

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2018

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

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2018

WEDNESDAY, APRIL 5, 2017.

OVERSIGHT HEARING—FEDERAL RESPONSE TO THE OPIOID ABUSE CRISIS

WITNESSES

BARBARA CIMAGLIO, DEPUTY COMMISSIONER, VERMONT DEPARTMENT OF HEALTH

BILL GUY, ADVOCATE, PARENTS HELPING PARENTS

NANCY HALE, PRESIDENT AND CEO, OPERATION UNITE

ROSALIE LICCARDO PACULA, SENIOR ECONOMIST AND CO-DIRECTOR, DRUG POLICY RESEARCH CENTER, RAND CORPORATION

Mr. COLE. Good morning. It is my pleasure to welcome our witnesses today to the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies to discuss the Federal response to the opioid abuse crisis. I want to thank all of our witnesses for coming and I look forward to hearing your testimony.

Today, we are here to learn about the Federal response to address opioid abuse. As we have all heard reported in the media, the growth of this epidemic is staggering. Data released by the Centers for Disease Control and Prevention for 2015 show a continued increase in the number of overdose deaths involving an opioid. On average, 91 Americans are lost each day due to an opioid-related overdose. That is one person every 16 minutes. And that literally means in the course of this hearing we will lose probably eight people.

In response to this growing epidemic, Congress has dramatically increased investments in this area. In the 114th Congress, as part of the 21st Century Cures Act, we established a grant program to supplement the State response to the opioid abuse crisis. We appropriated \$500,000,000 in the State response grants as part of the current year's continuing resolution in order to expedite the aid to the hardest hit States and communities. The proposed budget from the administration continues these activities for fiscal year 2018.

In addition, with leadership from our colleagues in the Senate, we passed the Comprehensive Addiction and Recovery Act, which included numerous initiatives aimed at reducing overdose deaths, expanding access to treatment, and supporting people through their recovery. Congress, understanding the urgency for resources,

supported these programs by including them in the continuing resolution.

As we finalize this year's appropriations and begin to work on the next fiscal year, we continue to look at programs that provide education to young adults, parents, and medical providers on prevention strategies, access to medication-assisted treatment, and training for first responders to prevent overdose-related deaths.

Today we look forward from hearing from our witnesses about the strategies we can most effectively help those who are addicted, their families, and their communities. The issue of opioid addiction is multifaceted and Federal efforts must be strategically coordinated with the States, cities, and community organizations for a comprehensive, holistic response. We hope to learn more about how we can best target our Federal investments in this area to ensure we are making a maximum impact.

Today I am pleased to welcome the following witnesses. Rosalie Pacula? I hope I got it right. We Okies don't always get these names very good. So Bill will help me through it, I am sure. As the senior economist at the RAND Corporation, she serves as co-director of RAND's Drug Policy Research Center. She has been actively engaged in evaluating the impact of recent policies to expand treatment for opioid use in the United States. Her work on prescription drugs has specifically covered misuse in a variety of populations, including the elderly, the disabled, and the poor.

Bill Guy, who is in full disclosure one of my constituents, comes to us from Norman, Oklahoma. Bill works with Parents Helping Parents, an addiction prevention advocacy group. Bill and his wife Rita are the parents of three grown children and have eight grown grandchildren. Bill works for the Oklahoma Education Association. He will be sharing his story of how addiction has impacted his family.

Barbara Cimaglio is a nationally recognized leader in the field of alcohol and drug abuse prevention, treatment, and recovery. Her career spans almost over 40 years of service at the State and local level. She is currently the deputy commission for the Vermont Department of Health, overseeing substance abuse, prevention, treatment, and recovery services, along with various public health programs. She is also on the board of the National Association of State Alcohol and Drug Abuse Directors.

Nancy Hale worked for 34 years as a teacher, career counselor, and administrative coordinator. She retired from public education in 2012 and joined Operation UNITE, where she currently serves as president and CEO. Congressman Hal Rogers, our good friend and colleague, started Operation UNITE in 2003. And just parenthetically, as everybody on this committee knows, the reason why we have been as bipartisan and focused on this issue as we have been is because of Chairman Rogers' leadership here for many, many years. He has really made an extraordinary difference for all Americans in this effort.

Operation UNITE, again, works to rid communities of illegal drug use through undercover narcotics investigations, coordinating treatment for substances abusers, providing support to families and friends of substance abusers and educating the public about the dangers of using drugs.

I want to add, I was looking at your biography and I don't know anybody who has ever won volunteer of the year for 4 years at the State level. So thank you for your personal commitment.

And before I close out, I want to point out my good friend Phil English is here somewhere, our former colleague. Right over here. I know he is involved in some efforts in this area as well. So we are delighted to have him here as well.

As a reminder to the subcommittee members and our witnesses, we will abide by the 5-minute rule so that everyone will have a chance to present their testimony and ask questions. I look forward to hearing from our witnesses.

I would like to now yield to my good friend, the ranking member, the gentlelady from Connecticut, for any opening remarks she would care to make.

Ms. DELAUR. Thank you very much, Mr. Chairman. Thank you for holding this hearing. I would like to welcome our witnesses this morning.

I think if it is Italian it could even be Cimaglio, so there you go.

So in any case, I know so many of you have traveled so far to be with us today and we are so grateful to have you with us for what is a very, very important hearing, and especially thankful, thankful, not only that you are here, but thankful for the work that you do every day in our communities to help families who are living with addiction.

Over the past year and a half I have heard a lot from community members from my community, experts across the State of Connecticut about the local impacts of the nationwide opioid epidemic. I have done a lot of events like forums at community health centers, townhalls, a productive meeting with the former Office of National Drug Policy Director Michael Botticelli. All of these folks came in and out of the city of New Haven and Hartford to talk us through this issue.

It was clear then and it is clear now that we have an epidemic, an opioid epidemic that requires a response from all levels of government. It has been sounding alarms for far too long. According to CDC, Centers for Disease Control and Prevention, about 90 Americans die every day from an opioid overdose, more than twice the rate in 2013. In 2015 more than 33,000 Americans died from an opioid or heroin overdose, more than the number of people who died in car accidents.

And sadly, opioid deaths are likely undercounted. In Connecticut, our State's medical examiner's office reported that 917 people died from overdoses in 2016. That was a 25 percent increase over 2015. The largest increase involved the synthetic opioid Fentanyl.

The Federal Government has a critical role to play in supporting State and local communities as they work to combat the tragic consequences of addiction. In 2016, this subcommittee included several important funding increases to address the opioid crisis on a bipartisan basis. I was proud of our work to increase funding for the Substance Abuse Prevention and Treatment Block Grant by \$38,000,000, increased targeted prevention and treatment program funding by \$35,000,000, and increase of the CDC's prescription drug overdose program by \$50,000,000.

