For example, in the fall of 2014, CDC developed guidance for monitoring and movement of travelers returning to the United States who had potential Ebola virus exposure. Within 7 days of issuing that guidance, State and local health authorities implemented a system to track all travelers returning from countries with widespread Ebola transmission.

By the end of the response, these health officials had tracked over 21,000 travelers through their 21-day potential incubation periods. Being able to detect and respond to public health threats is a top priority for CDC. Our biodefense portfolio is built on a foundation of broad and deep scientific medical and program expertise. Our longstanding partnerships with State and local health authorities ensures better responses and better health outcomes, both day to day and during emergencies.

Thank you for the opportunity to testify, and I look forward to answering your questions.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

Hearing Titled, "FY 2019 Budget - Health and Human Services Biodefense Activities"

Testimony before the

House Committee on Appropriations

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Stephen Redd, MD (RADM, USPHS)

Director, Office of Public Health Preparedness and Response

April 18, 2018

Centers for Disease Control and Prevention (CDC)

Chairman Cole, Ranking Member DeLauro, and Members of the Subcommittee. I am Rear Admiral Stephen Redd, Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention. Thank you for the opportunity to testify before you to discuss CDC's role in biodefense, and how it fits into the nation's overall preparedness to meet such threats.

CDC advances the health security of the nation by helping communities prepare for, respond to, and recover from the public health consequences of all hazards. These hazards include chemical, biological, radiological, and nuclear threats; natural disasters; and epidemics. For 75 years, this has been CDC's core mission. CDC's multidisciplinary workforce supports an integrated national system that continually monitors the public's health and is able to respond when a threat is identified. This ability is enhanced by our long-standing relationships and close collaboration with Federal, state, and local partners.

CDC's approach to biodefense falls into two distinct functional areas: Detection and Response.

Detection

World-class scientific expertise and laboratories ensure CDC is ready and able to detect and develop a response to a broad range of threats, including highly hazardous and infectious diseases like Ebola, smallpox, and H7N9 influenza.

CDC uses advanced molecular detection techniques that combine next-generation genomic sequencing, high-performance computing, and epidemiology to identify pathogens faster and more accurately. Laboratories from all over the world send specimens to CDC because they know CDC will be able to identify pathogens that other laboratories cannot.

Congress's support of our Advanced Molecular Detection investments allows CDC to detect outbreaks faster, before they have become widespread. These improvements are being applied in dozens of areas such as foodborne disease, influenza, antimicrobial resistance, hepatitis, pneumonia, and meningitis. Moreover, CDC shares genetic sequencing technologies with state and local health departments, and funds them to acquire new technology that helps them respond quicker and more efficiently at the local level.

CDC also has an international presence, including longstanding collaborations with countries and institutions around the world. Detection is a shared responsibility requiring interconnected laboratories working with common methods and which readily share findings. These strategic partnerships are strengthened by forward deployment of CDC scientists stationed in more than 60 countries.

A Strong Laboratory Response Network

Rapid identification of disease is critical to addressing public health threats before they become a crisis. CDC's Laboratory Response Network (LRN) is an integrated system of Federal, state,

local, and international laboratories that is scalable and flexible enough to respond to biological, chemical, and other public health threats. The linking of these laboratories over the last 15 years with the LRN advanced our preparedness capabilities and provided for rapid testing, timely notification, and secure communication of laboratory results.

For example, in response to the Zika virus outbreak, CDC collaborated with the Food and Drug Administration (FDA) to equip LRN laboratories across the United States with the ability to quickly test specimens for the outbreak strain of Zika virus.

Public Health Surveillance

Public health surveillance—the collection, analysis, and use of data to target public health prevention and intervention activities—is the foundation of public health practice. CDC monitors population health information around the clock to detect and track diseases. For example, following 9/11, CDC invested in using health-related data based on patient symptoms (syndromic surveillance) to detect a bioterrorist attack. Those investments are paying dividends as this system now allows officials to detect a much wider range of health threats, from opioid overdoses to chemical spills to disease outbreaks. Moreover, CDC collects, analyzes, and interprets human, animal, environmental, and food surveillance data, to identify and respond to potential health threats before they become emergencies.

To ensure a nationwide surveillance capability, CDC supports surveillance infrastructure and practice at the state and local level through the National Notifiable Disease Surveillance System (NNDSS), the National Syndromic Surveillance Program (NSSP), the National Healthcare Safety Network (NHSN), the Emerging Infections Program Active Bacterial Core Surveillance (EIP ABCS), and components of national influenza surveillance. As part of CDC's Surveillance Strategy, we are modernizing the tools and services used in the NNDSS and the NSSP and are implementing standards for exchanging data. CDC's Surveillance Strategy guides our agency's efforts to make U.S. surveillance systems:

- More adaptable to rapidly changing technology
- More versatile in addressing evolving health threats
- More adept at accessing and leveraging health-care data
- More capable of meeting demands for timely, population-specific, and geographically-specific information

CDC's Global Disease Detection Operations Center monitors outbreaks 24/7, assesses their potential risk to the United States and communities around the world, and improves global public health surveillance. Since 2017, CDC has tracked more than 170 unique diseases globally and identified outbreaks in more than 190 countries.

The surveillance data, collected in collaboration with domestic and international partners, provide an early warning system, inform CDC's threat assessments, and ensure response actions are at the right speed, scope, and scale to protect the public. When requested, CDC provides the subject matter experts to help develop and implement the appropriate response.

For example, the collaboration between CDC and the Assistant Secretary for Preparedness and Response (ASPR) during Hurricanes Harvey, Irma, and Maria provided vital real-time situational awareness for local jurisdictions that experienced the disasters. The processes and relationships used during these hurricanes now are in place for future collaborations.

Response

Investments in preparedness and response promote both CDC's readiness to act and that the state and local public health systems funded by the agency have the capacity to respond in times of crisis.

Medical Countermeasures for Public Health Responses

Through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), CDC works with HHS agencies and other Federal partners to enhance preparedness for chemical, biological, radiological, nuclear threats, and emerging infectious disease by prioritizing Federal investments in medical countermeasures (MCMs). CDC provides agent-specific and public health practice expertise that puts the use of treatments and prophylactics in context. We understand how these products can be used in outbreak response, and the implications of the limitations that individual MCMs have, so that they can be integrated appropriately into a response. Within the PHEMCE, CDC subject matter experts use evidence-based science to provide technical expertise to state and local partners for public health emergency response planning, which includes: receiving, handling, and dispensing PHEMCE developed MCMs. Specifically, CDC subject matter experts:

- Develop clinical guidance on the use of PHEMCE MCMs
- Provide technical expertise to state and local partners for the development of deployment and dispensing plans for PHEMCE MCMs
- Conduct regular operational readiness reviews and exercises with state and local partners to ensure they are prepared and have the capacity to receive and dispense PHEMCE MCMs when responding to public health emergencies
- Review previously FDA-approved MCMs to develop clinical guidance for the emergency use of these MCMs for a potentially new indication when an emergency use authorization is in effect.

Just as important as having the right MCM available for deployment is knowing that state and local public health partners can effectively and efficiently receive those MCMs and get them to people in need of treatment or protection. For this reason, CDC offers virtual and in-person training, guidance documents, technical assistance, exercises, and other training programs to ensure that our partners have the knowledge and skills they need to dispense MCMs in a timely manner. In FY 2016, CDC supported 18 full-scale exercises and trained 2,232 Federal, state, territorial, and local emergency responders representing 43 different jurisdictions on how to receive and distribute products from the Strategic National Stockpile.

Role of State and Local Public Health Agencies

State and local public health agencies are the front lines of public health preparedness and response. CDC provides ongoing technical assistance and, where requested, on-the-ground personnel and materials to assist with response efforts. CDC's established relationships with state and local health departments ensure that day-to-day public health systems function effectively and efficiently and that emergency response actions are appropriate to the threat. These relationships also ensure state and local interests are taken into account during CDC's emergency responses.

The daily delivery of public health services, such as disease detection, surveillance, vaccinating children, and lab testing, is critical to public health preparedness and response. CDC encourages public health departments to use routine public health activities and real incidents to demonstrate and evaluate their public health preparedness and response capabilities. For example, state and local public health workers perform surveillance for serious illnesses and diseases and, when necessary, perform contact tracing to monitor the spread of those conditions. These same activities were put to use by jurisdictions to monitor for the spread of Ebola from domestic cases.

CDC also tests its pandemic influenza response capabilities with Federal, state, and local partners through virtual tabletop and functional exercises. CDC evaluates and improves its response plans based on lessons learned from previous responses and exercises.

To support our state, local, and territorial partners, Congress established the Public Health Emergency Preparedness (PHEP) cooperative agreement program, managed by CDC. The PHEP cooperative agreement program currently funds 62 awardees—including all 50 states, eight territories and freely-associated states, and four directly funded localities (New York City; Washington, D.C.; Chicago; and Los Angeles County). In FY 2018, Congress included an additional $10 million for PHEP, providing a total of $670 million for the program. These funds support preparedness and, on a limited basis, response staff, enable exercises to test and validate capabilities, provide for timely training, and pay for laboratory and communications equipment essential to maintaining preparedness. In addition, CDC helps grantees to identify and address gaps in preparedness capabilities, providing planning resources to ensure the needs of at-risk individuals are incorporated into response strategies, and improving response capabilities from experience gleaned during public health responses.

State and local health departments have greatly increased their capacity to respond to an array of hazards. For example, when a mumps outbreak in December 2016 sickened more than 800 individuals in Washington, the state mobilized a PHEP-funded Epidemiology Task Force to support local health departments with tracking disease cases and educating vulnerable communities about the benefits of vaccination. The outbreak response resulted in a dramatic increase in mumps vaccinations, with 5,000 additional people vaccinated, strengthening the community's resilience to both the current outbreak and future outbreaks of measles, mumps, and rubella.

Lessons Learned Inform the Next Response

CDC's number one priority during any public health emergency is to save lives. We are committed to continuously improving our response capability and after each activation we conduct a thorough after-action review to identify strengths to sustain and areas for improvement. After-action reviews collect data about successes and areas for improvement identified during unexpected incidents, exercises, and real events such as festivals or concerts that draw large crowds. Use of this information is key to improving performance for the next incident or event.

In response to experience during recent public health emergencies, CDC created a new funding mechanism ("Cooperative Agreement for Emergency Response: Public Health Crisis Response") that will quickly fund pre-approved awardees during public health emergency responses. This mechanism will enable immediate response activities and help mitigate negative health outcomes. We anticipate this mechanism will speed CDC's process of awarding supplemental funds to pre-approved awardees, potentially within weeks of supplemental appropriations being enacted.

During the Ebola epidemic, a critical lesson learned was that West African and other countries need effective systems to detect and stop infectious disease threats. As a result, CDC works with partners across the government on global health security to accelerate other countries' progress toward detecting and mitigating infectious disease threats quickly and effectively.

An outbreak that starts in another country can hit our shores in a matter of hours. Strengthening global health security also protects Americans' health. New diseases, like MERS and H7N9 influenza, can emerge without warning and have the potential to cause widespread infection and fear. CDC works with 31 Global Health Security partner countries to help them build the core public health capacities necessary for identifying and containing outbreaks before they become epidemics that could affect us all. Our global work strengthens four critical areas: surveillance, laboratory, workforce development, and rapid response capability. In addition, CDC medical and public health officers staff United States Quarantine Stations that are located at 20 ports of entry and land-border crossings where the majority of international travelers arrive. These health officers are the first line of defense to prevent the introduction and spread of infectious diseases.

Conclusion

The ability to quickly detect, and effectively respond to threats to the public's health is a top priority for CDC, the Department of Health and Human Services, and the Nation. CDC works around the clock to not only ensure its readiness but the readiness of those on the front lines: our state and local partners. CDC cannot predict the next disaster, but we know it is coming. The work we do now ensures that, when it does come, we are able to protect the health of Americans and save lives.

Mr. COLE. Thank you for your testimony. I think you did well enough to be invited back. [Laughter.]

SUPPLEMENTAL FUNDING

Mr. COLE. So you are in the major leagues now.

Let me start, if I may, and my first question will be to Dr. Redd and Dr. Kadlec. In recent years, Congress has relied upon supplemental funding legislation to support the response to measure public health emergencies such as Ebola and Zika. This approach creates uncertainty and unnecessary delays in response and recovery from these disasters.

The creation of a rapid response reserve fund is one option for enabling public health agencies to respond more quickly. Indeed, my normal partner up here, the gentlelady from Connecticut, has had legislation that she introduces on a regular basis. This committee itself a couple of years ago actually put in $300,000,000, and we did not do that in the 2018 bill.

Our friends in the Senate I think had an objection, and it is interesting one to talk about or to reflect on. Their concern was, look, the Secretary already has reprogramming authority up to 3 percent. We can always move with a supplemental. And they were very afraid, and I have had private discussions with Dr. Kadlec, but very afraid that if we did this that it would turn it into a just normal fund that was used every year whether there was a disaster or not. And that it would be distributed, and there is nothing against it, for the global health infrastructure.

That is fine. We are for that. But a reserve emergency fund needs to stay a reserve emergency fund, if that is going to be the use. If it evolves into something else that just is operational, as opposed to something that we deploy as needed, when needed, then it will be sort of self-defeating.

So, anyway, I wanted to ask each of you to reflect on the merits of that idea, whether or not that would be helpful in the respective response duties that we tend to give you in crisis situations. Please.

Admiral REDD. Yes, well, I would say that—I am sure that Bob is going to agree—we are fully supportive of that type of proposal. In fact, the administration in the 2018 President's budget proposed an emergency fund. It would have been through a transfer authority rather than an appropriation, but I think the general idea is we need a reserve fund.

Just to really add to your remarks, for H1N1, 54 days after the request, we received an appropriation. For Ebola, it was 4 months. For Zika, it was 190 days. So this is something that we need. We are really hamstrung during that period of recognizing the problem and being able to fully respond when we don't have funding.

Mr. COLE. Thank you. Dr. Kadlec.

Dr. KADLEC. Thank you, sir, for the question.

And I would agree with Admiral Redd. I think the key thing here is the similarity with the Disaster Relief Fund, the DRF, for which Congress appropriates monies in advance, knowing that events will happen. I think if we can anticipate that these things can happen, for the very reason that Admiral Redd said, that speed is really necessary. And giving the Secretary the authority to do this under a declared public health emergency with, obviously, the obligation

to notify Congress as to not only the utilization of the fund, but how it will be utilized would seem like an appropriate and responsible way to better position the United States Government and HHS to basically respond.

And that would be in total. Whether it be need for enhanced diagnostics, deployment of personnel or logistics, or supporting State and local authorities in their response activities, it would seem that that would be vital to have.

STRATEGIC NATIONAL STOCKPILE

Mr. COLE. Let me follow up on a related matter because a lot of this hearing is about what do we need to do to give ourselves the ability to respond quickly when something like this happens. Dr. Kadlec, in your testimony, you have described the administration's proposal to transfer Strategic National Stockpile from CDC to ASPR. And you know, we are inclined to try to give you what you want.

But would you please describe the main concerns and problems the Department identified that led to the proposal and tell us how these challenges will be better addressed at ASPR? If we have any time left—and we probably won't, but I will get back to it—Dr. Redd, I would be very interested in your opinion, since we now house this down at the CDC.

So, Dr. Kadlec.

Dr. KADLEC. Well, thank you, sir, for your question.