We need to build on these investments in the 2017 budget, which we soon hope that we will have completed and moved forward on, and we need to do the same in 2018, because in fact what this is all about, what these issues are about today are life and death. And lives are on the line. This is not parks, roads, bridges, or other areas which we take up at the Federal level.

And the administration has proposed to maintain the 21st Century Cures Act funding for opioid abuse. Quite honestly, it is not specifically clear what they will propose for the remaining programs across Health and Human Services. There is a skinny budget that is out and for me the writing is on the wall in that regard. And I look at it and I see some reckless cuts. I hope that is not going to be the case in this area.

The administration's budget proposes really slashing the non-defense spending by \$54,000,000,000, and that would include \$15,000,000,000 from Health and Human Services, the sub-committee that you are appearing before today.

So we are in the middle of this crisis, which you can all identify, people are dying, and we have to make a determination of where our priorities are. And instead of starving those priorities, we need to deal with funding public health emergencies robustly. We have an obligation to react to this crisis with the urgency that it deserves.

Which is why, and the chairman knows this, I introduced something called Public Health Emergency Preparedness Act. It would provide \$5,000,000,000 to the Public Health Emergency Fund, which the Department of Health and Human Services could use to combat opioid epidemics.

We have a natural disaster emergency fund, which is between \$8,000,000,000 and \$10,000,000,000. I think health emergencies are equally important as natural disasters are. We should be able to react to public health emergencies like they are disasters, because for the millions of affected families they are.

I have also urged the Food and Drug Administration to reclassify naloxone from a prescription to an over-the-counter medication so that more have access to this lifesaving drug.

And above all, the issue that I hear the most about—and, Mr. Guy, you were very poignant on this issue—we need to increase access to immediate treatment. Delays to treatment put lives at risk. And the biggest issue is ensuring that people can quickly get the treatment that they need, not wait a week, 3 weeks, a month, because we know that that often leads to a very, very bad outcome.

We need to reduce the stigma surrounding substance abuse. We need to acknowledge substance abuse for what it is, a disease, a brain disease.

When individuals get out of treatment and they want their lives back on track, they run into countless obstacles. They have a hard time accessing jobs, they have a hard time accessing housing. And with the work requirements that are being thought about to be imposed on Medicaid or elsewhere, we create oftentimes an impossible situation for recovered members of our communities.

Let me also highlight the importance of the Affordable Care Act's Medicaid expansion. In many places, Medicaid is the most significant source of coverage and funding for substance use prevention

and treatment. Many States with the highest opioid overdose death rates have used Medicaid to expand access to medication-assisted treatment.

And I will just make a point of noting that that is something that the American Association for Opioid Dependency has said, that NIDA, N-I-D-A, has firmly established that Medicaid-assisted treatment increases patient retention, decreases drug use, infectious disease transmission, and criminal activity.

So we have good scientific data which tells us what we need to do, and the fact is that Medicaid has been used to expand that kind of access. In West Virginia, Kentucky, Pennsylvania, Ohio, Medicaid pays for 35 to 50 percent of all medication-assisted treatment. In some of those States, the uninsured rate would triple if the ACA were repealed.

If the Republican healthcare bill had passed, 14 million low-income Americans would have lost Medicaid coverage and their access to treatment along with it. That is unconscionable, in my view, and the repeal of the essential benefits package would have stripped millions of their access to substance abuse treatment as well.

Lastly, I would highlight the importance of passing a full-year Labor-HHS bill later this month. There is bipartisan support for addressing the opioid crisis. That is real. And we need to pass a full-year bill to show our strong support for these lifesaving programs by not just level funding these priorities, but by enhancing their funding. We cannot afford to wait to act when addiction affects the lives of so many of our neighbors and our families, our brothers, our sisters, and our community members.

I want to thank you all for being here today, not, as I said, for just testifying before us, but for what you have committed your professional lives to, to help to deal with this crisis every single day. I look forward, and I know we look forward to your testimony today.

Thank you, Mr. Chairman.

Mr. COLE. I thank the gentlelady.

I want to next go to the gentlelady, the ranking member of the full committee. As the ranking member of the full committee, she is a member of all 12 subcommittees. But she comes so frequently to our committee, I know we are her favorite subcommittee.

So with that, my friend is recognized.

Mrs. LOWEY. Should I say I love all of my family equally?

Well, first of all, I want to thank Chairman Cole and Ranking Member DeLauro for holding this very important hearing, and to our distinguished panel for joining us and for your important work that you have done on this absolutely critical issue.

In 2015, opioids, including prescription drugs and illegal drugs such as heroin, killed more than 33,000 Americans, just surpassing death by firearms. In my home State of New York more than 800 people lost their lives, the highest death toll due to opioids in our history. Sadly, as we await the 2016 data, the record could once again be broken.

The opioid epidemic knows no gender, racial, or socioeconomic lines. It is wide ranging. It is everywhere. This epidemic is destroy-

ing lives, breaking apart families, and wreaking havoc on communities big and small throughout our country.

Last year, Congress came together to pass the Comprehensive Addiction and Recovery Act, as well as the 21st Century Cures Act, providing \$1,000,000,000 over the next 2 years to support State efforts to address opioid abuse.

I do want to share Chairman Cole's praise for my colleague Chairman Rogers, who couldn't be here today, because he has really taken the lead on this issue.

As the Federal Government continues to combat this epidemic a few things are certain. We do not have a single day to waste with 91 Americans dying each day from an opioid overdose. Our response must rely on the best evidence of what will work, knowing that there may not be a silver bullet, and any person seeking help for substance abuse or mental health should never be told that help is not available. There are wait lists that delay treatment or—and I emphasize this point—that substance abuse or mental health treatment would not be covered by insurance.

I want to repeat that again. No one in this country should be told that mental health treatment or substance abuse, and they are very often interrelated, never should anyone be told that insurance will not cover their treatment, putting treatment out of the reach of millions of Americans.

Today, I look forward to hearing from our experts, those who chose to work in this field and those like Bill Guy who are called to this work after losing a loved one to the horrors of addiction. Thank you so very much for testifying and for sharing your stories with us.

Thank you, Mr. Chairman.

Mr. COLE. Thank you.

We will now go, Ms. Hale, to you for any opening statement that you would care to make.

Ms. HALE. Good morning. Thank you for giving me this opportunity to speak with you today. I am Nancy Hale, president and CEO of Operation UNITE. UNITE stands for Unlawful Narcotics Investigations, Treatment and Education. UNITE was launched in 2003 by Congressman Hal Rogers shortly after a special report, "Prescription for Pain," exposed the addiction and corruption in southern and eastern Kentucky.