And I think the key thing here is that when ASPR was created back in 2006, it was the original idea to transfer the stockpile over, realizing that the stockpile had moved around a lot in the early 2000s from CDC to Department of Homeland Security, back to CDC. But it was recognized at that point in time by the Secretary that ASPR was not capable of doing that.

And I think at the point in time now where ASPR has demonstrated its chops during the three hurricanes this past year, as well as the opportunity to kind of put the oversight—again, nothing is moving, per se—but put the oversight of the entire end-to-end spectrum of development, stockpile, and replenishment under the authorities of the ASPR, in collaboration with CDC, was his decision to basically do that at this point in time. That won't come into effect until 1 October.

And clearly, our responsibility in doing this, besides trying to get better efficiencies in the medical countermeasure enterprise, is to work closely with CDC and our State and local authorities to basically respond in a way that is enabling to mitigate the potential public health risks.

Last night, Tom Frieden, at the end of our dinner, grabbed me and said, "Are you going to federalize the SNS as a result of this move?" And I said, "No, not at all." I think everything we are trying to do and the role that I play in this is to make sure that we bring the full weight of the Federal Government in support of State and local authorities.

So everything we will need to do is really helping them be successful to help their citizens, and we will do that in close collaboration with CDC, as we have done in the past.

Mr. COLE. Well, thank you. I am abusing my time here. So I don't want to do a follow-up, but I do want to make sure as we continue our dialogue on this that, you know, the excellent relationship CDC has established with State and local officials, that that sort of—that we don't either duplicate it or that we preserve it, and that we make this—this organizational change in a way that makes it stronger, not one that either, you know, is duplicative, let alone something that might disrupt the relationships we have.

That would be my main concern, as we have talked about privately.

Mr. WOMACK. Mr. Chairman? Look, as one member of the panel, I think it is a great question. I would really like to get Dr. Redd's response, and I don't know if the other Members——

Mr. COLE. Well, only with the gentlelady's permission.

Ms. ROYBAL-ALLARD. Absolutely.

Mr. COLE. Well, thank you. Please.

Admiral REDD. Thank you.

We are moving forward with the decision to relocate the stockpile, the leadership of the stockpile from CDC to ASPR. I think our focus has really been on making sure that we are able to achieve the mission of delivering countermeasures when there is an emergency.

We have established five subcommittees working with ASPR to make sure that we are addressing all of the issues that need to be addressed. I would say that the two most important ones of those five are the continuing relationship of the subject matter expertise in the—kind of in the bookends of the countermeasure development process. On the front end, making sure that the product-specific requirements are going to produce a product that is usable by the end-users. And then, at the end of that, making sure that the link with the State and local health departments is there.

That second—the second thing really is that linkage with the State and local health departments. We have got that long-established thing. We are working closely with ASPR on this. Actually, yesterday, Dr. Kadlec's chief of staff was in Atlanta to work on those issues. So we are really diligently applying ourselves to making sure that those two—there would be a little bit more distance organizationally, but that doesn't compromise the mission.

Mr. COLE. Well, I thank you. And I want to thank the indulgence of the committee for allowing me to pursue that a little bit longer, and I apologize for abusing my time.

So I am going to have to be generous with the rest of you now, something I don't like to do. [Laughter.]

Ms. ROYBAL-ALLARD. You said that.

Mr. COLE. Yes. But so I now turn to my good friend, the acting ranking member, the gentlelady from California.

ANTIMICROBIAL RESISTANCE

Ms. ROYBAL-ALLARD. Thank you.

I mentioned that some of our panelists have at least seen Sunday's article in the New York Times about the dangerous rise of antimicrobial resistance in Yemen. According to that article, and I am going to quote, "After years of bombardment that has crippled the food supply, destroyed basic infrastructure, and disrupted med-

ical care, Yemen has become a breeding ground for antibiotic-resistant disease. More than 60 percent of the patients admitted to the Doctors Without Borders hospital in Aden have antibiotic-resistant bacteria in their systems."

And this is another quote from a Dr. Nagwan Mansoor, who says that, "Doctors in Yemen struggling to treat the rush of patients often use broad-spectrum antibiotics on even simple infections. This creates a new generation of multi-drug resistant bacteria." The article also notes that similar findings have been in Syria, although it is extremely difficult to conduct studies in these war-torn religious—or regions, rather.

And I realize that this panel does not include anything from CDC's Center for Global Health, but I do think that in this hearing on biodefense, it needs to include a discussion on our activities to prevent, identify, and respond to potential outbreaks in developing countries and war-torn countries where diseases are likely to arise.

Can the panel please talk about what HHS is doing to detect outbreak and antimicrobial resistance in places that don't have the healthcare infrastructure to identify and respond to these threats?

Dr. REDD. Thank you, ma'am, for that question.

CDC has been working very hard on the Global Health Security Agenda since 2014, and I want to thank the committee for the 2018 appropriation that added $50,000,000 to that work. It is a very important bridge from the supplemental funds from the Ebola response. Fighting antimicrobial resistance is one of the 11 action packages in the Global Health Security Agenda.

I would point out one thing that also came up at the dinner last night, that the locations that you cited as having these problems are challenging areas to work in. And I think that may be beyond the hearing today, but I think that the civil disorder makes it very difficult to either provide medical care or to intervene from a public health standpoint.

CDC's antimicrobial resistance program in the U.S. has got—has got five—four components, and this is separate from developing new antibiotics, which we know we need. But there are ways to use the antibiotics that we have more effectively and to prevent resistance.

The first is actually to prevent infections, which, if you don't have an infection, that limits the chances for that microorganism to become resistant. The second is work we are doing both in the laboratory and in surveillance to identify these infections as early as we can to limit their spread. Third is to improve the stewardship of antimicrobials. So not everybody gets an antibiotic. Those are really limited to the people for whom they will be most useful. And then lastly is really on the innovation front, new antibiotics and also new diagnostic tests to identify antimicrobial resistance.

Dr. FAUCI. Ms. Roybal-Allard, let me just add that that is a very important point that we consider, all of us, and certainly from a research standpoint, antimicrobial resistance as an integral part of what we call biodefense against emerging infections. Because we do consider an antibiotic-resistant bacteria an emerging infectious disease.

And not only in Yemen, we have a problem also in India. We have been getting infections, particularly carbapenem-resistant

Enterobacteriaceae and others, that when people go there, for example, with medical tourism, to come back, and in our hospitals we now have problems with things that have originated elsewhere. So not only do we feel we have the responsibility to help them over there, but any time you have a resistant microbe that emerges in another country, inevitably, it will come to the United States.

ANTIBIOTIC RESISTANCE IN PUERTO RICO

Ms. ROYBAL-ALLARD. Well, let us come a little bit closer to home then because I am concerned about the ongoing recovery effort in Puerto Rico. And Dr. Redd, has CDC's surveillance and lab testing discovered any increase in antibiotic resistance since last September's devastating hurricane?

Admiral REDD. I would like to get back with you for a confirmed answer. My understanding is that we have not. We are providing reference laboratory services to Puerto Rico in their process of their bringing their reference laboratory back up to speed. But I am not aware of any and will confirm that.

[The information follows:]

There have been no specific reports about antibiotic resistant (AR) pathogens stemming from the effects of the 2018 hurricanes in Puerto Rico. Irrespective of the hurricanes, Antibiotic resistance in Puerto Rico is a well-established problem in many communities and health systems.

COMBATING ANTIBIOTIC RESISTANT BACTERIA BIOPHARMACEUTICAL ACCELERATOR

Ms. ROYBAL-ALLARD. Can you give us an update on CARB–X, the joint venture between NIH and BARDA to stimulate innovation of new antibiotics and other products to respond to the threats of antimicrobial resistance?

Dr. KADLEC. Ma'am, I think I can, and then I will turn to Dr. Fauci to add additional insight. It is kind of a unique program in the sense that it has taken about $70,000,000 of Government funding and, working with a public-private partnership, resulted in about a $485,000,000 investment by private equity to fund 28 different companies and to work on 8 new classes of antibiotics. And there are 20 potential high-quality antibacterial products that are coming out of that effort.

Again, it is a unique kind of venture, capital kind of model, and quite frankly, we are working with international partners, such as the Wellcome Trust, as well as private and public entities in the United States.

Dr. Fauci.

Dr. FAUCI. Yes. The NIH's role in that is, again, what I mentioned in my opening statement, is that very strong partnership between ourselves and BARDA in which we provide not only the intellectual expertise about the research, but actually, the concept development so that we can partner with private industry to develop a product. Because it all starts off with a concept, which often the pharmaceutical companies don't make the investment that early on in the process. So the combination of our doing that early on and BARDA taking it further in the advanced development is the major part of the CARB–X program.

Ms. ROYBAL-ALLARD. Thank you.

Mr. COLE. Okay. I am now absolved. We are back on the 5-minute clock. So very good.

With that, we will go to my good friend from Tennessee, Mr. Fleischmann.

SYNTHETIC OPIOIDS

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And to this distinguished panel, thank you for being here and allowing us to have this most beneficial hearing. Appreciate that.

Gentlemen, we have been talking a lot in this subcommittee and the Homeland Security Subcommittee about the threat posed by synthetic opioids recently. During a hearing with CBP, where they recounted a recent seizure of carfentanil, my distinguished colleague Dr. Harris caught my attention after doing some quick math in noting that the seizure alone was capable of killing over a billion people.

Obviously, we have been focused on the opioid issue with the danger it presents to public health, but I have quickly realized that synthetic opioids could be utilized as a chemical weapon. Indeed, it is believed that Russians deployed synthetic opioids as a riot control agent in the 2002 Moscow theater hostage crisis, which saw heavy civilian casualties.

Is there a reason to fear—for Congress to fear that organizations seeking to do us harm could be looking at these substances as possible chemical weapons, and if so, do you all have any recommendations on confronting this challenge?

Dr. KADLEC. Thank you, sir. I think I will take a first swipe at your question.

And I think the answer is to your question, yes, there is a concern. Number two is there is more detail that could be provided in a classified setting that I am happy to provide. But the third thing is, is that Department of Homeland Security has issued a material threat determination for fentanyl products. So it has identified, if you will, it as a material threat to our national security. That was signed out by Secretary Nielsen about 2 weeks ago.

And our expectation with BARDA is that we will be researching. We have done already some market surveys to see what is available out there already in the pipeline. We see this as a great opportunity to get a two-for, if you will. To not only look for the homeland security benefit of this, to protect our—potentially our first responders and others, but also to find things or products that could be useful in the opioid crisis that we are experiencing here domestically.

So we are in the midst of that. We will be working closely with Dr. Fauci and his colleagues at NIH, with our SAMHSA colleagues as well, and obviously CDC to figure out what would be the best kind of products to do that. But we are early in that evolution.

Mr. FLEISCHMANN. I thank the gentleman.

Admiral REDD. The opioid crisis is huge without this other potential threat, and I think the work that we are doing to combat that crisis that exists without the terrorist threat is going to help us be more effective in responding to a terrorist threat.

So I think that it—I agree with Dr. Kadlec. It is a two-for. I think the work that we are doing day to day is going to make us better able to respond should an attack occur.

INTERAGENCY COLLABORATION

Mr. FLEISCHMANN. Thank you.

A follow-up question. Dr. Kadlec and Dr. Redd, in your testimonies, you both note the work that the Department of Health and Human Services is doing to prepare for various public health hazards, including radiological releases or attacks. I am sure you are aware the Department of Energy and the National Nuclear Security Administration, NNSA, also have important resources devoted to the same missions.

For example, the Radiation Emergency Assistance Center Training Site, REACTS, is located in my district. REACTS is prepared to provide emergency medical assistance in the event of radiological or nuclear incidents and also provides educational opportunities to students and professionals in the areas of radiation emergency medicine and radiological or nuclear incident medical management.

Could you describe how assets from your Department would work with experts from the Department of Energy in the event of a radiological or nuclear emergency and how you ensure that the roles are not duplicable and the responsibilities are clear?

Dr. KADLEC. Thank you for your question. I will take, again, first take on this question.

And the first thing is our National Disaster Medical System would be the primary entity within HHS, at least in my organization, that would have the benefit of the expertise that resides with REACTS and the other programs in DOE. We believe that this provides an excellent opportunity to build a regional medical kind of disaster response system, where we could use the assets, particularly the educational assets that are created by your institutes to basically promote educational awareness within the healthcare community around the country.

We are working to create a model that would be very similar to the Ebola model that was created where we identified some Centers of Excellence around the country, again to promote not only best practices, but also to propagate information and training and also consultation should there be an emergency.

So I think there is great opportunities to do that. I know Director Lisa Gordon-Hagerty from NNSA, and I served on Oak Ridge's scientific board. So I am very familiar with the capabilities that reside out there, and they are ones that we will utilize going forward.

Thank you, sir.

Mr. FLEISCHMANN. Thank you.

NUCLEAR AND RADIATION EXPOSURE

Admiral REDD. Radiation and nuclear get put together. I think they actually are quite separate in terms of the kind of response that would have to be mounted. An exposure either through food contamination or from a radiation dispersal device would be an event that would expose people to radiation, but not to a nuclear detonation. And that would—that would have a lot of laboratory

components to it. It would be a public health response largely, of course, with law enforcement elements.

Nuclear detonation, I am in total agreement with what has been said. This would be a huge—a huge infrastructure-destroying event. FEMA and DOD would be in the lead. We would be supporting all of that.

We have spent a lot of time thinking about what our role would be and how we would interface with the rest of the Federal Government response. We have laboratory capabilities. We have communication abilities and basically how to explain to people what radiation exposure is. We have clinical expertise, and in the aftermath of the event, we would be establishing registries to follow people who have been exposed.

Mr. FLEISCHMANN. Thank you. Mr. Chairman, I yield back.

Mr. COLE. Thank you very much. Mr. Pocan.

SYNTHETIC OPIOIDS

Mr. POCAN. Sure. Thank you, Mr. Chairman.

And thank you all for being here.

I want to echo what Mr. Fleischmann just asked about. My first question was the same first question you had around the synthetic fentanyl and how it could be weaponized as an opioid and perhaps used by terrorists and others. So I think you answered a lot of what I also had a question on. I just hope also that we are working with—across agencies, DHS, FDA, and others who are working on this issue.

Because, you know, clearly, it is of concern to a number of us, and I appreciate you asking that question. So you also saved the committee now a little time on doing that. So thank you.

Do you want to say something, Dr. Kadlec?

Dr. KADLEC. Sir, I would just like to highlight one thing. In our collaborations, I didn't mention earlier is with Department of Defense on this issue as well. They have a particular interest because it is a national security threat. So we are hoping to leverage, as we are doing in other areas, with Department of Defense a lot of their unique capabilities and a lot of their research and really trying to forge a closer partnership so we can benefit from the things that they are doing that now are more relevant to what we are doing in terms of addressing some of the threats that we look forward to in the not-too-distant future.

Admiral REDD. Just to add briefly, the list of groups that we are working with, of course, FBI, but Department of Justice and DEA on the fentanyl question.

Mr. POCAN. Right. Yes, Dr. Fauci?

Dr. FAUCI. I just want to comment because it has been brought up two or three times. Last week at the hearing of the NIH's budget, we spent, as you remember, Chairman Cole, a lot of time, questions and discussions particularly with Nora Volkow, about the effort that we are putting in with fentanyl. But this is a typical example of the resources that this committee generously put into the fentanyl situation that the NIH clearly has that double advantage of being able to address particularly some of the countermeasures that you need if you are dealing with fentanyl in an entirely dif-

ferent setting than we generally see it with overdoses and with the natural addictions.