Many of us were shocked to learn that per capita we were the top painkiller users in the entire world. Congressman Rogers and other local leaders feared that if we did not take swift and decisive action an entire generation would be wiped out. We held community meetings to find out the scope of the problem and what should be done. Teachers, preachers, parents, judges, police officers, everyone we spoke to had stories, personal stories, and they were ready for action.

Operation UNITE then pioneered a holistic approach that has become a model for other States and the Nation. Let me start with the first pillar, investigations and enforcement.

Over the last 14 years UNITE detectives have removed more than \$12.3 million worth of drugs from the streets, arrested more than 4,400 bad actors, achieved a conviction rate of more than 97 percent, and processed nearly 22,000 calls to our drug tip line. But

we have long recognized that we cannot arrest our way out of this unique epidemic. That is why treatment is our second pillar.

Long-term recovery transforms substance users into healthy and productive members of their families and communities. We staff a treatment help line to connect people to resources and we have supplied vouchers to help more than 4,000 low-income people enter long-term rehabilitation. In addition, UNITE's assistance has helped increase the number of drug court programs in the region from five to one in all 32 counties we serve.

The final pillar is education and prevention. To make progress we must not only cut off the supply, but decrease the demand as well. Our education programs introduce youth and adults to a life without drugs. We have reached more than 100,000 students thus far.

Federal funding has been critical, from ARC grants helping us to educate prescribers to SAMHSA's assistance in providing treatment vouchers. Through AmeriCorps we provide math tutoring, teach antidrug and wellness curricula, and sponsor antidrug UNITE clubs. And the results are dramatic. Students have shown an average 30 percent growth in math knowledge and a 35 percent growth in drug awareness and healthy decisionmaking.

I am pleased that the Federal CARA legislation enacted by this Congress last year will enable regional organizations like UNITE to take advantage of these new Federal funds focused on addressing the opioid epidemic, and I am grateful to each of you who supported that bill.

Congress' collaboration on CARA must be replicated elsewhere. In the antidrug world we have to collaborate with stakeholders across a variety of professions, institutions, schools, and faith-based organizations.

When it became unfortunately clear that the challenges we had been experiencing in rural Kentucky had exploded across the country, we worked to share UNITE's holistic approach through the establishment of the National Prescription Drug Abuse and Heroin Summit, now the largest gathering of medical professionals, advocates, law enforcement, and policymakers in the United States. Our next summit, by the way, is April 17th through 20th in Atlanta. Many of your colleagues have attended in the past and I hope to see you there.

Now I would like to touch on a few of the lessons we have learned over the last 14 years that may benefit similar organizations in your home district.

The first is that you must bring all stakeholders to the table at the beginning. For example, we did not engage the medical community early enough. It was not until a local physician was tragically murdered for refusing to give a patient pain medication that we all rallied together at the same table.

Second, UNITE could have done a better job working with families in the beginning, helping them understand that addiction is a chronic disease and teaching them how to support their loved ones.

Third, you must have a champion to lead, to motivate, to encourage, and to fight alongside you, and for us that champion is Congressman Rogers.

Another lesson is that you cannot expect short-term treatment to yield long-term results. Models of recovery should be based on long-term goals.

The final and most important takeaway is that education and prevention are the tools to achieve those long-term results. The longer I am involved in fighting this epidemic, the more I am convinced that education, particularly K through 12 prevention education, is the key to saving our next generation. And it is only through collaboration and a holistic approach that we will succeed.

Thank you for your time.

[The information follows:]

**Nancy Hale
President and CEO of Operation UNITE
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Statement for the Record, April 5, 2017**

Good morning. Chairman Cole, Ranking Member DeLauro and members of the subcommittee, Thank you for giving me this opportunity to speak with you today. I am Nancy Hale, president and CEO of Operation UNITE.

UNITE is an acronym for Unlawful Narcotics Investigations, Treatment and Education. It is a three-pronged, comprehensive approach to create long-term success in combating substance abuse.

Operation UNITE was launched in April 2003 by Congressman Hal Rogers shortly after a special report, “Prescription for Pain,” was published by the *Lexington Herald-Leader*. This series of articles exposed the addiction and corruption associated with drug abuse in southern and eastern Kentucky, which largely included Congressman Rogers’ Fifth Congressional District.

Many of us were shocked to learn that, per capita, we were the top pain killer users in the entire world. Tragically, as a result, our commonwealth has been the epicenter for the explosion of opioid abuse: The drug overdose rate in Kentucky currently is more than 1.5 times higher than the national average. Rates in several counties are triple the national average.

Congressman Rogers and other local leaders feared that if we did not take swift and decisive action, an entire generation would have been wiped out. We held community meetings to find out the scope of the problem and what should be done. Teachers, preachers, parents, judges, and cops. Everyone we spoke to had stories – personal stories. And they were ready for action.

Based on their feedback, Operation UNITE pioneered a holistic approach that has become a model for other states and the nation. This comprehensive method involves law enforcement, treatment, and education/prevention initiatives working together.

Through collaborative partnerships, UNITE’s progress in our 32-county region is evident. Fourteen years later, more than 100,000 youth have participated in UNITE’s programs, tens of thousands of community members have volunteered, and more than 4,000 people have entered treatment using a UNITE voucher.

Let me start with the first pillar: Investigations and Enforcement.

UNITE has long been a leader in the state, participating in or overseeing many of the largest drug busts in Kentucky history.

For example, UNITE had one-fifth of the cases in Operation Flamingo Road -- a federal, state, and local law enforcement effort to arrest 518 people suspected of obtaining or distributing prescription pills from here to Florida. Over the last 14 years, UNITE detectives have:

- Removed more than \$12.3 million worth of drugs from the street,
- Arrested more than 4,400 bad actors,
- Achieved a conviction rate of more than 97 percent, and
- Received and processed nearly 22,000 calls to our drug tip line.

But we have also long recognized that we cannot arrest our way out of this unique epidemic. As one law enforcement official so powerfully observed: Investigations will grab headlines. Treatment and education will result in long-term results.

That is why Treatment is our second pillar.

Getting justice is only part of the equation. Getting into long-term recovery is what transforms substance users into healthy and productive members of their families and communities.

Many of the drug abusers who have their first experience with UNITE's law enforcement officers then benefit from our multi-faceted approach that includes treatment. We staff a treatment help line to connect people to resources and have supplied vouchers to help more than 4,000 low-income people enter long-term drug rehabilitation.

The UNITE treatment team responds to approximately 1,200 inquiries per month. Although the vast majority of these inquiries are seeking information about applying for a UNITE treatment voucher, a substantial number of inquiries are from individuals wanting information about Casey's Law (involuntary commitment), general information about the signs and symptoms of addiction, types of treatment available, or people who simply want to speak to someone about the addictive behavior of their loved one.

In addition, UNITE's assistance has helped increase the number of Drug Court programs in the region from five in 2003 to one in all 32 counties we serve. Participants obtain treatment and are more likely to return to productive lives, stay gainfully employed, pay child support, and meet other obligations.

Drug Courts in our service area have collected more than \$1.4 million in fines, restitution, and court costs, along with more than \$900,000 in child support. Participants also complete thousands of hours of community service each month.

UNITE has provided more than \$4 million to create 30 new Drug Court programs in 24 counties in addition to programs operated by the Kentucky Administrative Office of the Courts. Kentucky drug courts currently operate in 113 of the state's 120 counties.

The final pillar is Education and Prevention.

To make progress, we must not only cut off the supply, but decrease the demand as well. Education and prevention are the keys to reducing the demand for abusing or misusing legal substances or using illegal drugs. When demand is high, users are willing to use what is most available and affordable, and suppliers are creative in meeting these needs, whether it is prescription pills, heroin, meth, or synthetic drugs.

Offering youth alternatives to drug use through programming and hands-on education makes a huge difference. We must give them the facts. Children should be taught the effects of drugs on their minds and bodies from K-12. Repetitive, consistent messaging is needed.

And our focus should not only be on presenting facts and providing information on the effects of drugs on their bodies and brains, but should be on helping our youth make that one decision to not use any addicting substances, including alcohol, tobacco, marijuana, and other drugs. That focus holds great promise of a stronger, clearer, and more effective goal for public education and prevention.

UNITE's education programs and activities introduce youth and adults to a life without drugs. Some programs are geared to help youth avoid the dangers of the streets, but, for many, the danger is much closer – it is at home. UNITE shows children a different path, and it also helps them teach their parents or caregivers. For example, one Leslie County parent sought help for an addiction after her 4th-grader told her about UNITE and what she was learning in her "Too Good for Drugs" class.

Thus far, we have reached more than 100,000 students through various drug education programs and summer activities.

Our anti-drug programming includes "On the Move," a mobile and interactive one-of-a-kind education initiative. It provides a hands-on experience to simulate distracted and impaired driving. "Life With A Record" is a prevention initiative that helps youth examine the criminal justice system and how seemingly harmless acts can impact their futures.

Camp UNITE is a free, weeklong leadership and adventure camp that provides middle school youth with an opportunity to engage in fun, constructive activities using a small group, peer mentorship format. Many participants have been directly impacted by substance abuse or are unable to afford a traditional summer camp program.

Other summer activities include "Shoot Hoops Not Drugs" and "Hooked On Fishing – Not On Drugs."

Federal funding has been critical. It has helped UNITE reach across jurisdictions and county lines – and across professional territories.

For example, ARC grants have enabled us to educate prescribers on addiction, pain management, and state monitoring systems for prescription drugs known as PDMP's.

SAMHSA has helped us provide treatment resources through UNITE's vouchers, which is vital in a region faced with high poverty and unemployment. It also funded substance abuse counselors in the middle school and high schools, which was extremely effective. The impact was large, not only in the schools but also in the community. Unfortunately, schools were not able to sustain that effort when the grant money ran out.

In addition, AmeriCorps has been an invaluable part of our education efforts. Our 54 UNITE ServiceCorps members serve 17 school systems in 14 counties. They provide math tutoring, teach anti-drug and wellness curricula, have recruited more than 8,200 volunteers, and sponsor anti-drug UNITE clubs that have impacted more than 4,000 students in the last year alone.

And the results are dramatic: Last school year alone, the more than 1,500 students they tutored showed an average 30 percent growth in math knowledge. And the 3,300 students who took the anti-drug and health information curricula showed an average of 35 percent growth in drug awareness and healthy decision-making knowledge.

I am pleased that the federal CARA legislation enacted by this Congress last year will enable regional organizations like UNITE to take advantage of these new federal funds focused on addressing the opioid epidemic, and I am grateful to each of you who supported that bill.

Congress' collaboration on CARA must be replicated elsewhere. In the anti-drug world, we certainly have to collaborate with stakeholders across a variety of professions, institutions, schools and faith-based organizations. Not just law enforcement. Not just treatment. Not just education. Everyone must work together.

We were founded on community input, and that involvement continues and grows. Our nonprofit UNITE Coalitions in each of our counties know what their communities need. These coalitions are the key to after-care. People in recovery will eventually come back to their communities. They need support when they come home. Our coalitions make that happen. UNITE provides guidance and small amounts of funding to create those strong, local partnerships.

As a result, tens of thousands of people have participated in UNITE events and coalition activities to educate and deter people from taking drugs.

When it became unfortunately clear that the challenges we had been experiencing in rural Kentucky had exploded across the country, we worked to share UNITE's holistic approach through the establishment of the National Rx Drug Abuse & Heroin Summit – now the largest gathering of medical professionals, advocates, law enforcement and policy makers in the United States.

Our next Summit is April 17th through 20th in Atlanta. Many of your colleagues have attended in the past, and I hope to see you there this year.

That is a quick overview of some of Operation UNITE's strategies. Now, I would like to touch on several of the lessons we have learned over the last 14 years that may benefit similar organizations in your home districts.

The first is that you must bring all stakeholders to the table at the beginning. For example, we did not engage the medical community early enough. It was not until a local physician was tragically murdered for refusing to give a patient pain medicine that we all rallied together at the same table.

The second lesson learned is that UNITE should have done a better job working with families and helping them understand that addiction is a chronic disease that their loved ones would deal with for the rest of their lives. We needed to do more to help the families understand the disease and how to support their loved one when in long-term recovery.

A third lesson learned is that you must have a champion to lead, to motivate, to encourage, and to fight alongside you. For us, that champion is Congressman Rogers. Today, there are bipartisan caucuses in both the House and Senate to facilitate bringing a unified national approach to this difficult effort.

A fourth lesson is that you cannot expect short-term treatment to yield long-term results. Models of recovery should be based on long-term goals.

The final, and most important, take-away is that education and prevention are the tools to achieve those long-term results. The longer I am involved in fighting this epidemic, the more I am convinced that education – particularly K-12 prevention education – is the key to saving our next generation.

Through private donations, we are able to provide \$1,500 need-based scholarships to youth who have been actively involved in UNITE programs or have been impacted by substance abuse in their families.

It is only through collaboration and a holistic approach that we will succeed. And there is no better illustration of this than that of a young women who was awarded an “I Am UNITE” college scholarship last year. I’ll call her Sarah.

Sarah is a scholarship recipient who devoted 300 hours of service learning during high school. She also was one of only four students in the country selected by Jobs for America’s Graduates for the honor of placing a wreath at the Tomb of the Unknown Soldier.

But before those successes, she had some stumbling blocks – like when she had to step over her father who was passed out on the floor from a drug overdose. Her father later was arrested as part of a UNITE drug investigation. But UNITE’s efforts in her life did not end there. If they had, her story – and his – might have turned out differently.