So it is really, I think, a classic example of how efforts in one area indirectly and sometime directly benefits another area.

PANDEMIC AND ALL HAZARDS PREPAREDNESS ACT

Mr. POCAN. Again, thank you, gentlemen. And obviously, interests both sides of the aisle. If you need additional assistance, talk to us.

The other area, the Pandemic and All Hazards Preparedness Act, I think you talked about and you showed on the slide where BARDA works with some local companies on things. You work with a company in my district, Stratotech, right now on a product. And it is—Steny Hoyer was in my district 2 weeks ago, I think it was, and we took him to Stratotech to tour it because, really innovative, they make a synthetic skin. Essentially, that should you have burns, flesh-eating virus, severe abrasion through whatever it might be, rather than taking your own skin, this actually 28 days later heals better than your own skin, and you don't have that secondary, you know, problem.

And they have had some above—better than expected test results out of this. You are working with them right now. We really appreciate that. I think that is a classic example of how well that is working now, you know, in doing something like that and having some stockpile.

I was just wondering what we are doing to ensure those programs that support medical countermeasure development continue to get the adequate funding and invest in innovative breakthroughs that we can respond to all sorts of other threats. But this is just one I see in my backyard. And again, it has been a great partnership, and we are very appreciative of it.

BIODEFENSE SPENDING

Dr. KADLEC. Well, sir, I just would just add that one of the great challenges we have, since you just raised it, is the sustainment of some of this over time. Not only in terms of the development, but the procurement and also the replenishment, which is a real issue that probably down the road that you will probably see as you will see our 5-year multi-year budget reflecting some of our increased costs around the Strategic National Stockpile to make sure that we can maintain these capabilities.

Part of this is trying to figure out how we can do it a little bit better, hopefully a little bit cheaper. But in the end, and I made this allusion to Chairman Cole yesterday, that in the course of events, we spend about half what it costs for an aircraft carrier. And quite frankly, if you look at the USS *Gerald Ford*, that is $17,000,000,000 to build that one aircraft carrier. The Navy has 10 of them.

And so the question is, is what is the appropriate level of funding and sustainment we need for the biodefense enterprise? And that is not just for medical countermeasures, that is to create a robust public health infrastructure and laboratory capability. It is to ensure that we have the kind of R&D foundation that is represented by Dr. Fauci and his colleagues at NIH, as well as supporting the

abilities to basically create the kind of health surge capacity that we need out there and having the kind of mobilizable teams that we need to respond to disasters as we did with the Hurricanes Maria, Irma, and Harvey.

So as you kind of reconsider this or consider going forward, I would just argue to you, you can't do much with a half an aircraft carrier. Won't float. Won't fight. But that is one of the areas that, quite frankly, drives me forward in terms of how we can do things better to inform you all, to work with your staffs in a way that understands the challenge not only today, but over the long term.

And to your point, Mr. Chairman, how can we basically create a sustainable institutionalized system to protect America going forward?

Mr. POCAN. Thank you, Mr. Chairman.

Mr. COLE. Thank you. What an eloquent way to ask us to double your budget. [Laughter.]

Mr. COLE. That was really well done. I asked him to use that half an aircraft carrier deal. I didn't know I was going to open myself up for this.

But I just do want to make the point before I go to my friend Dr. Harris, who really is—got probably more expertise than anybody else on these subjects. I think you just put your finger on something that is really important, which is if you look at the security of the country, this is part of the security of the country and very much the same way what we do at the Department of Defense.

And resource wise, we look at the danger, the real danger for thousands of Americans being killed, it is much more likely to come from this direction than a foreign actor, quite frankly. Although we are obviously concerned with that, too. So having that kind of robust defense capability, if you will, is surely important I think to the security of the country.

With that, I want to go to my friend Dr. Harris, who does know a lot about this, to say the very least.

ADVANCE APPROPRIATIONS

Mr. HARRIS. Well, thank you very much, Mr. Chairman.

Maybe we will go on off on a little tangent that wouldn't require quite doubling the budget. But Dr. Kadlec, you know, we increased in this year's—in the omnibus bill, increased the appropriations for ASPR, but we didn't do one thing, which is to do advance appropriations. And the reason why I say that is because your carrier analogy is perfect. I mean, the Navy would never start building a carrier without knowing that they could finish building it. They just don't do it.

Because they are pretty confident that they can build into—they have an idea of what future budgets are. They can build into it. But in fact, as you know, that there has been volatility in the funding for biodefense, and that volatility is the uncertainty that the Navy would never—would never build the aircraft carrier if they had that uncertainty.

So with that, what do you think—I mean, should we—do you believe that we should be providing advance appropriations? And is it—I noticed that it was—I think the concept was in the fiscal year

2018 add-on, but not in the fiscal year 2019 budget. So you can expand on that.

Dr. KADLEC. Well, sir, I kind of view it personally as a vital element of the strategy going forward. I think you highlighted the volatility, and again, the way we can functionally do what we do at BARDA or at NIH or at CDC is really working with the private sector, who has the capacity, who have these great ideas for which we kind of help them down the pathway from concept to candidate to a licensable product to an FDA-approved product.

And quite frankly, it is a risky and long proposition. Eight to 10 years, $800,000,000 to $1,000,000,000, depending on the product. And quite frankly, BARDA has demonstrated they can do it a little bit cheaper, and I think the CARB–X model highlights the role, the positive role the Government can play when it basically asserts interest and commitment to an endeavor like they did with CARB–X.

And so I think it is very clear in the cases of these products that have no commercial value that an advance appropriation is vital to ensure that companies who have to consider the opportunity costs, the risks, to know that if they do this, both for the virtue of their own financial benefit, but also for the security of this country, that they will be a willing partner and, if you will, consumer of that product, if you want to call it that, a purchaser of that product at the end point.

Mr. HARRIS. Sure. And I would imagine that would be a much more efficient way of doing it because with higher risk, obviously, has to come higher cost.

Dr. KADLEC. Yes, sir.

STRATEGIC NATIONAL STOCKPILE REPLENISHMENT

Mr. HARRIS. Higher price to us. Admiral Redd, the SNS maintains many products, many of which obviously expire, like medical products do, and need to be replaced. Do you know what the current funding estimate of the required replenishment needs are?

Admiral REDD. That is a moving target. Let me get back to you on that.

Mr. HARRIS. Okay. I would appreciate that. And you know, it is——

Admiral REDD. I would say it is in the several hundred million dollar range, but we can—we can get you a specific number.

Mr. HARRIS. What was the fiscal year 2019 funding request for that, do you know? Or you can get back to me at that, too.

Admiral REDD. Well, the 2019 request is actually in the ASPR.

Mr. HARRIS. Oh, it is ASPR. That is right because the move is going to occur. All right.

Admiral REDD. For fiscal year 2018, I believe it was $700,000,000.

Mr. HARRIS. Okay.

Dr. KADLEC. Sir, $575,000,000 for the fiscal year 2019.

Mr. HARRIS. Seven what?

Dr. KADLEC. Five seventy-five, sir.

NATIONAL INSTITUTES OF HEALTH DIAGNOSTICS

Mr. HARRIS. Five seventy-five. Okay, $575,000,000.

And Dr. Fauci, you know, your slide was kind of fascinating about what the NIH's role is in terms of the products being the therapeutics, the vaccines, and the diagnostics. And in all three of those areas, it appears that this double advantage you talk about is true in all those areas. I mean, you know, the discoveries, for instance, on vaccine development can be for a disease unrelated to bioterrorism. The discoveries on therapeutics, I mean, you know, when you get the flu, it is there are standard measures that are good for other disease as well.

And with the diagnostics especially, I would imagine that mainly the ability to have the diagnostic capability revolves around having what I will call the organizational infrastructure. You have to have places where you can do the diagnostic tests and get things, and then you have to have the technology. And I imagine the technology is transferrable from other—from other things that are investigative.

Dr. FAUCI. Right.

PLATFORM VACCINE TECHNOLOGIES

Mr. HARRIS. So it seems that that would be a good investment on our part to—and again, the NIH has that double advantage because these things are good for more than one. But I do want to ask about the technologies around vaccines because it appears that the platform vaccine technologies are important. Obviously, developing a universal flu vaccine is important, but they are not the same. I mean, they are different pathways.

Are both important in terms of—in terms of the bioterrorism, it would appear that the—that the emerging platform technology would be a priority because it is just—it is more applicable. It is applicable across a broader range of disease. What is your——

Dr. FAUCI. Yes. I feel very strongly about the new platform technologies being very clearly extrapolatable from the dual use that you are talking about, emerging infectious and responding to a deliberate outbreak. There is no question about that.

If you look at the technologies that we are perfecting now that once you get the platform perfected from the standpoint not only of using it, but the FDA being comfortable with the use of that platform, the rapidity with which you can go from the identification of a microbe particularly to a vaccine is just stunning in the difference between having to like the old days, getting a pathogen, growing it up, and activating it or killing it or attenuating it, and then putting it into a system.

Right now, for example—and I think I may have mentioned this briefly at the last hearing—when you have something like the DNA platform, which is a plasmid that you just stick a gene in. And that gene can be anything. It could be the gene for influenza. It could be the gene for Ebola. It could be the gene for Zika. Once you get used to that platform, you can move much more quickly.

So you really hit on something by what you said. It is probably one of the most important advantages of developing platforms that you could use in virtually any setting.

Mr. HARRIS. Okay. Thank you. I yield back.

Mr. COLE. I thank the gentleman very much for his questions. I am going to do chairman's prerogative here real quickly, and not

to actually disagree, but remember, we don't forward fund defense, for instance. Because we have built in the habit, the Navy is going to be back asking for that carrier, and no administration is going to be silly enough.

And that is actually one of the aims of this hearing is to try and build the institutional memory in relationship. So we look in this. You look at the reasons for those variations. Quite often, it is this committee deciding we have got to move money here rather than there. Or quite often, it is the administration.

And I am just suggesting we are now in an era now where we can't do that. And what you are proposing is a good way to institutionalize it. So I am not arguing with that. But the real aim here is we have got to start approaching these issues where each and every year, okay, this is a real to national security. We will make these appropriations. We will make the appropriate—and sort of like what we are doing with NIH. We sort of made, okay, muscle memory. We are going to do this every year to some level.

It doesn't mean you can't look at it, cut it, change it. But you know, I just—we have not thought about this, I think, as much as we should institutionally. The Congress has not. So, but great points, as always.

With that, I am going to go to my friend, the patient Ms. Clark down at the other end of the table. Thank you very much for your indulgence.

CLIMATE CHANGE

Ms. CLARK. Thank you, Mr. Chairman, and thank you for—I really appreciate your comments on making this muscle memory and making sure that we understand how critical this is to our national security and that we can't do it, the nature of research requires that we have a constant funding stream that you can rely on.

It doesn't mean we can't change things, be adaptable, flexible, look for better efficiencies. But that it is really critical to how we move forward together.

And I want to thank Dr. Redd. Got a chance to go to the CDC. I really appreciate the tour you gave me, however brief we had to make it, and the work that you are doing.

And there were a couple of threads from that tour, combined with Dr. Kadlec's—in his testimony, you noticed extreme—you referenced extreme weather events and climate change. And when I was at the CDC, one of your staff asked what keeps you up at night? And your answer was influenza that we are not ready for, a pandemic flu. And then I went across campus to the laboratories, and one of the concerns that was raised there were pathogens and viruses that may be released from melting polar caps that we are not ready for, that we haven't seen.

And I wondered if anyone on the panel, this is a question to all of you, if you can tell us a little bit more about the relation between climate change, the increase in natural disasters, and what we are doing as far as public health and planning for that future?

Dr. KADLEC. Ma'am, I will take a first shot at this and then turn to Dr. Fauci and Dr. Redd.

I would probably just suggest that there is a wonderful, I guess now historic, tome that was written by two people, Lederberg and Shope, back in, I believe, 1990-1991 on emerging infectious diseases. And they elegantly and eloquently kind of identified the relationship between the risk of emerging diseases now almost two decades ago, almost three decades ago, to the risks of not only global climate change, but also the change of human behavior as we become more of an urbanized environment, where we have higher density of people living together.

I think the thing is, is that even though that in some ways what they have historically written now has come to pass, it just demonstrates the prescience of their intellect and insight. But I think the thing is that as we live it today, it just highlights the role that the CDC plays in terms of its early warning and identification and detection and diagnosis, both domestically and internationally and how it promotes that.

It certainly reflects, I think, the responsibilities of what Tony's portfolio has done in the past, Dr. Fauci's portfolio has done. He can talk about that, looking broadly at the risks that are out there. And then really relates to what we needed ASPR and BARDA to do, is be prepared to respond when those things, God forbid, become a potential pandemic or are used by no-gooders against us.

So it does reflect, I think, the need for a responsive, agile, robust set of capabilities across the domain to respond, and now I will turn to Dr. Fauci.

Dr. FAUCI. One example among many of how there can be an impact on climate change and global warming on an outbreak of infectious disease is less so an acute outbreak, but more subtle things like the range of vectors, particularly mosquitoes. So when you have a situation where you are dealing particularly in temperate climates where you can tell as you get further north and the weather gets colder earlier, you have the shut-off of a mosquito biting season.

If you get even very slight degree of temperature changes, not only do you increase the range, but also when you talk about altitude. For example, mosquitoes don't get any problem above a certain altitude merely because of the temperature. When you get down lower, you can get much more mosquito activity. Even a slight change in temperature can impact in the long range, ranges of not only mosquitoes, but ticks and other vectors of important diseases.

NOVEL DISEASES

Admiral REDD. Let me just add that the kinds of diseases that emerge can't always be predicted, and if we think back to Zika and Ebola, those were diseases that were known. But their impacts really hadn't been imagined before their events—those events actually occurred.

When we are responding to diseases like that, since we haven't planned and we are unlikely to have a countermeasure that is going to be effective against them, what we really need to be able to do is to collect, analyze, understand the situation and adapt our response to that. And that may mean using almost 19th century

interventions, quarantine, person-protective equipment, things that can prevent exposure or transmission of disease.

The thing that is different about these is it really requires a flexibility and nimbleness and an adaptability as the primary capability.

Ms. CLARK. Thank you.

Mr. COLE. Thank you. We will go next to my good friend from Michigan, Mr. Moolenaar.

INFRASTRUCTURE

Mr. MOOLENAAR. Thank you, Mr. Chairman, and good to see you all today.

As we were talking, in recent years, the Ebola and Zika virus outbreaks have demonstrated that global infectious disease emergencies are unpredictable and that outbreaks in distant countries can reach our shores. Several years ago, an NIH working group on construction of research facilities identified a disturbing trend that much of the Nation's biomedical research infrastructure, including laboratories and research facilities at academic institutions, nonprofit organizations, and hospitals, is fast becoming outdated or insufficient.

It is my understanding that funds to support upgrades to such facilities have not been issued for some time. And Dr. Fauci, this is, I guess, a question for you. The issue was also highlighted in Dr. Collins' testimony and statement last week during the hearing on fiscal year 2019 National Institutes of Health budget request.

He stated, "The President's budget includes a much-needed increase in buildings and facilities." And in his statement, he cited that, "This budget will allow the NIH to continue to repair and upgrade deteriorated infrastructure," and that, "The condition of NIH laboratories ranks near the lowest in the Federal Government."

As you are also aware, the fiscal year 2018 omnibus also included $480,000,000 to the CDC to build a new containment project lab. And two questions. Is there is a need for upgraded or additional extramural biomedical research facilities in order for the United States to be better prepared to handle major outbreaks and maximize the increased Federal investment in medical research?

Dr. FAUCI. The answer is yes, Congressman. You mention two separate things. The specific NIH problem is an acute problem that we have with regard to the on-campus infrastructure, particularly with regard to the clinical center. That is much more acute than the second part of your question, which is the infrastructure to carry out the kinds of protected experiments that we do. And you really have to divide it up into BSL–4 versus BSL–3.

We have now in our—now that the Boston University BSL–4 is up and running, we have what we need right now to address the situation regarding the study of microbes that would require that type of containment. We have Boston. We have the University of Texas Medical Branch. We have the Rocky Mountain laboratory in Hamilton, Montana, and we have the integrated research facility in Frederick, Maryland. We are okay with that.

What we feel we probably do need more of is a much lesser, a BSL–3 type facilities. And in fact, we have now, over the last couple of years, converted the original research Centers of Excellence

into the research centers of translational research that we now have throughout the country. So we do have a need, but the need at the NIH is more acute than we have extramurally.

Mr. MOOLENAAR. Okay. I guess the second part of that question, and you somewhat addressed it. But in addition to investing in the research facilities within Government, the NIH, should the committee also prioritize investment in the Nation's biomedical research infrastructure at academic institutions, nonprofit organizations, and hospitals?

Dr. FAUCI. Yes. The answer is yes, and I can tell you that because I am right now in discussions with some of our leading groups, including the University of Texas Medical Branch, about some of the things that they are going to need to continue. Because they are a first-class organization. We need to get them upgraded a little bit.

Mr. MOOLENAAR. Okay. Thank you.

And then to Dr. Kadlec, your office is responsible for the public health response for everything from anthrax to influenza to hurricanes to volcanos, quite a huge range. In your view, you have been on the job now for about 6 months or so?

Dr. KADLEC. Closer to 8.

Mr. MOOLENAAR. Eight months, okay.

Dr. KADLEC. I live in dog years. [Laughter.]

BIOMEDICAL THREATS

Mr. MOOLENAAR. Well, based on this experience you are having and your extensive experience throughout your career, what sense do you have of the greatest threats our Nation is facing among these kinds of threats? And how well are we prepared to address them, and what can we be doing to better be ready for these threats?

Dr. KADLEC. Well, thank you, sir, for that question. And I am going to give you a two-part question here. One is that I can say in maybe the public forum, and one that I think is reserved for a more classified environment.

But here is how I would describe it, and it was referred to in my opening statement, which is when the events or when the ASPR was created back in 2006, it was really predicated on the experience from Katrina, which recognized that there wasn't a very coordinated robust medical public health response in light of the terrible disaster in Louisiana and to the Gulf Coast.

I think maybe the good news is, based on my fifth day on the job, when Harvey was barreling into Texas and then followed by Irma and Maria, is that in some ways, we have demonstrated some, I think, means to respond to hurricanes. Though quite frankly, it highlighted some significant vulnerability. So in terms of our personnel, our disaster personnel who were responding, our logistics, and some other areas. So we are trying to work to correct that, and the $80,000,000 from the committee is going a long way to help us there.

But in terms of the things that also existed at the time of ASPR's origin was the idea of terrorism. Well, I think everybody's expectation is, is that terrorism, once we got rid of Osama bin Laden, that that was going to be a kind of flickering flame. But it hasn't turned

out to be. In fact, much more distributed, a much more, if you will, global entity.

So terrorism has changed, and their aspirations remain to do WMD events. And they are becoming sadly with cyber. And then add to that, which I think is the biggest inflection point since my time on the committee, is the whole nation-state challenge. Whether it be Iran, North Korea, Russia, China, however you want to define it, is that we are susceptible to a range of activities now. Cyber being one in particular that is, again, maybe not in the bio domain, but has significant impact, as we saw with WannaCry in the U.K. and the national health system there.

That we are going to have to basically build a more resilient healthcare system generally and a much more responsive one because I didn't include the natural events that with emerging diseases and the like. And so it is a much more varied set of threats than I think we confronted in the early 2000s. The frequency of emerging diseases and potential pandemics, we didn't talk about H7N9 here today, but that looms large out on the horizon.

So it is not one thing. It is everything. And in some ways, we just have to build the capacity and set of capabilities that are flexible, agile, and responsive. And again, the issue here is not to have a Federal response. The issue here is to support State and local authorities and help their citizens in need.

And so it is really a supporting role we play, and it really does require a greater integration with our State colleagues in a way and our local colleagues to make sure that they have means that they have and we can bring the extraordinary means that are necessary to deal with some of these unique exotic threats.

Mr. MOOLENAAR. Thank you.

Mr. COLE. And now for the last person, our first round of questions, is the gentlelady from Alabama.

REGIONAL DISASTER RESPONSE

Mrs. ROBY. Thank you, Mr. Chairman.

And I will build upon my colleague's conversation he was just having with you, but thank you all for being here today.

Of course, I was as pleased as others to see the administration's fiscal year 2019 budget proposal prioritizing biodefense and preparedness programs to ensure that the United States has the necessary capabilities to respond to infectious diseases as well as chemical, biological, radiological, and nuclear agents.

In recent testimony before Congress, the Director of National Intelligence stated that North Korea will continue its longstanding chemical and biological warfare programs. The global threats we face today make it critical for the United States to prioritize biodefense preparedness. Just earlier this month, in my home State of Alabama, a suspicious package was delivered to Fort Rucker, one of the fine military installations in my district.

And thankfully, this package was deemed not to be a threat. However, the incident served as a very clear reminder of how important, as you were just saying, State, local, and Federal coordination is in detection and response efforts to all potential threats, including chemical and biological threats.

And so, Dr. Kadlec, you know, could you expound upon your office's role in emergency preparedness and response specifically, though, to military bases like Fort Rucker, including all of the thousands of civilians that live around our military installations?

Dr. KADLEC. Well, ma'am, thank you very much for that question. I think it highlights one of the areas of initiatives in our efforts right now, priorities for a regional disaster response healthcare—regional disaster health response system.

And recognizing—in fact, yesterday I spent the morning up at Walter Reed National Medical Center up in Bethesda, talking about how we need to coordinate our efforts not only for those specific events at bases, but also more broadly how can we basically leverage some opportunities that the Department of Defense can help us with, with some of the CBR training and how we can help DOD with some of their needs for trauma preparation for future wars, God forbid we need to do that. And the thing is, there is a whole range of collaborations we can do with DOD that we have initiated.

I have met with the head of the National Guard Bureau to look at how we can more—it is just a coincidence on that matter that we have 57 national disaster medical assistance teams around the country. In fact, the Alabama one is a great one from your State, ma'am.

And we are trying to work and understand how we can work closely with the National Guard assets, like the civil support teams that have chemical/biological capabilities that our disaster teams don't have. And so how we can build greater collaboration to respond there.

We are working on the elements of medical countermeasure development to do that, as well as this regional medical system that if there were to be a crisis in the Gulf Coast, that we could enlist the support not only of DOD, but the VA——

Mrs. ROBY. Sure.

Dr. KADLEC [continuing]. To respond in a way that would be meaningful——

MEDICAL COUNTERMEASURES

Mrs. ROBY. And I want you all to weigh in, and I appreciate your answer. But if you could also talk about medical countermeasures? You mentioned the word "countermeasures."

Dr. KADLEC. Yes, ma'am.

Mrs. ROBY. Anything specific that you can provide?

Dr. KADLEC. Yes, ma'am. We are working, basically, right now with the Department of Defense chem/bio defense program. The people at DTRA, Defense Threat Reduction Agency, the Joint Science Technology Office, as well as the Joint Program Executive Office for Chem/Bio Defense up at Aberdeen. We identified a number of countermeasures that we are going to work collaboratively on—a vaccine, a couple of monoclonal antibody, a couple of drugs, as well as some detection capabilities.

Mrs. ROBY. Do you have any timeframe for the development of these things?

Dr. KADLEC. Like now.

Mrs. ROBY. Okay.

Dr. KADLEC. How is that, ma'am? [Laughter.]

Dr. KADLEC. We are not going to let the—we are not going to let the moss grow on this.

Mrs. ROBY. Okay.

Dr. KADLEC. But the whole idea is, is that if we—what we found is that because of this kind of merger of threat pictures, that many of the things that DOD has historically been working on are now a matter of interest and concern for our domestic populations.

Mrs. ROBY. Sure.

Dr. KADLEC. And so we want to leverage some of our successes with BARDA. A little boast here, 35 FDA approvals with BARDA that would help DOD along in terms of our ability to navigate some of the regulatory challenges. So we see there is a great opportunity to work closer together, and it gets to the chairman's vision, I think, of demonstrating that this activity really is a national security one, one where we can benefit not only our men and women in uniform, but also our civilian population.

Mrs. ROBY. Absolutely. I know you want to jump in, and I have got just a little bit of time. So——

Mr. COLE. We are being pretty generous with the clock.

Mrs. ROBY. Okay, okay. I am always trying to be respectful of that.

Dr. FAUCI. Just very briefly and just to echo what Dr. Kadlec said, and I am sure Steve is going to say the same thing. In NIAID, we have been working historically for decades closely with the Department of Defense, particularly the U.S. Army Medical Research Institute of Infectious Diseases up in Fort Detrick, as well as a variety of others and Walter Reed. So the relationship between the Department of Health and Human Services and the Department of Defense is really very strong.

And that is the reason why what you said, Mr. Chairman, it really becomes a defense issue for us. So in some respects, we are part of the defense of the Nation when it comes to this.

Admiral REDD. I don't disagree with the need to work and to continue to work closely with DOD, but that scenario that you described, I think really points out how day-to-day systems are the basis for our responses, that the initial work with that package was local public health. And the stronger that local public health system is, the quicker we are going to identify these kinds of problems and the more effective we will be in solving them.

Mrs. ROBY. Absolutely. Well, thank you all again for being here.

And thank you, Mr. Chairman. I yield back.

Mr. COLE. Thank you very much.

And just to advise the committee, we will probably try to hang to 5 minutes only because I want everybody to have a second round here that cares to stay.

Well, Ms. Herrera Beutler, I didn't realize you had arrived. So you will be the concluding first round then.

DETECTION OF BACTERIA IN HOT SPOTS

Ms. HERRERA BEUTLER. All right. Thank you so much.

And I apologize, gentlemen. I have been in another subcommittee this morning. So I may re-ask a question, but this is such an important issue, what you do is so critical. You know, I have seen it

from when you talk about antimicrobial resistance, you know, for those of us who have been in hospitals for long periods of time, it is not just a policy issue. It is something you pay very close attention to.

I will say I am now officially probably the most hand-washing member of Congress you will ever meet because simple things make a huge difference, I have learned. But when you get past the simple things, it can be very scary.

I met with a group of researchers, an amazing group, in—I am from Washington State, but they—and that is where they are based, but it is both researchers, it is international workers, it is DOD, and I was both terrified and excited about their work. Terrified because of what they are facing and what you all are facing, but excited that there are people taking—paying attention.

So I am going to read their question just because I want to get this on the record for my purposes. So, again, bear with me if you have already spoken to some of these issues.

And we can all understand the role of prescription guidelines and appropriate antibiotic use here in the U.S., given the emergence of the resistance that we are seeing globally and the hotspots we are seeing globally in the South and Southeast Asia, Africa, and Central and South America, where most of the world's population live and infectious disease burden and subsequent antibiotic use is highest.

How can we improve detection and communication of emergent resistant bacteria in hotspots prior to their impact in the U.S. healthcare system, and what is our commitment to increasing capacity in these hotspots to mitigate antibiotic-resistant threats where they originate obviously prior to the global spread?

Admiral REDD. Very, very important question. If we lose the ability for antibiotics to do what they are designed for, more than the 23,000 people that died last year will die. So this even today is an important problem in the U.S., but we could even be facing a situation where routine surgery is impossible because antibiotics are affected or cancer treatment. Or if you have a condition that requires a drug that suppresses your immune system, then all of those problems could be worse.

Overseas, what we need to be doing at the outset is being able to identify these bacteria, and that is a laboratory issue, and it is an epidemiological issue with surveillance. That is what we are doing in the U.S. We are identifying these bacteria. We are rapidly taking action to prevent their spread to other people, and that is the same kind of work that we need to be able to do overseas.

ANTIBIOTIC RESEARCH

Ms. HERRERA BEUTLER. It is remarkable. You know, I heard a story of a service member who had—basically needed surgery at some point, was sent home, went to one of our major centers in Washington State, and there was an outbreak there. And we were so far behind. I mean, that is kind of, I think, what started this group in terms of just following it. It wasn't even containing it. It was what is happening? I mean, it happened that quickly.

The other thing I was thinking about and I have seen, you mentioned routine surgeries and how these antibiotics for someone who

needs it, cancer treatment, someone who is immunocompromised or suppressed, something I have been following with regard to antibiotic use is in terms of the research for the next generation of antibiotics that we would need, the shortage there. And I was hoping someone could speak to that.

I can't remember what I saw somewhere. This was a number of years ago, but I have obviously paid very close attention to it. That is scary. Who is doing the research?

Dr. FAUCI. Well, it is a problem, and the problem is that antibiotics are not one of those big blockbuster money makers for the companies. It is a high-risk proposal for them. So what we have been doing at the NIH is trying to de-risk the development of drugs. And when we say "de-risk," if you look at the process from the concept of a new intervention to the actual product, if the industry feels comfortable that when they make an investment, they are going to get a big back—economic gain of it, they will do everything from advance development, intermediate development, early development, and even the concept.

That doesn't happen very often with antibiotics. So what we need to do, what we are doing is doing some of the early concept development and bringing it along the way of early preclinical and then early clinical development so that they get the confidence that when they take a risk, it is not going to be the total $750,000,000 to $1,000,000,000 risk.

We do that alone and together with BARDA because when you look at what BARDA does is BARDA also plays an important role in de-risking the companies from what they are doing.

Ms. HERRERA BEUTLER. And are we doing this sufficiently with regard to antibiotics?

Dr. FAUCI. You know, we are doing it much better than we were in the past. If you look at the charts that people show about the number of new antibiotics that have appeared over the last couple of decades, it sort of dropped down almost to nothing.

In the last 4 or 5 years, it has come up much more than in the past. But it is still, as I think you are alluding to, not nearly at the level where it needs to be.

Dr. KADLEC. And just to add, ma'am, with BARDA, since BARDA belongs to ASPR at this point, they have identified, as Dr. Fauci said, is those promising candidates that get past the Phase II stage. We have 11 candidates. One that has received FDA approval. Two that are actually under review by FDA as a new drug application.

And just to give you an idea of the scope and scale of the 28 projects that are ongoing to address the multi-drug resistant problem that reflect 8 new classes of antibiotics. So, again, it is a great collaboration between ourselves. And again, critically up in the front end is what CDC does to basically identify those cases and quickly characterize them and provide the information so that Dr. Fauci and his colleagues can start looking for those conceptual frameworks.

Ms. HERRERA BEUTLER. Thank you, and I thank the chairman's indulgence.

STRATEGIC NATIONAL STOCKPILE FUNDING

Mr. COLE. Well, we have been indulgent to everyone today. So, but I will again ask Members, and I will start with myself, to stay within 5. Because I do want all of you that want to stay to have the opportunity for one more round.