Her father went to jail, but UNITE provided a voucher for him to enter long-term treatment. After he successfully completed treatment, he addressed an assembly at her high school. Sarah confessed that she was proud of him for the first time.

Sarah is now headed to college, and her father is making strides of his own with his recovery.

The day after she received a UNITE scholarship, a gentleman called us inquiring about funds to get a Celebrate Recovery group started in his county so he did not have to travel to a neighboring county. He explained he did not know anything about computers and was illiterate, so he would need help downloading and completing the forms. That man was Sarah’s father.

Sarah and her family illustrate why the multi-pronged approach is the key to saving our families and communities. They also offer us hope, which is another important part of recovery.

That is why we created the Hope Wall, which features dozens of people who have been drug free for at least 18 months. When I look at those faces and think about these men and women returning to their families, my eyes are always drawn to one photo in particular – that of my own son. Knowing how each of these people, in long-term recovery, are giving back and helping others, is what should give us all hope.

Thank you for your time.

Mr. COLE. Thank you very much.

Ms. Cimaglio, you are recognized for whatever opening statement you would care to make.

Ms. CIMAGLIO. Chairman Cole, Ranking Member DeLauro, members of the subcommittee, my name is Barbara Cimaglio, and I oversee Vermont's substance use disorder treatment, prevention, and recovery system. It is a privilege—

Mr. COLE. Would you turn your mike on?

Ms. CIMAGLIO. Oh.

Mr. COLE. Thank you very much.

Ms. CIMAGLIO. I will move it closer. Okay. Is that better?

It is a privilege to be here and it is a privilege to serve Vermont under the leadership of Governor Phil Scott and Dr. Mark Levine, the health commissioner. I have held similar positions in the States of Illinois and Oregon and have been a longtime member of the National Association of State Alcohol and Drug Abuse Directors, NASADAD.

First, I would like to thank the subcommittee for the Federal funding that flows through agencies like the Substance Abuse and Mental Health Services Administration, CDC, HRSA, and others. And second, we are very appreciative of the decision to allocate a billion dollars over the next 2 years to help support States' work on the opioid issue.

In a time of very tight budgets, we fully appreciate the significance of this action and the importance of managing public dollars in an effective and efficient manner.

Vermont, a small State of only 625,000 people, has been greatly impacted by the opioid problem. This impact is felt in every community, particularly in most rural areas.

In 2014, heroin overtook prescription opioids as the most commonly used opioid among those in treatment for substance use disorders. From 2010 to 2016, overdose death rates more than doubled.

Although we face many challenges, I am proud to report actions that are truly making a difference in Vermont. Because of the opioid problem, we developed our Vermont "Hub and Spoke" model of treatment. This model began when we set up regional opioid treatment centers around the State to treat those with the most complex needs with medication-assisted treatment and counseling. This part of the system represents the hubs. Primary care physicians who lead a team of nurses and clinicians in office-based treatment are the part of the system that represent the spokes.

All patients' care is supervised by a physician and supported by nurses and counselors who work to connect the patient with community-based support services. This model ensures that more complex patients are supported at the appropriate level of care. In addition, the system ensures opioid use disorder treatment is part of the overall healthcare system.

Between 2012 and 2016, medication-assisted treatment capacity increased by 139 percent. While we still experience small waiting lists, we are moving toward achieving our goal of treatment on demand. An initial evaluation of the Hub and Spoke system suggests that our approach saves money by reducing the utilization of more expensive interventions. This includes cutting down the number of

hospital admissions and outpatient emergency department visits, for example.

We also saw longer treatment stays for patients in our Hub and Spoke system. In 2016, from January to June, 74 percent of new clients in the Hub and Spoke system were in treatment for 90 or more days, which is the evidence-based recommendation.

Treatment is an important part of our work, but we are also doing work on prevention, intervention, and recovery. Vermont supports 12 recovery centers located throughout the State. The Vermont Recovery Network, through our Pathway Guides program, initially funded through a SAMHSA grant and now carried forward through our Medicaid waiver, supports clients in accessing peer recovery. Of the 216 people connected to a Pathway Guide in 2015, 73 percent sustained abstinence from opioid misuse by a 6-month follow up.

We recognize that investments in prevention services are critical. Our efforts include funding through the Substance Abuse Prevention and Treatment Block Grant or regional prevention consultants who support staff in schools and in community prevention coalitions.

There are additional initiatives described in my written testimony, but I will now turn to my recommendations.

First, Federal initiatives must specifically include involvement of State substance abuse agencies like mine, given our expertise and authority over the addiction prevention, treatment, and recovery system. Collaboration with public health, criminal justice, and other partners should be expected.

Second, I recommend strong support for the Substance Abuse Prevention and Treatment Block Grant, a vital part of our network that averages 70 percent of State substance abuse agencies' funding for primary prevention, which supports our community work. These funds form the foundation of a comprehensive system.

And finally, I encourage Congress and the administration to continue to work with State-based groups heavily involved in this issue, including the National Association of State Alcohol and Drug Abuse Directors and the Association of State and Territorial Health Officers, and also our parent group the National Governors Association, which has provided critical leadership in this area.

Thank you for the opportunity to testify. I look forward to answering any questions.

[The information follows:]

Congressional Hearing on the Opioid Crisis

Testimony Submitted to the House Appropriations Subcommittee on Labor, Health and Human Services (HHS), Education and Related Agencies

The Honorable Tom Cole, Chairman
The Honorable Rosa DeLauro, Ranking Member
2358 Rayburn House Office Building

April 5, 2017

Submitted by
Barbara Cimaglio, Deputy Health Commissioner
Department of Health
State of Vermont

Member, Board of Directors, National Association of State Alcohol and Drug Abuse Directors (NASADAD)

Chairman Cole, Ranking Member DeLauro, and members of the Subcommittee, my name is Barbara Cimaglio and I serve as Deputy Health Commissioner within Vermont's Department of Health. In this role, I lead the Department's oversight and development of the State substance use disorder treatment, prevention and recovery service system. I am also a longtime member of the Board of Directors of the National Association of State Alcohol and Drug Abuse Directors (NASADAD). Thank you for the opportunity to testify before the Subcommittee today to discuss actions we are taking in Vermont to address the opioid problem and offer considerations related to federal funding for substance use disorders.

States appreciate recent actions taken by Congress to address the opioid crisis: I wish to begin by thanking this Subcommittee in particular and Congress in general, for recent work to address the opioid crisis.

We appreciate passage of the 21st Century Cures Act which included the creation of a \$1 billion fund for FY 2017 and FY 2018 to help States enhance treatment, prevention and recovery services. The first installment of these funds, or approximately \$500 million, was approved by Congress late last year. Applications for the Cures funding for the States, now known as the *State Targeted Response to the Opioid Crisis (STR) Grants*, were due February 17, 2017. It is my understanding that all fifty States have applied for these dollars – mapping out plans to address their own unique needs and circumstances. In testimony presented to this Subcommittee last week, Secretary Price said awards through this program may be released as soon as April.