Dr. Kadlec, your budget justification document states that the fiscal year 2019 budget request for the Strategic National Stockpile would support replenishment of the countermeasures currently in the stockpile, but would be insufficient to address the priorities and gaps that HHS has identified. What level of funding would be necessary, in your view, to accomplish something like that?

Dr. KADLEC. Sir, I would have to probably get back to you with a calculation because some of the issues in terms of the numbers that would be required are, one, at the present time in certain categories, some of our requirements are—the quantities we have on hand are not fully addressing the requirements we have established and then with the expiration of products going forward.

So if I can get back to you, I can give you probably a pretty good laydown over the next couple years with some fidelity. I think after 3 years, it would get a little fuzzy, but I think 3, we could probably give you a good horizon, if that is okay?

Mr. COLE. That would really help because I think we are going to have to make some tough decisions in this budget. I would be surprised, quite frankly, if our allocation is as generous for next year as it was this year.

Dr. KADLEC. Yes, sir.

STRATEGIC NATIONAL STOCKPILE COUNTERMEASURES

Mr. COLE. So these kind of things we are going to have to make a lot of tough calls, and it would really help us, if you could.

I will follow up one more quick one. Do you expect that the composition and countermeasures in the Strategic National Stockpile will change as a result of the move over to ASPR. In other words, you think changes are necessary to alter the balance between, say, low-risk, high-likelihood threats and high-risk, low-likelihood threats or in between?

So I am just, again, trying to understand the nature of the move, and will it change what we have got?

Dr. KADLEC. Sir, not immediately. I think one of the areas that, quite frankly, will probably take a longer analysis is to see where we can get some efficiencies in terms of opportunities, working with the VA, with vendor-managed inventories, things that could potentially change, if you will, some of the quantities in the stockpile, but maybe not the composition.

I will give you an example. One of the anti-radiation drugs that we have, Neulasta, is something that is commercially available and used to treat cancer patients, particularly oncology patients who receive radiation. And so, in some ways, there may be opportunities in that space.

In some cases, a smallpox vaccine that we have probably doesn't have a dual use quality to it, but there may be some opportunities as we go forward that could do it. One of the exciting opportunities that has been presented by Congress was in the 21st Century

Cures Act, which is the Medical Countermeasure Innovation Partnership, which will be announced soon and, sir, we will owe it to you and your colleagues to get a briefing of that when it is finalized.

But it is the opportunity to make major changes to the whole medical countermeasure enterprise to see how we can maybe manufacture things more on demand so you don't have to have a stockpile on hand. Maybe find opportunities where you could find novel ways of administration and stability so that in some ways you don't need some of these fancy biologics that we have currently. So there are a whole set of opportunities we think going forward that we can basically make changes to the stockpile reflecting what could be opportunities.

One of the fascinating ones that FDA developed is actually making pharmaceuticals on demand. Where conceivably in the future, you go to CVS with your prescription, and they will manufacture the drug that you need or combination drugs you may need.

So there are some really exciting things, and we owe it to you and your committee to basically talk about those probably in a fulsome setting where we can answer your questions and really talk to you about your idea and how we hope to give it wings going forward.

Mr. COLE. If you care to comment on that, Admiral Redd?

Admiral REDD. Just in addition, I think one of the things that we are very interested in making sure continues is the consultative process that FDA, NIH, CDC provide input to those decisions.

Mr. COLE. Yes, we would have exactly the same concerns. One of the reasons I raised the question.

I won't use all my time so that we make sure we get other Members in. I want to go to my good friend—you certainly, if you need my time, you can have my time. [Laughter.]

COUNTERMEASURES AND BIOSHIELD

Ms. ROYBAL-ALLARD. And let me just say I have the same concerns as the chairman does on that issue.

But before I ask my question, I want to make a quick point about the administration's request for advance funding for BioShield. I believe the revised 10-year request came to $5,500,000,000, which would be about $550,000,000 per year. But in the 2018 omnibus, we provided $710,000,000.

So if we maintained that funding for the next decade, it would come to more than $7,000,000,000, which is significantly higher than the administration's proposal. So I would say that we are on pace to do well in this particular area.

When we discuss biodefense and emergency preparedness, I am oft concerned about whether there is enough consideration of populations with unique needs or populations that are more difficult to reach. So, Dr. Fauci, can you talk about the status of research to ensure that medical countermeasures are safe and effective for pregnant women and children?

Dr. FAUCI. Thank you for that question, Ms. Roybal-Allard.

It is a very important question that is not that easy to address, but we try to do that as best we can. And let me give you a real-time example of what is going on.

For example, Dr. Kadlec had mentioned just a moment ago the issue of how we would prepare for the possibility of an H7N9 pandemic influenza. And when we develop countermeasures, we are right now in the middle of clinical trials that we are using first with adult healthy people and then with elderly. But if, in fact, there is an increase in what we perceive as the risk, we will do it in children and in pregnant women.

But you have got to be careful when you are dealing with situations with pregnant women because you really want to make sure you show in an otherwise healthy nonpregnant population it is safe before you make that. And there is always that tension about you don't want to delay it too long that you don't have a situation where you know whether it is safe in women, but we tend to do that when we are dealing with countermeasures.

We pay particular attention to try and have a good representation of the population when we do that. We are not always successful on that, but we do have it as something in the front of our mind.

Ms. ROYBAL-ALLARD. Dr. Kadlec and Dr. Redd, my district is very economically, culturally, and linguistically diverse. How are we making sure that our emergency preparedness and response network reaches all Americans, regardless of their age, religion, language, health status, or disability status?

Admiral REDD. It is a very important issue. We have significant experience in that through H1N1 and in Zika in particular in, you know, at the minimum, translation services, in a larger way doing more work with anthropologists, social scientists to make sure that our interventions are resonating with the people that they are intended to reach. So we recognize that as an issue, and we are devoting resources to it.

EMERGENCY PREPAREDNESS

Dr. KADLEC. Yes, ma'am. And in terms of those who are medically in need, we developed a program with CMS to basically identify individuals in a given area, zip code, down to the home address and phone number, to identify people on durable medical equipment. So in the cases of the hurricanes, we can identify those people early, at the request of the States, and provide them the information so they can make notifications to those individuals to either identify themselves or identify the needs they have, or even advise them to evacuate even before the general population because of their medical needs.

In addition, one of the things that we are doing—we are moving with FEMA now is to actually try to integrate closer with the States so that we have a much tighter bond, if you will, working relationship on a day-to-day with their emergency managers who do know their States, who know their communities so that we have a closer interface with those—with the State and local authorities. So that we can better understand what the needs may be and particularly the specialized needs.

Ms. ROYBAL-ALLARD. And after CDC's recent operational readiness review, what are the biggest challenges at the State and local level for the last mile of getting countermeasures to the appropriate person at the appropriate time, and how do you plan to ad-

dress those challenges, especially for some of those populations that are more difficult to reach?

Dr. KADLEC. Well, ma'am, I think the thing is, is we are actually investigating that right now. We are taking the report's findings, and we actually have set up a workgroup to look at that. The issue that has been identified, and I will turn to Dr. Redd as well to comment on this, is that you have to use multiple modalities. Some of them will be nontraditional through either—you know, through charitable groups, through religious groups, through you can imagine Meals on Wheels, if they are informed, or even the Postal Service. So nothing is off the table in terms of identifying the best way to reach everybody or most everybody.

And then have means to basically identify those groups that are particularly vulnerable or particularly at risk and target them for specialty distribution networks.

Admiral REDD. Just to very briefly summarize a huge effort of visits to every grantee work that States have done to assess the capabilities of their jurisdictions, plans are in pretty good shape. The ability to execute those plans and with one special area of weakness is staffing, that that is—it is not universal, but that is a recurrent problem that the plans require more staff than are available.

We have worked hard to try to find solutions to those. I think in some cases, the plans are going to have to be changed to match the people who are there. We think this is really a problem that requires a local solution and mobilizing people from the community since for some of these emergencies, that countermeasure dispensing effort has to be activated nearly instantaneously.

Ms. ROYBAL-ALLARD. Thank you.

Mr. COLE. I was going to say you are now just about out of my time. [Laughter.]

Mr. COLE. So I want to go to my friend, Dr. Harris.

Mr. HARRIS. Thank you very much. I am sure—I thought I was going to get to use the rest of your time.

Mr. COLE. Well——

Mr. HARRIS. Mr. Chairman——

Mr. COLE [continuing]. The Republicans are going to have pretty good lineup here.

COUNTERMEASURE FUNDING AND INFLUENZA

Mr. HARRIS [continuing]. Let me just place, and again, you know, my comments and perspective on the appropriations. Because the hazard, I think, is that, you know, we do an NDAA every year, but we don't do an authorization for this every year. It is this subcommittee, I mean it is on our shoulders to make sure that this is adequately funded. And put in perspective, and Dr. Kadlec, if I am wrong, I mean, the PHEMCE Strategy and Implementation Plan generally says that for this entire medical countermeasure emergency, the Federal Government should be spending about $4,000,000,000 a year. Is that right? It is about $20,000,000,000 over 5 years.

So to put that in perspective, that is, by my calculation, less than 1 percent of the defense budget. It is actually, you know, 1/15th of the increase in the defense budget this year, cybersecurity. And the

analogy to cyber is interesting because, and I came across an article—and Dr. Fauci probably knew this. You know, this scientist at the University of Alberta that synthesized horsepox virus.

I mean, there is technology now that is completely changing how these bioterrorism agents can be developed, and just like cyber is, you know, an expanding threat, I think this is actually an expanding threat. And if I have to place the risk of us having a major bioterrorism event versus conventional Department of Defense threat, I probably put it more in the 1 percent.

So with that, I mean, it falls on us to do this and by whatever means we can. But this is an Article I responsibility of Congress. So that is why I think it is so important that we look at this in the context of what is the true risk, and is it, in fact, increasing over time and not decreasing because we have developed countermeasures? And I think the fact is it is increasing over time because of technology to develop and deliver some of these agents.

But anyway, I turn to a totally different—well, not totally different subject. But Dr. Kadlec, the universal influenza technology still may be several years away. I mean, you know, it is a great idea. And if we get there, that is great. But in the meanwhile, how—what are we doing to prepare for an epidemic before we have this ability to inoculate our entire population? And you know, have we provided the resources to allow ASPR and BARDA to do this?

Dr. KADLEC. Well, first of all, sir, the supplemental that you all provided, going back now almost a decade, has certainly bear fruit. At a time, I think in 2005, there was a capacity to domestically produce 60 million doses of flu vaccine, and now we can do 600 million. And that is a huge capability, particularly if you have to use two doses to address a highly virulent avian flu virus, if it were to be a pandemic.

So there is much that has been done and, quite frankly, much that needs to continue to do. To your point of the universal flu vaccine, it clearly is very important going forward. But there are things we need to do currently to sustain the capacity that we have.

One of the things we learned in the most recent seasonal flu event was, if you will, the drift of the vaccine strain, that basically even though we could do that, and the challenge was, is those were the doses that were made in eggs, for which 70 percent of our influenza vaccine supply is made from eggs. And that is, quite frankly, a vulnerability because the chickens that laid those eggs may be vulnerable to virulent avian flu, and quite frankly, so I think there are two areas in cell-derived or cell culture manufacturing where we could find better, faster ways of doing that.

And we have internally looking to do that, as well as looking at recombinant technologies. The critical thing here is the domestic capacity. And so I think it has been Congress' intent to invest in that, and quite frankly, there has been volatility in that, with sales of companies and potentially the transfer of technologies overseas that put at risk those capabilities to respond to a pandemic.

And to make one last point and then turn to my colleagues is that, quite frankly, the cell culture capacity and recombinant technologies offer you greater flexibility. You can only produce two vaccines from eggs, and that is yellow fever and flu. And so if we were

to build a greater domestic capacity through recombinants and cell-derived cultures, we could do a lot more against a lot more potential pathogens.

Dr. FAUCI. This relates to the point you made about platform technology, Dr. Harris. It is exactly pinpointed on that. As much as eggs and growing a pathogen is time-honored and we are used to it, it is antiquated. We have really got to graduate into the next level, which is what you were talking about before.

Admiral REDD. Actually, I think that your point also shows how the things that we do day to day have an influence on our ability to respond to a catastrophic event. In flu, every year we are doing the things that we need to to promote vaccination, to promote the use of antiviral drugs, to make sure that we understand what the situation is. It is exactly what we would need to do during a pandemic.

And I think as these new technologies become available, we will have more effective tools, but they will all be implemented through the system that exists today.

Mr. HARRIS. Thank you very much.

Mr. COLE. I thank the gentleman. Next, we will go to Ms. Herrera Beutler. Mr. Moolenaar, you will close us out, and then we will have time for any final comments my good friend from California cares to make.

Ms. ROYBAL-ALLARD. I have another question.

Mr. COLE. You can do either.

Ms. ROYBAL-ALLARD. Oh, okay. Thank you.

Mr. COLE. Ms. Herrera Beutler.

INFLUENZA VACCINE INNOVATION

Ms. HERRERA BEUTLER. Quick follow-up because I wanted to understand what you were saying, your ability to do recombinant and cell-derived culture. What cell, like how would you—so you are moving from culturing and using egg?

Dr. FAUCI. So the way—the way influenza is done mostly now, except for a couple of percent, which is recombinant, is you grow the virus. And you could either grow it in an egg, or you can grow it in a cell.

Ms. HERRERA BEUTLER. When you say in a cell, like?

Dr. FAUCI. Like, for example, there are a variety of cell lines that you can grow viruses in because viruses——

Ms. HERRERA BEUTLER. Just to clarify, so like the fetal cell lines. Is that what you are talking about?

Dr. FAUCI. Well, it could be, or it doesn't necessarily have to be a fetal cell line.

Ms. HERRERA BEUTLER. So is that what you are talking about in terms of where you are going?

Dr. FAUCI. No. What we want to do is we want to get away from, ultimately, the necessity of having to grow the virus. What we want to do now, since we have the capability of sequencing a virus that is a new virus, let us say, not only influenza, but a new virus. Years ago, it would take months and months to do. We can do it almost overnight now.

So if there is a new virus that comes out, you sequence it. And once you sequence it, it has a bunch of genes. One or more of those

genes are going to code for the part of the virus that you want to make an immune response against. So instead of having to grow it, you bypass that. You take the gene out of the sequence——

Ms. HERRERA BEUTLER. You are reprogramming the gene?

Dr. FAUCI. No. You just pull the gene out. And you stick it in a particular vector, let us say a DNA plasmid. And then that becomes your vaccine. So now when you inject that into me, my body sees just the protein that you wanted to make an antibody response——

Ms. HERRERA BEUTLER. So completely getting away from growing, egg or anything?

Dr. FAUCI. That is the point. That is exactly the point.

Ms. HERRERA BEUTLER. You are getting away from growing at all?

Dr. FAUCI. Right.

Ms. HERRERA BEUTLER. Culturing in a petri dish, for lack of a better—okay. Huh, I didn't—I wasn't following that. I mean, I am sure you went through it again before I got it. I appreciate that.

Dr. FAUCI. No, that is fine. That is fine.

RAPID RESPONSE FUNDS

Ms. HERRERA BEUTLER. I wanted to ask about spending and the delivery of funds in terms of rapid response. I know, what, a year and a half ago, we had a—with regard to Zika in committee, there was quite a bit of work in making sure that there was money where it needed to be. And I wanted to ask about the delay of funds for Ebola and for Zika.

And I don't know, I feel like I saw 4 months, around 4 months in terms of a delay from when funding was released, but when it was spent, and 90 days—the 4 months was for Ebola, and 190 days for Zika. And I wanted to ask, I guess, why? Is there something that we can help fix, right?

And what kind of impact does that have? Or maybe there is—it is negligible. But I wanted to ask.

Admiral REDD. So this question came up with regards to a response fund that would be available to be mobilized when an overwhelming emergency occurred. And you are correct. For the H1N1 response, 54 days between request and appropriation. For Ebola, 4 months. For Zika, 190 days. I think that the short answer to the question, maybe there is two parts.

One is a response fund would really help with that. The second question is just shortening that interval, that appropriating the money more quickly.

Ms. HERRERA BEUTLER. So is it literally the——

Mr. COLE. Gentlelady, would you allow me to kind of address your——

Ms. HERRERA BEUTLER. Mr. Chairman, yes.

Mr. COLE [continuing]. Question a little bit? Provide a bit of history. And again, I am in favor of a response fund. So this is not meant to contradict anybody.

But there was Ebola money sitting there, a lot of money. And that money, looking forward, would eventually be spent. And so the committee's response was use that now. We promise you we will re-

place it. Give us time to figure out exactly how much this is going to cost.

And so the idea wasn't that we didn't do anything. They were doing everything they could do. They weren't waiting on the appropriations. The disagreement at the time or debate at the time, quite frankly, was, okay, you have got a big pile of money. Use that. Let us figure out what the real cost is going to be, then we will replace the funds.

Ms. HERRERA BEUTLER. So, but was the delay because of the—so what was causing—because I understand that. There is money sitting there. Was it—is it an issue of we say use it, and then there is a bureaucratic piece that it just takes time to cut the check?

Is it the—that is what I am curious about is the time. What is that piece? I understand the——

Admiral REDD. So let me—I am going to answer a slightly different question about what happens when the money gets to——

Ms. HERRERA BEUTLER. It is approved, however we approve it.

Admiral REDD. Yes. Okay. And you are correct. There are delays. The way the usual systems operate could take months. There are applications that States fill out. There is a review process. There is the budget negotiation.

What we have done in the past year is create a mechanism to basically skip over some of those steps. We have allowed States to apply for a response that is not funded, and so there is a vehicle to——

Ms. HERRERA BEUTLER. You mean like forward apply?

Admiral REDD. It is not applying funding, but it is basically allowing us to skip some of the bureaucratic steps that introduce so much of the delay.

Ms. HERRERA BEUTLER. And that is where—okay. So that is where you feel like the delay, the delay—these delays are——

Admiral REDD. Multiple——

Ms. HERRERA BEUTLER [continuing]. Functional logistic delays? Okay.

Admiral REDD. Multiple places where there are delays.

Ms. HERRERA BEUTLER. And this response fund you feel like would be an easier way for these emergent——

Admiral REDD. It would. It would allow—it would solve one part of the problem. It is not the entire problem. We are also working with grantees to make sure once they get the money that they don't have a multi-month process.

Ms. HERRERA BEUTLER. Yes, to spend it.

Admiral REDD. And that happened during H1N1. It varied very much by State, but some of them were maybe able to immediately spend. Others not. And so it is really the—there are three parts. Appropriating the money to the executive department, then the work within the executive department to release it to the grantees, and then the work that goes on downstream from there.

Dr. FAUCI. Even under the best of circumstances, when even the committees that try to move quickly, as the chairman was alluding to, there still is the delay if you don't have something just sitting there. And that is really what we are talking about, not delay and not doing something you should be doing. Because as you mentioned, we had the Ebola money and moved the Ebola money.

But I remember when we were sitting down in my own conference room, when we said, hey, we have to get a Zika vaccine. I told my staff let us start moving, and they looked at me and said, like, "With what money?" And the answer would have been if we had a fund there, we could have said right away, we could start right now.

Ms. HERRERA BEUTLER. Got it.

Dr. FAUCI. So what we did is we moved money from other places temporarily. But what we are all arguing is that we shouldn't have to do that. We should be able to move quickly.

Ms. HERRERA BEUTLER. Got it. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. You bet. And for our final round of questions, my good friend from Michigan, Mr. Moolenaar.

ANTIMICROBIAL DRUG DEVELOPMENT

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And I will go pretty quickly on these, but this is for Dr. Kadlec. I want to take us back to the topic of how we spur the development and investment of new antimicrobial drugs to combat antimicrobial resistance and future public health threats, and my understanding is there has been progress increasing investment through FDA regulatory actions, as well as push incentives like the GAIN Act, the ADAPT Act, the BARDA CARB–X funding, and that has been helpful in providing premarket incentives to help aid the development of necessary products, but we still are lacking in a truly robust antimicrobial pipeline.

And I guess the question is do you believe that a post market pull incentive concept, such as a transferable exclusivity voucher or a market entry reward, would help to further bolster development in this critical area of unmet need?

Dr. KADLEC. Well, thank you for your question, sir.

And just to highlight some of the things that have been done, and you mentioned CARB–X because I think in some ways what we have learned from the CARB–X experience, we have leveraged with every dollar that the Government has invested into multidrug resistant antibiotic development about eight times of that of private equity funding. So we feel that that is a pretty powerful push, if you will.

To your point about whether or not a post market incentive is necessary, I think there is an active debate going on on that. You know, my view at this point is kind of trying to understand, and more, I think it has been a sizable benefit identified that could be generated for this. But I have to admit, I am kind of—I am kind of displaying a little bit of the Missouri in me by, you know, kind of wait and see and show me at this point, whether we will functionally do it.

Our CARB–X experience has identified a number of very promising candidates—11 at this point, with 1 FDA approval and 2 other drugs going through new drug applications. So my question is, is how is that going to functionally do anything different to that? But I will turn to my colleagues to see if they have alternative views.

Dr. FAUCI. Well, I think your point—that Dr. Kadlec's point is correct. I mean, there is a lot of talk about that. If you talk to the pharmaceutical companies, there is no doubt that they would say that they would be able to move more quickly not only necessarily more quickly, but have more of an incentive to get involved if you have the post marketing mechanisms.

And several of them have been thrown out as possibilities, extending by a year a patent on a particular drug that is a very good seller for them, which would give them the incentive to take that money and invest it into the new drugs. So the answer is, as Dr. Kadlec said, it is a little bit uncertain as to what that actually is going to do. But if you talk to the pharmaceutical companies, they feel strongly it will help.

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Mr. MOOLENAAR. Okay. Thank you.

And then I wanted to ask a question about BARDA. BARDA has had other transaction authority since it was first established in 2005, and I understand BARDA has used this authority on a number of occasions, but typically only with the larger pharmaceutical companies.

My question is why hasn't BARDA used OTAs to provide funding to smaller companies like DOD has? And it seems that BARDA's use of this authority has also been very limited, and I wonder why that is, and if there are suggestions on how this authority might be improved or expanded?

Dr. KADLEC. Well, thank you, sir, for the question.

I want to do two things. One thing, I am going to give you a real brief answer, which is I think we are looking at it right now to see how we can adopt more DOD practices to this. But I am going to turn to Dr. Bright. I think he is behind me still, I hope, and offer him a chance to answer this because he has been actively working it.

Dr. BRIGHT. Thank you for the question.

And we think it is a very important authority, and we are very grateful that we were provided that authority in the original proper PAHPA language, and it has been continued through all the other reauthorizations of PAHPA, in PAHPA. Again, it took us a while to understand the authority. We were traditionally using a lot of far-based traditional contractual mechanisms to work with our public-private partnerships.

And it was about 3 years ago we initiated our first other transactional authority. We now have six of those. And as a practice going forward, as Dr. Kadlec described, we are learning from the best practices in this area and how DOD has used these more widely to develop medical countermeasures not only with smaller companies, but with consortiums and the consortium-based approach so we can accelerate those medical countermeasures.

We are extremely grateful, and we are using them more and more.

Mr. MOOLENAAR. Okay. Thank you, Mr. Chairman.

Mr. COLE. Thank you. And I want to next move to my friend from California for any closing questions or comments she cares to make.

Ms. ROYBAL-ALLARD. Thank you.

Well, first of all, I just want to say thank you to the panel. I found it to be extremely interesting and informative. So thank you for being here.

The question that has to do with the fact that last fall, the U.S. was hit by an unprecedented series of natural disasters. And as FEMA and HHS and other Federal and State entities responded to these natural disasters, we saw that there was a wide variation in the ability of States to respond to these emergencies.

What is needed to address this variation? For example, Dr. Kadlec, I understand that you have proposed a regional system to improve the emergency response in the areas that are less prepared. Can you tell us a little about what that would be and what it would take to make it happen, as well as how would a new regional disaster health response system incorporate HPP-supported healthcare coalitions into networks that would be responsible—capable, rather, of the response we saw in Houston and Hurricane Harvey? What elements of the coalition are needed to be replicated in other regions?

Dr. KADLEC. Well, thank you, ma'am, for the question.

And I think, just simply to describe it is basically to understand that right now the hospital coalitions have been proven to be very useful and helpful in the regions that have and the areas that have done this. These are sub-State areas typically in cities, major metropolitan areas, some rural areas. And the intent here is really to grow those and basically expand it.

So in our view, we would be able to use the hospital preparedness grant program in part, and again, we acknowledge that the additional funds you provided us this year with the omnibus, but as well with some of the work that we have been doing with our National Disaster Medical System, to kind of create that hybrid.

I think the best example, quite frankly, was what was done with Ebola. When it was recognized that the risk of Ebola was out there, identifying three if you want to call it national centers—Bellevue, Nebraska University, and Emory down in Atlanta—as and recognizing the NIH facility as well, was basically recognizing those would be very, if you will, tertiary care treatment centers for Ebola patients. But yet you may have a need to have regional-based capabilities to respond and manage patients in different regions.

And so with that system, they basically created 10 regional centers to be satellite centers from those 4 other centers that would basically be trained, be equipped, be prepared to respond if there were to be additional Ebola patients that may have to be managed at a regional level rather than at the national centers. And with that, those regional centers train other hospitals in their regions to be assessment centers, which could initially evaluate patients, provide interim treatment until those people could be transported to either a regional or national center.

We think that could be emulated in other areas, particularly around burns, particularly around radiological emergencies. But realizing, and we haven't talked about this in this context, is and there is a kind of a parallel move afoot, trying to create a national

trauma system. And again, ideally, that would be the foundational kind of capability that the Nation would have. Something that every day, it is kind of like the counterpoint to Dr. Redd's issue with public health systems. Every day we have a trauma, we have trauma centers around the country that are taking care of people and managing people on a given basis.

And certainly in extraordinary circumstances, as we saw in Las Vegas, trauma systems can get overwhelmed. And so the idea is to build on a system like that that would be regionalized. Again, take advantage of the hospital preparedness funds and grow that, make it part of the National Disaster Medical System, but regionally focused so that the benefits would be every day potentially to the State and locals who would be beneficiaries of this with targeted funding from HPP grants.

There probably would have to be some kind of increased appropriation around that, honestly, to manage these kinds of things. But then to build it as a way we could basically have a range of capabilities—trauma; highly infectious diseases; burns; pediatric emergencies, trauma, or burns; radiological emergencies that could be managed, God forbid we needed them; if you had a nuclear event, you had a radiation event, if you had a chemical event, if you had a large-scale fire or other kind of a disaster—so that you could have more regional capacity and capabilities.

Ms. ROYBAL-ALLARD. Thank you. And thank you for being so generous with the time.

FINAL STATEMENTS

Mr. COLE. No, absolutely. First of all, I want to—I conclude. I don't have any questions. But I just want to thank our witnesses.

This has been, I think, exceptional testimony. You have been extraordinarily helpful to the subcommittee in deepening our understanding of this particular area. And frankly, I want to thank the committee. They are all gone because they have work to do, but I thought the questions were really thoughtful, and really, it was interesting to watch the interplay back and forth. You wouldn't have known there was anything partisan about Congress if you watched it.

And you know, occasionally committee hearings—it doesn't happen very often here—can degenerate into partisan back-and-forths or sort of gotcha moments where we go after the witnesses instead of trying to learn something. And I think we avoided all that. The aim here was really to think deeply about what I think is an ongoing national challenge that, you know, we have been handling sort of episodically and pretty—pretty successfully, and all of you have been part of that.

But maybe we need to do some real thought here and create, as my friend Mr. Harris pointed out, some stability in the funding stream here so that both the agencies responsible and, frankly, the private industry, which is pretty important in providing the capacity that we need, can plan ahead.

And then, hopefully, strengthening the institutions we have, which are excellent. But you know, in some areas, probably need to be more robust or realigned as been suggested by a number of you. And then build over time capacity and cooperation in this area

because I am quite convinced that the challenges that we talked about here, certainly the pandemics, are just a fact of life. They are going to keep coming, and if anything, the last few years should have taught us that everything from national disasters to what nature throws at us is going to get worse probably, not better. So we better build the capacity to deal with them now while we have got the time and the focus and the interest.

And then we are all, I think, very concerned about a bioterrorism event because bad things can be pretty easily replicated by bad people, unfortunately. And if we don't have the ability to respond and contain quickly, it could really be a really bad day for the American people.

So, again, just in concluding, thank you very much for helping us understand the problem, for offering some really thoughtful advice about some of the things this committee needs to consider going forward, and we will try and build on it as we wrestle with the 2019 funding request and the 2019—hopefully, we will get to an agreement in 2019. Did a pretty good job in 2018.

But thank you again. Hearing is adjourned.

House Appropriations Committee

Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

"HHS Biodefense Activities"

Tuesday, April 18, 2018

Chairman Tom Cole Questions for the Record

Strategic National Stockpile

Cole 1: Dr. Kadlec, CDC plays a critical role in the stockpiling and distribution of medical countermeasures in public health emergencies. In particular, CDC's depth of subject matter expertise among its scientists and public health professionals, as well as it strong relationships with state, local, and territorial health departments are important assets in responding to public health crises. How will ASPR work with CDC to maintain its role in both the PHEMCE and in the distribution of countermeasures after the transfer of the Stockpile from CDC to ASPR?

ASPR Response: ASPR recognizes and appreciates the tremendous expertise of CDC subject matter experts including on infectious diseases, other public health threats, epidemiological surveillance, as well as understanding of the capabilities of state and local public health departments. CDC is an active part of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which is led by ASPR and provides a venue for sharing information across HHS agencies with a role in medical countermeasures requirement setting, research, development, regulatory review, procurement, stockpiling, distribution and use. CDC will remain an active participant in all PHEMCE workgroups and committees.

In order to ensure a smooth SNS transition with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate all aspects of the program transition. Some of the details involved in the transition have not been finalized. However, we would be pleased to provide a full briefing for Committee staff at any time before the end of the fiscal year.

Further, to continue to increase collaboration across the Department, ASPR has invited and instituted a new senior CDC liaison who is working within the ASPR Immediate Office.

2018 ASPR Funding Increases

Cole 2: Dr. Kadlec, the fiscal year 2018 omnibus provided significant funding increases for several ASPR programs. For the following programs, please describe how ASPR will spend these additional resources, what outcomes ASPR expects to achieve, and how NIH proposes to build off of this progress in fiscal year 2019:

a) National Disaster Medical System,

b) Hospital Preparedness Program,
c) BARDA,
d) Project BioShield, and
e) Pandemic Influenza activities.