The 21st Center Cures Act also included key provisions reauthorizing the Substance Abuse and Mental Health Services Administration (SAMHSA). This included the reauthorization of programs within SAMHSA's Center for Substance Abuse Treatment (CSAT), Center for Substance Abuse Prevention (CSAP), Center for Behavioral Health Statistics and Quality (CBHSQ) and others. NASADAD supports actions to ensure a strong SAMHSA and appreciates the leadership of Ms. Kana Enomoto, SAMHSA's Acting Deputy Assistant Secretary for Mental Health and Substance Use.

Thank you also for your work to pass the Comprehensive Addiction and Recovery Act (CARA) which authorized programs seeking to promote a coordinated and multi-sector approach to addressing the opioid crisis. CARA created several important initiatives, including:

Improving Treatment for Pregnant and Postpartum Women (Section 501): Reauthorizes the Residential Treatment Program for Pregnant and Postpartum Women program to help support family treatment services – where women and their children can receive the help they need together in a residential setting. CARA also created a pilot program to afford States flexibility in providing new and innovative family-centered services in non-residential settings.

State Demonstration Grants for a Comprehensive Opioid Abuse Response (Section 601): For State applications of this grant, there is an emphasis on coordination between an applicant's State alcohol and drug agency and its corresponding State administering authority for criminal justice. This initiative is designed to help promote coordinated planning on issues related to justice-involved individuals with substance use disorders.

Community Coalition Enhancement Grants (Section 103): Authorizes the Office of National Drug Control Policy (ONDCP), in coordination with SAMHSA, to make grants to community anti-drug coalitions to implement community-wide strategies to address their local opioid and methamphetamine problem.

Building Communities of Recovery (Section 302): Authorizes SAMHSA to award grants to recovery community organizations (RCOs) to develop, expand and enhance recovery services. RCO's across the country are doing an excellent job of helping individuals in recovery with the assistance they need to once again contribute to their families, employers and communities.

Financial Burden of substance Use Disorders: The National Institute on Drug Abuse (NIDA) estimates that illegal drugs, alcohol, and tobacco cost society roughly \$700 billion every year or \$193 billion for illegal drugs, \$224 billion for alcohol, and \$295 billion for tobacco. According to SAMHSA's 2016 report, *National Expenditures for Mental Health Services and Substance Abuse Treatment, 1986-2014*, spending on substance use disorders decreased as a share of all health spending from 2.0 percent in 1986 to 1.1 percent in 2002, and remained stable ever since. Expenditures for substance use disorders represented only 1.2 percent of all health expenditures in 2014.

Benefits of prevention, intervention, treatment, and recovery: A primary message for this Subcommittee is that services to prevent, treat, and maintain recovery from substance use disorders help millions across the country. These services are literally life saving for both individuals and families. In addition, research demonstrates the investments in services save money.

- **Prevention:** \$1 invested in substance abuse prevention saves \$10–\$18 in costs associated with health care, criminal justice, and lost productivity
- **Intervention:** Substance abuse screening and brief counseling is as effective as other health prevention screenings
- **Treatment:** \$1 invested in addiction treatment saves between \$4–\$7 in costs associated with drug related crime, criminal justice, and theft
- **Recovery:** Relapse rates for addiction resemble those of other chronic diseases such as diabetes, hypertension, and asthma

Importance of State-Federal Partnership: NASADAD promotes the work of the National Governors Association (NGA) in its Principles for State-Federal Relations policy position which recommends a strong, cooperative State-federal partnership and maximum State flexibility when managing federal resources.

States recognize the importance of these federal resources and greatly benefit from funds managed by different agencies under this Committee's jurisdiction. In addition to SAMHSA, these agencies include the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Centers for Medicare and Medicaid Services (CMS), National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA). We also appreciate the work of agencies outside this Committee's jurisdiction – including the Office of Justice Programs (OJP)/Bureau of Justice Assistance (BJA), the Drug Enforcement Agency (DEA) and others within the Department of Justice (DOJ).

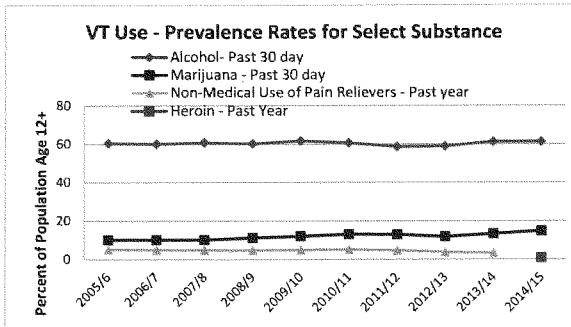
Vermont in particular has leveraged multiple sources of State and federal funding to address opioid use in Vermont. Federal funding opportunities have been fundamental to implementing programming. Examples of these important programs include:

- SAMHSA's Substance Abuse Prevention and Treatment (SAPT) Block Grant,
- SAMHSA's Strategic Prevention Framework (SPF)/Partnerships for Success (PFS) Grants
- ONDCP's/SAMHSA's Drug Free Communities Program
- SAMHSA's Medication-Assisted Treatment (MAT) Prescription Drug and Opioid Addiction Grant
- SAMHSA's Screening, Brief Intervention and Referral to Treatment (SBIRT) Grant
- CDC's Prescription Drug Overdose Prevention grant
- DEA's drug takeback program to support state drug takeback initiatives

Vermont is interested in utilizing 21st Century Cures Act funds to better coordinate care between substance use disorder treatment and medical providers; implement programs to improve and expand the substance use disorder workforce; add peer recovery coaches to emergency departments to support individuals who have overdosed on opioids and assist these individuals in seeking treatment for addiction; and providing funding to support community-initiated opioid prevention programs.

Scope of the substance use disorder problem in Vermont: It is worth stepping back for a moment to examine the impact of all substance use disorders in the State first before focusing on the unique issues related to prescription drug abuse and heroin.

Alcohol has consistently been the most frequently used substance in Vermont and an estimated 21,250 Vermonters are alcohol-dependent (NSDUH 2013/14). Marijuana is the next most frequently used substance. Vermont has among the highest rates of alcohol and marijuana use in the United States.



Vermont prevention activities have focused on regional approaches and it is estimated that substance abuse prevention activities reach 65% of Vermont residents at a cost of approximately \$9 per person.

Intervention services are provided in schools, medical settings, in other State programs, and at specialty

providers. Intervention services were provided in 34% of Vermont supervisory unions in 2016. Intervention activities reached 5.2% of Vermonters at a cost of \$151 per person.

The SAPT Block grant funded treatment system served nearly over 11,000 in 2016. Treatment costs in 2016 averaged \$3,253 per person. An additional 3,800 people also receive medication assisted treatment in medical settings.

Vermont has a Statewide network of recovery centers that served nearly 6250 Vermonters in 2016 at a cost of \$364 per person. These centers provide peer recovery services and other activities to support individual recovery.

Vermont's Strategy for Addressing Opioid Misuse and Dependence

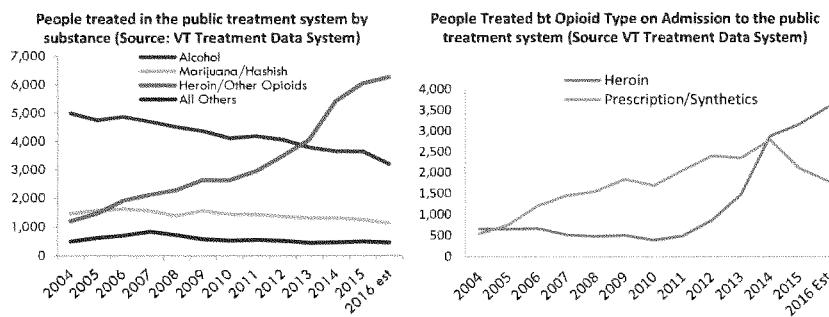
Importance of a comprehensive and aligned approach: Vermont recognized and publicly acknowledged the increasing challenges associated with opioid use when former Governor Shumlin's 2014 State of the State speech was devoted entirely to the topic. Vermont focused on opioids as a public health and medical issue. State and federal resources have been leveraged to address prevention, intervention, treatment, and recovery for opioid use disorders. Such disorders have a far-reaching effect in Vermont families and communities, and increased pressure on Vermont' health care, child protection and criminal justice systems. When Governor Phil Scott took office in January, 2017 he immediately appointed a Drug Prevention Policy Director to bring focus across State agencies on the continuing opioid crisis. The Governor is also convening an Opioid Coordinating Council to develop a multi-disciplinary strategy that will frame his administration's work.

Critical involvement of public health, Medicaid and other insurers, and prescribers: The Division of Alcohol and Drug Abuse Programs (ADAP) within Vermont's Department of Health (VDH) is the designated State substance abuse agency. As such, ADAP is responsible for overseeing the public prevention, intervention, treatment, and recovery service system as well as the prescription drug monitoring program. VDH also coordinates service delivery with the Medicaid division, which oversees physician office-based opioid treatment and pays for most opioid use disorder treatment in Vermont. Vermont has implemented a unique treatment program for opioid use disorders, known as the "Hub and Spoke" model, and has worked with third party payers to assure care is consistent regardless of payer. A more detailed overview of the Hub and Spoke model is offered later.

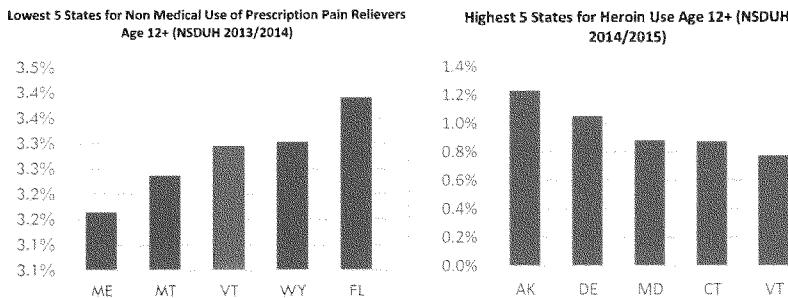
Vermont has a multifaceted and Statewide approach to addressing opioid addiction that involves multiple community partners. The State alcohol and drug agency director plays a prominent role in guiding this comprehensive strategy. The components of this strategy are:

- **Public Information and Messaging** – campaigns targeting the public, prescribers, and those using opioids
- **Pain Management and Prescribing Practices** – training, technical assistance, and tools provided to prescribers, required use of the prescription drug monitoring program
- **Prevention and Community Mobilization** – regional prevention capacity increases to provide assessment and planning, education and outreach, policy change, school-based services, and community-led triage programs
- **Drug Disposal** – implementation of a statewide system
- **Early Intervention** – screening for risky substance use in medical settings and within state programs that directly serve individuals
- **Overdose Prevention and Harm Reduction** – wide distribution naloxone overdose reversal kits, syringe services programs to prevent spread of HIV and hepatitis C, good Samaritan laws to encourage people to seek care in case of an overdose
- **Expanded Access to Treatment and Recovery Services** – rapid increases in medication assisted treatment capacity for opioid use disorders with buprenorphine and methadone through the hub and spoke system of care as well as services for pregnant women with opioid use disorders. Development of peer recovery services
- **Legislation and Rules Enacted** – laws around prescribing opioids for chronic and acute pain, use of the prescription drug monitoring program, good Samaritan protections, drug disposal program funding, pretrial services and alternatives to incarceration

Scope and changes in opioid use in Vermont: Like many States, Vermont saw demand for treatment services for opioid use disorders increase rapidly. In 2014, more people were treated for opioid use disorders than alcohol. Treatment demand was initially driven by prescription drugs. Heroin use, however, began to increase rapidly in 2011. By 2014, heroin overtook prescription opioids as the most commonly used opioid among those in treatment for a substance use disorder.



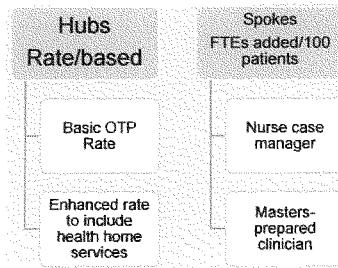
Vermont's data describing the high rate of heroin use is reflected in data collected by SAMHSA's National Survey on Drug Use and Health (NSDUH). In particular NSDUH found that Vermont has one of the lowest rates of past year use of prescription pain relievers and one of the highest for heroin use in the country.



Vermont's Hub and Spoke Treatment System: Vermont's Hub and Spoke system is a Statewide partnership of clinicians and treatment centers designed to provide medication assisted treatment to Vermonters who are addicted to opioids. The Hub and Spoke model ensures that each person's care is effective, coordinated and supported. Depending on need, these services may include mental health and substance abuse treatment, pain management, life skills and family supports, job development and recovery supports. The key goals of the system are to improve access to substance use disorder treatment and integrate substance use disorder treatment with general health care. Services include enhanced health homes for substance use disorder treatment.

A person may enter care by requesting services at a regional opioid treatment center (Hub) or their primary care provider (Spoke).

- Regional Opioid Treatment Centers (Hub) located around the State treat those patients who have especially complex needs with medication assisted treatment.
- Physicians lead a team of nurses and clinicians (Spoke) to treat patients with medication assisted treatment
- Each patient's care is supervised by a physician and supported by nurses and counselors who work to connect the patient with community-based support services to ensure care coordination.