ASPR Response:

- National Disaster Medical System – ASPR appreciates the additional $7.5 million provided in FY 2018 to support the National Disaster Medical System (NDMS). NDMS is an integral part of ASPR's proposed new regional disaster health response system. NDMS is comprised of medical personnel who are intermittent federal employees that deploy to help state and local officials meet medical and public health emergency needs following a disaster or emergency. However, NDMS Disaster Medical Assistance Teams and Disaster Mortuary Teams are currently understaffed. The FY 2018 funding increase will assist in the timely hiring of, training for, and equipping of NDMS team members for a diverse range of threats. Moving forward in FY 2019, ASPR intends to offer annual training for the approximately 3,600 NDMS employees, ensure personal protective equipment for CBRN threats is up to date, fill approximately 2,000 NDMS vacancies, and provide specialized training in patient air transport.

- Hospital Preparedness Program – ASPR appreciates the $10 million increase for HPP in FY 2018. HPP is an integral part of ASPR's proposed new regional disaster health response system. The U.S. healthcare infrastructure is a $3 trillion mostly private sector enterprise. Enhancing healthcare readiness for current national security threats – both state and non-state actors, naturally emerging infectious diseases, severe weather and cyber threats – requires a commitment to healthcare preparedness. FY 2018 funds will be used to increase support for healthcare coalitions that have been established across the country through the HPP State formula grant. Healthcare coalitions are groups of individual health care and response organizations (e.g., hospitals, EMS, emergency management organizations, public health agencies, etc.) in a defined geographic location that play a critical role in developing health care delivery system preparedness and response capabilities. In addition, FY 2018 funds will be used for innovative tiered, regional demonstration projects that can serve as a model for building a regional disaster health response system across the country.

- BARDA – ASPR appreciates the $25 million increase in FY 2018 for BARDA's advanced research and development program. These funds will be used to implement the medical countermeasure innovation partner (MCIP) authorized in the 21st Century Cures Act. As such, BARDA is implementing a new Division of Research, Innovation and Ventures, DRIVe. DRIVe and its network of accelerators and venture capital partners will invest in transformational technologies that have the potential to solve daunting, cross-cutting health security problems. DRIVe has two initial impact areas. The first is ENACT, "Early Notification to Act, Control and Treat", which aims to empower Americans to know when they are getting sick. The second is solving sepsis, which is the body's life-threatening response to an infection and affects more than 1.5 million people annually in the United

States. Approximately 250,000 people in the U.S. die every year from sepsis, making it a daily concern for doctors and their patients and an imminent concern if the U.S. faces a chemical, biological, radiological or nuclear attack. In FY 2019, ASPR intends to identify additional cross-cutting health security challenges in which DRIVe can make a transformational impact. We would be happy to brief Committee staff on this initiative at any time.

- Project BioShield – ASPR appreciates the $200 million increase provided for PBS in FY 2018. Through partnerships with biotechnology or pharmaceutical companies, PBS supports late-stage development and initial procurement of medical countermeasures (MCMs) for DHS-identified CBRN threats to national security. The development of a new vaccine or drug often takes over 10 years and over $1 billion per product. PBS-supported MCMs are stockpiled and would be available to be used if an FDA Emergency Use Authorization (EUA) is issued covering those MCMs, to protect civilians in case of a deliberate, accidental or natural release of one of these life-threatening agents. Gaps remain in meeting CBRN MCM requirements. These additional FY 2018 funds will be used for late stage development and procurement of products necessary to close some of these gaps, including cytokines for radiological and nuclear agents, anthrax antitoxin, smallpox antivirals, and Ebola vaccines and therapeutics. In FY 2019, ASPR/BARDA intends to continue addressing shortfalls in our MCM stockpile for major national security threats through strong partnerships with industry.

- Pandemic Influenza activities – ASPR appreciates the $138 million increase provided in FY 2018 to support BARDA's pandemic influenza preparedness program. The last influenza season demonstrated the need for better, faster, more flexible flu vaccine technologies and antiviral drugs right now.

  BARDA will use FY 2018 funds to:
  1. sustain and expand domestic influenza vaccine manufacturing capacity gains made to date and ensure cell and recombinant vaccine technologies are available;
  2. conduct clinical trials and support domestic production capabilities of novel antiviral drugs and therapeutics to ensure more than one class of antivirals is available to treat resistant strains;
  3. develop in-home and wearable diagnostics to speed up earlier infection detection and earlier, more effective treatment of influenza;
  4. improve efficacy of existing influenza vaccines and support modern, rapid platform-based enabling technologies for the production of influenza vaccines.

  In FY 2019, ASPR/BARDA intends to continue implementing the better, faster flu vaccines strategy, and ensure additional classes of antivirals and diagnostics are available as quickly as possible.

2018 CDC Funding Increases

Cole 3: Dr. Redd, the fiscal year 2018 omnibus provided significant funding increases for public health preparedness programs at CDC. For the following programs, please describe how CDC will spend these additional resources and what outcomes CDC expects to achieve.

a) Public Health Emergency Preparedness Cooperative Agreement, and
b) Strategic National Stockpile.

CDC Response:

- Public Health Emergency Preparedness Cooperative Agreement – CDC appreciates the increase in PHEP funding, and will allocate most of the additional $10 million directly to PHEP awardees, either to increase the amount of the awards to the 50 states, Chicago, Los Angeles County, New York City, Washington, D.C., Puerto Rico and the seven other U.S. territories, and the Freely Associated States, or to support new equipment for the Level 1 chemical laboratories in the Laboratory Response Network (LRN-C). The LRN-C equipment includes highly specialized laboratory instruments that detect toxic metals and other chemical threat agents in people at extremely low concentrations. It should be noted that the increased appropriation to $670 million in PHEP funding triggers a change in how CDC must calculate PHEP funding awards. Per statute, an appropriation of at least $667 million results in a minimum award of $5 million for the 50 states, Washington, D.C., and Puerto Rico. CDC plans to increase amounts from FY 2017 awards for twelve states to reach the $5 million minimum award for FY 2018. States will allocate funding according to their program needs to plan, train, and prepare for emergencies so that their communities are ready when disasters strike.

- Strategic National Stockpile – CDC appreciates the increased funding provided in the FY 2018 appropriation. The additional $35 million provided to the Strategic National Stockpile allows for increased preparedness for children ages 18 and under through procurement of antibiotics that will expand CDC's ability to respond to biological threats. The increased procurement of antibiotics follows a recommendation from the SNS Annual Review to increase holdings of antibiotics for anthrax for use in pediatric populations.

BioShield Multiyear Contracting Authority

Cole 4: Dr. Kadlec, since fiscal year 2014, this subcommittee has included language that allows BARDA to enter into multi-year contracts to purchase medical countermeasures in the absence of a large amount of multi-year funding. This language has been included to provide a greater degree of certainty to industry partners as well as to save taxpayer dollars because the government can take advantage of price discounts from bulk purchases. Can you tell me how many times BARDA has used this authority? If this authority has not been used, can you please explain why not and whether improvements need to be made?

ASPR Response: Multiyear contracting authority would be most beneficial if BARDA awarded contracts with the sole purpose of procuring medical countermeasures. However, under PBS, BARDA executes contracts to both support late-stage development and procure medical countermeasures. For this reason, BARDA has not used multiyear contracts for any of the 14

PBS contracts awarded since 2014. The Administration supports advanced appropriations for PBS to provide a predictable source of funding for late-stage development and procurement of medical countermeasures.

Emergency Preparedness Resources to Tribes

Cole 5: Dr. Redd and Dr. Kadlec, It is often the case that Tribal communities are left out of the nationwide funding structure to provide emergency services to populations living on their reservations. Like other governments, Tribes have a responsibility to their citizens to provide basic services that ensure the health, wellness and safety of their communities. Funding through Public Health Emergency Preparedness (PHEP) Cooperative Agreements at CDC and the Hospital Preparedness Program (HPP) at ASPR is not currently available to Tribes.

a. With funding mechanism flowing primarily to the states, how is each of your agencies ensuring that Indian Country is protected in health emergencies?
b. How do you ensure that the nationwide response in Tribal communities is consistent and effective?
c. What will your agencies do to ensure that Tribes are included in programming for emergency preparedness?

CDC Responses:

As a condition of receiving the PHEP award, awardees with federally recognized tribes within their jurisdictions must describe how they obtain programmatic input from these tribes regarding the content and implementation of jurisdictional public health emergency preparedness and response plans. These awardees must also provide a letter signed by the jurisdiction's state health official or preparedness director on official agency letterhead confirming those tribes approve or have provided input on the approaches and priorities described in PHEP applications. Awardees unable to gain 100% input, despite good-faith efforts to do so, must submit a separate attachment with their applications describing the reasons why and the steps taken to address tribal input. In addition, many PHEP awardees provide funding to tribal entities in their jurisdictions. For instance, in fiscal year 2017, 20 states with at least one federally recognized tribe planned to allocate PHEP funding to tribal health programs in their jurisdictions.

Awardees also must show evidence that they are integrating the access and functional needs of at-risk and vulnerable population(s) as indicated in their planning. They must describe the structure or processes in place to integrate the access and functional needs of at-risk individuals, including but not limited to children, pregnant women, older adults, people with disabilities, and people with limited English proficiency and non-English speaking populations. Strategies to integrate the access and functional needs of at-risk are identified and addressed in operational work plans. Awardees must ensure that tribes are included in this planning.

CDC will release in the summer of 2018 updated public health preparedness and response capability standards that will incorporate new content related to tribal populations. The revised

capability standards will reflect current public health practice, operational readiness components, and other public health emergency preparedness and response priorities.

In addition, to help ensure that states and tribes are able to meet urgent needs during a public health emergency, CDC created a new funding mechanism that can be set in motion when supplemental or emergency funds are appropriated during a public health emergency.

Expedited access to funds will enable awardees to immediately respond so that the negative impacts on health and safety will be reduced. Eligible applicants for this public health crisis response notice of funding opportunity (NOFO) include federally recognized tribal governments that meet the NOFO requirements and serve at least 50,000 people.

ASPR Responses:

a. With funding mechanism flowing primarily to the states, how is each of your agencies ensuring that Indian Country is protected in health emergencies?

   Response: Building readiness and response capacity for threats across all communities is a high priority for ASPR and is the rationale for ASPR's proposal to create a regional disaster health response system that is capable of responding more effectively and efficiently to manage the health impacts of 21st century threats.

   The Hospital Preparedness Program (HPP) authorization (section 319C-2 of the Public Health Service Act) defines awardee eligibility for the cooperative agreement program as the states, territories and freely associated states, and up to three political subdivisions. While Tribes are not eligible for a direct award under the authorizing statute, Tribes do participate in HPP through health care coalitions (HCCs). HCCs are groups of individual health care and response organizations (e.g., hospitals, EMS, emergency management organizations, public health agencies, etc.) in a defined geographic location that play a critical role in developing health care delivery system preparedness and response capabilities. HCCs coordinate activities among health care organizations and other stakeholders in their communities; these entities comprise HCC members that actively contribute to HCC strategic planning, operational planning and response, information sharing, and resource coordination and management. As a result, HCCs collaborate to ensure each member has what it needs to respond to emergencies and planned events, including medical equipment and supplies, real-time information, communication systems, and educated and trained health care personnel. Indian Tribes and Tribal Organizations are integrated as key members of many HCCs across the country. Further, with HPP funds, Arizona is piloting a statewide Tribal HCC.

   In addition to HPP funding, ASPR staff have recently met with the National Indian Health Board, the HHS Intergovernmental and External Affairs staff in support of the Secretary's Tribal Advisory Committee and the Acting Director of the Indian Health Service to identify opportunities for ASPR to better assist Indian Country in preparing for and responding to health emergencies.

b. How do you ensure that the nationwide response in Tribal communities is consistent and effective?

Response: States and political subdivisions that receive HPP funds are required to include healthcare preparedness planning for all areas within their jurisdiction, including the development of all-hazards emergency preparedness and response plans to meet the capabilities called out in the grant award. Awardees must provide an opportunity for each healthcare coalition (HCC) in their jurisdiction, as well as the public generally, to review and provide comments on their preparedness and response plans. This provides an opportunity for input from other state, local, and Tribal stakeholders, the health care delivery system, and the public, including members of at-risk populations and those with an expertise in integrating the access and functional needs of at-risk individuals. However, the level of coordination between States and Tribes varies across the country.

As stated above, ASPR staff recently met with the National Indian Health Board, the Secretary's Tribal Advisory Committee and the Acting Director of the Indian Health Service to identify opportunities for ASPR to better assist Indian Country in preparing for and responding to health emergencies. We would be happy to provide an update to Committee staff as such plans are developed.

One example of existing related activities within HPP is the special version of the Healthcare Coalition Response Leadership (HCRL) course that ASPR is providing onsite for Tribal Organizations in Arizona. The HCRL is a three-day course developed in collaboration with ASPR and FEMA's Center for Domestic Preparedness that provides instruction and facilitated discussion in best practices and lessons learned in establishing an effective HCC framework and conducting HCC planning, as well as achieving preparedness. The course provides instruction on the development of indicators, triggers, and tactics for proactive coalition planning; and approach techniques, and instruction on the considerations for HCC response and recovery leadership.

c. What will your agencies do to ensure that Tribes are included in programming for emergency preparedness?

Response: While Tribes are not eligible for a direct award under the authorizing statute, HPP is critical to regional health care preparedness and response efforts. HPP aims to enable the health care system to save lives during emergencies that exceed the day-to-day capacity of the health and emergency response systems. It is the only source of federal funding for health care system preparedness and response. For the past 15 years, HPP investments have improved individual health care entities' preparedness and have built a system for coordinated health care delivery system readiness and response through healthcare coalitions.

Since 2012, HPP has encouraged its 62 state, local, and territorial public health department awardees to invest in forming and developing healthcare coalitions, which are groups of individual health care and response organizations (e.g., hospitals, EMS, emergency management organizations, public health agencies, etc.) in a defined geographic location that coordinate activities among health care organizations and other stakeholders in their communities (urban, suburban, rural, frontier, or a combination thereof). As of June 30, 2017, over 31,000 health care facilities and community organizations were participating in 476

8

coalitions nationwide. HPP estimates that 17 percent of HCCs across the country (n=83) include representation from Tribes or health care entities focused on the needs of Tribes or tribal communities (e.g., Indian Health Service facilities or community and tribal health centers).

Rep. Mike Simpson Questions for the Record

Questions to Assistant Secretary Dr. Robert Kadlec M.D.

Pandemic Flu

Simpson 1: I was pleased to read the Department's FY19 budget justification states, "Influenza poses one of the world's greatest infectious disease challenges. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands of people die from flu every year." I'm pleased HHS has set a goal of responding to an influenza outbreak within 12 weeks of a declaration. However, I understand our current ability to respond to a pandemic influenza outbreak is 6 months, according to HHS' 2017 Pandemic Update. We must do better. What technologies are you considering to meet HHS' goal of responding to a pandemic within 12 weeks of a pandemic declaration?

ASPR Response: ASPR/BARDA has made significant gains in pandemic influenza vaccine preparedness over the last 10 years, including supporting the licensure of faster, more flexible cell-based, recombinant and adjuvanted influenza vaccines, while modernizing and expanding the domestic manufacturing capabilities for influenza vaccines. However, there remains much work to be done in making the right vaccine available even faster, which is essential to an effective pandemic response. There are steps that can be taken right now to make better, faster flu vaccine.

BARDA is applying new technologies to improve multiple steps in the current vaccine manufacturing process and delivery. First is sustaining and expanding the domestic manufacturing capacity and availability of cell and recombinant vaccines (such as Flublok®, an FDA licensed influenza vaccine, for which BARDA supported the advanced development), which provide the shortest timeline from pandemic declaration to release of vaccine. Second, is development and implementation of new assays/technologies to fully modernize and optimize for speed, the end-to-end production and release process for influenza vaccines. Third is targeting the last mile of vaccine delivery and administration to develop new approaches (such as microarray needle patch delivery or jet injectors) that would reduce reliance on needles and syringes supply chain surge capacity and allow faster and more efficient immunization with pandemic vaccine. Fourth is to implement the addition of currently approved adjuvanted influenza vaccines for all ages into both seasonal and pandemic vaccines, while also developing additional adjuvant options that provide safe and enhanced effectiveness to influenza vaccines that are faster to produce.

Simpson 2: With the development of novel technologies capable of cutting response time from months to weeks, what is the Department doing to encourage and support these solutions?

ASPR Response: ASPR/BARDA is taking a multifaceted approach to reducing pandemic influenza vaccine response times, to make sure the right vaccine is available when we need it.

First BARDA is partnering with companies to support the development of these novel technologies that rely less on viral growth properties to improve the speed and robustness of vaccine production. For example, BARDA was a major funder of the first licensed recombinant influenza vaccine (Flublok®), and BARDA continues to fund recombinant vaccine-related efforts. Second is supporting the sustainment of domestic production capabilities to ensure these newly licensed, more responsive vaccine options are available and ready to respond when necessary. Third BARDA is supporting further development of recombinant and cell-based vaccines through comparative efficacy clinical studies to expand use indications for a broad range of high-risk and special populations.

Simpson 3: The FY 2019 request for ASPR's Biomedical Advanced Research and Development Authority (BARDA) is $512 million – a $3 million increase over FY 2018 – to "support a robust development pipeline of biodefense products that address gaps in national preparedness." The justification also highlights ASPR's efforts to strengthen the nation's emergency medical response and biodefense capabilities by "collaborating with public and private partners on advanced research, development, and procurement of medical countermeasures."

As you know, the 3 Centers for Innovation in Advanced Development and Manufacturing aim to support domestic infrastructure to produce countermeasures for pandemic flu and other diseases. However, according to a 2017 GAO report, the centers are not yet able to manufacturing the contracted quantity of pandemic influenza vaccine. Should HHS sustain or augment existing investments in rapid vaccine response capabilities?

ASPR Response: It is vitally important that HHS both sustain and augment existing investments in rapid vaccine response capabilities. While we have made substantial gains, critical gaps remain in our ability to quickly respond to new threats. BARDA is supporting the development of platform-based enabling technologies that will be responsive to emerging and rapidly spreading outbreaks for both known and unknown threats.

Simpson 4: Does our nation have the vaccine manufacturing capabilities available to rapidly respond to a pandemic influenza outbreak? What gaps need to be prioritized and filled?

ASPR Response: With benefits to both pandemic and seasonal influenza preparedness and response, ASPR/BARDA has prioritized partnering with industry partners to build domestic vaccine manufacturing infrastructure, and develop and license better and faster manufactured influenza vaccines. With supplemental funding from Congress over the last decade, BARDA has invested heavily in increasing the domestic capacity for monovalent vaccine antigen production—from approximately 60 million doses to 600 million doses.

There are significant strides that can be made to improve the effectiveness of our existing vaccines in preparation for the long-term vision of an ultimate universal influenza vaccine. Leveraging the successful development and licensure of both recombinant and cell-based influenza vaccines, we should: continue to expand the domestic capacity of cell-based and

recombinant influenza vaccines; explore ways to enhance their effectiveness, such as through the addition of adjuvants and higher doses of vaccine; conduct clinical trials in support of applications to expand their licensed indications for all age groups; and, fully integrate manufacturing process improvements to realize efficiencies to increase flexibility and robustness while reducing response time and establishing a 21st century foundation for next generation vaccines.

Simpson 5: What investments or approaches should our country be taking to better respond to potential outbreaks?

ASPR/NIH Response: To respond to pandemic influenza, in addition to sustaining domestic manufacturing capacity and improving our manufacturing and fill/finish capacity, continued focus on approaches to allow faster testing/release of vaccine, improved efficacy, and faster delivery are important elements to address to better respond to potential outbreaks. It is also critical to continue to develop platform-based enabling technologies that would provide a flexible capability to respond to new or re-emerging threats. Beyond vaccines, we must not forget the importance of having additional influenza antivirals available to treat resistant viruses.

The National Institute of Allergy and Infectious Diseases (NIAID), the lead institute for research on influenza at the National Institutes of Health, is supporting influenza research that will improve our ability to prevent or respond to a potential a pandemic influenza outbreak. In addition to the pursuit of improved diagnostics, influenza antivirals, and vaccine manufacturing methods, NIAID is focused on working to address two major challenges in influenza vaccinology. These challenges are: 1) to develop new production strategies to allow for rapid response to seasonal and pandemic outbreaks, including the use of modern platform technologies rather than growth of the virus in eggs or cells; and 2) to develop strategies to induce broader immune responses to protect against multiple influenza strains. With respect to the second challenge, NIAID is prioritizing the development of universal influenza vaccines that could provide long-lasting protection against multiple influenza strains. Universal influenza vaccines would be important tools to help limit the spread of both seasonal and pandemic influenza. NIAID is appreciative of the additional $40 million in funding for universal influenza vaccine research that Congress provided through the Consolidated Appropriations Act, 2018 (P.L. 115-141). Targeted research investments, such as those made by NIAID, will be required to generate the critical information necessary to enable the development of universal vaccines that could be utilized against outbreaks of both seasonal and pandemic influenza.

NIAID is galvanizing research efforts to develop universal influenza vaccines. In 2017, NIAID convened influenza experts from the U.S. and throughout the world at a research agenda-setting workshop, "Pathway to a Universal Influenza Vaccine." Following this meeting, NIAID outlined its research priorities in a strategic plan for a universal influenza vaccine. NIAID universal influenza vaccine research will focus on three key areas outlined in the strategic plan: improving knowledge of the transmission and pathogenesis of influenza infection; characterizing influenza immunity and immune factors that correlate with protection against influenza; and supporting the

design of universal influenza vaccines. NIAID is actively engaging Federal partners, including HHS agencies, and other key domestic and international stakeholders involved in influenza vaccine research to coordinate and advance activities outlined in the strategic plan. For example, NIAID continues to collaborate with BARDA to advance the development and clinical testing of promising influenza vaccine candidates. The ultimate goal of these research efforts is to facilitate the design and development of a safe and effective vaccine that will provide durable protection against outbreaks of seasonal and pandemic influenza.

Simpson 6: Has the Department considered pursuing successful capabilities already funded by other agencies to include DOD's Defense Advanced Research Projects Agency (DARPA)?

ASPR Response: ASPR/BARDA is actively collaborating with DARPA and other components of the DoD to ensure a coordinated and effective approach to developing medical countermeasures that intersect our targeted threat areas. BARDA will continue to pursue opportunities for additional collaboration to reduce redundancy and to synergize product development functions.

Ranking Member Rosa DeLauro Questions for the Record

Influenza Antivirals

DeLauro 1: As we all know, this has been a particularly challenging flu season. As of this week, a total of 151 children have died, and the hospitalization rate has been more than 60 percent higher than in 2014-2015 – which, until this winter, had been the worst flu season in years. Can you provide additional information about the importance of developing influenza antivirals—including for use in severely ill and hospitalized patients—as well as the role of antivirals in the public health response to influenza?

ASPR/NIH Response: While vaccination is the best way to prevent influenza infection every year, and especially in the event of a pandemic, a large number of individuals will nevertheless become ill and will need urgent treatment. As a result, new and improved antiviral therapies are an essential component of the public health response to influenza. Early treatment with these therapies can shorten the duration of symptoms and may reduce the risk of complications from influenza.

The National Institute of Allergy and Infectious Diseases (NIAID) remains committed to supporting research advances in influenza therapeutics and vaccines, including the development of influenza antivirals. Currently, five antiviral medications are licensed by the FDA to treat influenza infection; however, two are not recommended for use during the 2017-2018 influenza season due to resistance in currently circulating influenza A strains. These belong to the adamantanes class of drugs.

The remaining three antivirals are neuraminidase inhibitor antiviral drugs and are recommended by CDC this season. They share a common mechanism of action, suggesting that should an influenza strain develop resistance to one of these antivirals, it could have resistance to the other two. The effectiveness of these three antivirals has largely been studied in less severe cases of influenza, thus their effectiveness in patients hospitalized with severe influenza is not well established. This patient population represents a large, unmet medical need and gap in our preparedness. The development of new and more effective antiviral drugs with different mechanisms of action and understanding how they work in diverse patient populations are important components of ongoing research to develop new influenza countermeasures.

NIAID supports research to develop broad-spectrum antiviral drugs and other innovative influenza therapeutics such as monoclonal antibodies (mAbs), several of which have advanced to clinical trials. NIAID intramural researchers are developing two mAbs, including one that is being tested in a human influenza challenge trial and a second that has completed a Phase 2a clinical trial. NIAID scientists and grantees also are developing mAbs to help limit influenza virus disease. Several of these mAbs are in clinical trials, including novel mAbs targeting regions of the virus that are likely to remain constant from one influenza season to the next. NIAID also has launched three clinical trials to assess the effectiveness of novel influenza therapeutics in high-risk populations. NIAID remains committed to supporting the development of new and

improved antivirals capable of decreasing the severity of illness and limiting the number of deaths resulting from influenza.

ASPR/BARDA is also committed to the development of novel treatments for people infected with influenza. In 2017, ASPR/BARDA utilized Other Transactional Authority to forge flexible, portfolio-based public-partnerships with Janssen, and Regeneron to address this critical need.

DeLauro 2: In addition, can you give us an update about antiviral candidates that are currently in the advanced research and development pipeline?

ASPR Response: There are multiple antiviral candidates in Phase 2 and Phase 3 development for treatment of influenza. These candidates form two main drug classes; 1) small molecule influenza polymerase inhibitors, and 2) broadly cross-reactive monoclonal antibodies against conserved regions of the virus. ASPR/BARDA is currently supporting three novel influenza therapeutics in advanced development; one candidate is through an Other Transactional Agreement portfolio partnership with Janssen. Antibody-based therapeutics in development against influenza are in Phase 2 clinical trials and are focused on evaluating effectiveness in the severely ill hospitalized patient population for which there is a large unmet medical need.

Specific examples of influenza therapeutics in the advanced development pipeline include:

1. Baloxavir marboxil inhibits the influenza virus cap-dependent endonuclease (polymerase PA subunit). This small molecule antiviral has been approved in Japan for the treatment of patients infected with influenza and is currently in Phase 3 development in the United States.
2. Pimodivir specifically targets the PB2 subunit of influenza polymerase complex and is currently in Phase 3 development in the United States for the treatment of severely ill patients hospitalized with influenza.
3. Multiple companies are developing broad-spectrum monoclonal antibodies that target the stem region of the influenza hemagglutinin protein. These antibodies are all in Phase 2 development for the treatment of patients hospitalized with influenza.

Rep. Lucille Roybal-Allard Questions for the Record

Influenza

Roybal-Allard 1: This has been a particularly challenging flu season. A total of 151 children have died, and the hospitalization rate was more than 60 percent higher than in 2014-2015 -- which, until this winter, had been the worst flu season in years. For this reason I was pleased to see that the President's FY 2019 budget request includes funding for the development of influenza antiviral drugs for use in severely ill and hospitalized patients. Can you tell us more about why it's so important to develop these antivirals and how they fit in to the public health response to influenza?

ASPR/NIH Response: While vaccination is the best way to prevent influenza infection every year, and especially in the event of a pandemic, a large number of individuals will nevertheless become ill and will need urgent treatment. As a result, new and improved antiviral therapies are an essential component of the public health response to influenza. Early treatment with these therapies can shorten the duration of symptoms and may reduce the risk of complications from influenza.

The National Institute of Allergy and Infectious Diseases (NIAID) remains committed to supporting research advances in influenza therapeutics and vaccines, including the development of influenza antivirals. Currently, five antiviral medications are licensed by the FDA to treat influenza infection; however, two are not recommended for use during the 2017-2018 influenza season due to resistance in currently circulating influenza A strains. These belong to the adamantanes class of drugs.

The remaining three antivirals are neuraminidase inhibitor antiviral drugs and are recommended by CDC this season. They share a common mechanism of action, suggesting that should an influenza strain develop resistance to one of these antivirals, it could have resistance to the other two. The effectiveness of these three antivirals has largely been studied in less severe cases of influenza, thus their effectiveness in patients hospitalized with severe influenza is not well established. This patient population represents a large, unmet medical need and gap in our preparedness. The development of new and more effective antiviral drugs with different mechanisms of action and understanding how they work in diverse patient populations are important components of ongoing research to develop new influenza countermeasures.

NIAID supports research to develop broad-spectrum antiviral drugs and other innovative influenza therapeutics such as monoclonal antibodies (mAbs), several of which have advanced to clinical trials. NIAID intramural researchers are developing two mAbs, including one that is being tested in a human influenza challenge trial and a second that has completed a Phase 2a clinical trial. NIAID scientists and grantees also are developing mAbs to help limit influenza virus disease. Several of these mAbs are in clinical trials, including novel mAbs targeting regions of the virus that are likely to remain constant from one influenza season to the next. NIAID also has launched three clinical trials to assess the effectiveness of novel influenza therapeutics in high-risk populations. NIAID remains committed to supporting the development of new and

improved antivirals capable of decreasing the severity of illness and limiting the number deaths resulting from influenza.

ASPR/BARDA is also committed to the development of novel treatments for people infected with influenza. In 2017, ASPR/BARDA utilized Other Transactional Authority to forge flexible, portfolio-based public-partnerships with Janssen, and Regeneron to address this critical need.

Roybal-Allard 2: Please give us an overview of promising antivirals that are currently in the pipeline.

ASPR Response: BARDA is currently supporting advanced development of several new treatment options for influenza. Treatment options for influenza that use a different mechanism of action than the currently available neuraminidase inhibitors, and that are effective in severely ill, hospitalized patients are critically needed. Some examples of influenza therapeutics in the advanced development pipeline include:

1. Baloxavir marboxil inhibits the influenza virus cap-dependent endonuclease (polymerase PA subunit). This small molecule antiviral has been approved in Japan for the treatment of patients infected with influenza and is currently in Phase 3 development in the United States.
2. Pimodivir specifically targets the PB2 subunit of influenza polymerase complex and is currently in Phase 3 development in the United States for the treatment of severely ill patients hospitalized with influenza.
3. Multiple companies are developing broad-spectrum monoclonal antibodies that target the stem region of the influenza hemagglutinin protein. These antibodies are all in Phase 2 development for the treatment of patients hospitalized with influenza.

Roybal-Allard 3: What resources needed to ensure their development?

ASPR Response: ASPR/BARDA appreciates the $138 million increase provided in FY 2018 to support BARDA's pandemic influenza preparedness program, including clinical trials and advanced development of novel antiviral drugs. The last influenza season demonstrated the need for better, faster, more flexible flu vaccine technologies and antiviral drugs right now. HHS also supports a dedicated authorization for appropriation for BARDA's pandemic influenza preparedness program in the 2018 reauthorization of the Pandemic and All-Hazards Preparedness Act.

WITNESSES