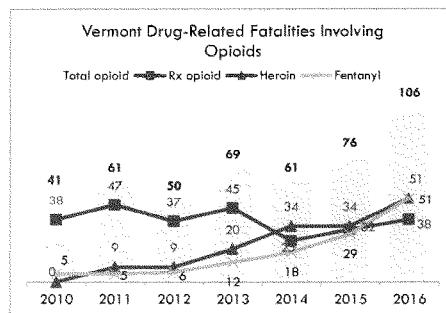


This system has significantly improved access to care – between 2012 and 2016 medication assisted treatment capacity increased by 139%. Approximately 7,150 Vermont adults age 18-64 are currently receiving medication assisted treatment for opioid use disorders and there is still demand for additional services. An initial evaluation of costs suggests that medication-assisted treatment in hubs and spokes is associated with reduced general health care expenditures and utilization, such as inpatient hospital admissions and outpatient emergency department visits, for Medicaid beneficiaries with opioid addiction.

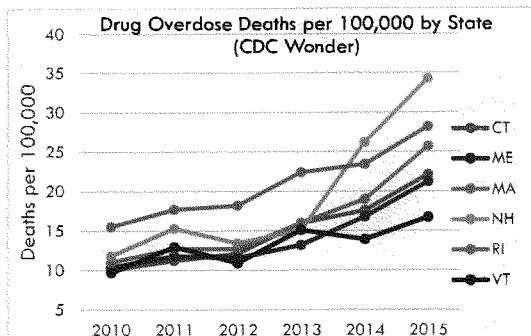
A review of 2015 Medicaid claims supports these positive outcomes and indicates that those with opioid use disorders have higher rates of health conditions than the general Medicaid population. It is also important to note that total Medicaid expenditures for those with opioid use disorders on medication assisted treatment are lower than those with opioid use disorders that are not receiving medication assisted treatment. An ongoing evaluation of patients receiving care shall focus on how patients' lives and functioning have been affected by their involvement in the Hub and Spoke system. Initial interviews indicate that those involved typically use heroin for about 10 years before treatment. Finally, more people seem to seek treatment if there are more accessible treatment services available in the community.

Opioid overdose deaths: New England has been particularly impacted by opioid use, resulting in overdose deaths from prescription drugs, heroin, and synthetic opioids such as fentanyl and tramadol. Vermont's overdose death rate is statistically similar to the U.S. rate (CDC, Wonder).

Vermont's accidental and undetermined manner drug-related fatalities involving an opioid (the categories not mutually exclusive – people use multiple substances – and are from the VDH Vital Statistics System) are due to a combination of heroin, fentanyl and prescription opioids. The number of deaths involving heroin and fentanyl are increasing while those for prescription opioids are trending downward. Preliminary 2015 numbers show those trends have continued.



While deaths are increasing, they are increasing more slowly than other New England States despite high rates of heroin use in Vermont. We attribute this largely to access to medication assisted treatment and widely available naloxone reversal kits.



Naloxone Overdose Reversal Kit Distribution: In 2013, Vermont’s Department of Health developed a Statewide naloxone (Narcan®) pilot program for distributing emergency overdose rescue kits to people at risk of an overdose, and to family members and others who may be able to help in the event of an overdose. The project has expanded emergency use kits by providing them free of charge at distribution sites across Vermont, and many town and city police departments are also carrying kits. Naloxone is currently available by prescription and stocked by many pharmacies and is also available over the counter.

In August 2016, the Department of Health issued a standing order for the opioid overdose rescue drug naloxone for all of Vermont. This allows any pharmacy to dispense the life-saving drug to anyone – without a prescription. The standing order is designed to ensure people who are addicted to opioid drugs, as well as their friends and family members, have easy access to naloxone in the event of an overdose. The order also allows insurers and Medicaid to cover the cost of naloxone.

Funding for the naloxone initiative was provided through the State evidence-based education program. The Department of Health and the Attorney General determine the funding sources for the program. This may include lawsuits brought by the Attorney General against pharmaceutical manufacturers.

Three Important Considerations for the Subcommittee: I offer the Subcommittee three key themes to consider as deliberations move forward.

Key nature of sustained and predictable funding through the Substance Abuse Prevention and Treatment (SAPT) Block Grant: We recommend that Congress maintain robust support for the SAPT Block Grant, an effective and efficient program supporting prevention, treatment, and recovery services. The SAPT Block Grant provides treatment services for 1.5 million Americans. At discharge from SAPT Block Grant funded treatment programs, 81.5 percent were abstinent from alcohol and 72.1 percent were abstinent from illicit drugs.

By statute, States must dedicate at least 20 percent of SAPT Block Grant funding for primary substance abuse prevention services. This “prevention set-aside” is by far the largest source of funding for each State agency’s prevention budget, representing on average 70 percent of the primary prevention funding that states, U.S. territories, and the District of Columbia coordinate. In 33 states, the prevention set-aside represents at least 50 to 99 percent of the substance abuse agency’s budgets.

It is important to continue this work given the positive gains moving forward in a number of areas. For example, according to the Monitoring the Future (MTF) study funded by the National Institute on Drug Abuse (NIDA), from 2000 to 2014, past year alcohol use among high school seniors in America has declined by 18 percent; past year use of cocaine has declined by 48 percent; and since its peak in 2004, the country has seen a 36 percent decline in past year use of prescription opioids.

An important feature of the SAPT Block Grant is flexibility. Specifically, the program is designed to allow States to target resources according to regional and local circumstances instead of predetermined federal mandates. This is particularly important given the diversity of each state's population, geography, trends in terms of drugs of abuse, and financing structure.

We appreciate the difficult decisions Congress must face given the current fiscal climate. We believe it is equally important to note that trends in federal appropriations for the SAPT Block Grant have led to a gradual but marked erosion in the program's reach. Specifically, the SAPT Block Grant has sustained a 29 percent decrease in purchasing power since 2007 due to inflation. In order to restore this important program back to the purchasing power for 2006, Congress would have to provide an increase of \$442 million.

Critical role of State alcohol and drug agency directors and National Association of State Alcohol and Drug Abuse Directors: State substance abuse agencies work with stakeholders to craft and implement a statewide system of care for substance use disorder treatment, intervention, prevention, and recovery. In so doing, State agencies employ a number of tools to ensure public dollars are dedicated to effective programming. These tools include performance and outcome data reporting and management, contract monitoring, corrective action planning, onsite reviews, training, and technical assistance. In addition, State substance abuse agencies work to ensure that services are of the highest quality through State established standards of care. Federal policies and resources that promote working through the State substance abuse agency ensure that initiatives are coordinated, effective, and efficient.

NASADAD serves as the voice of State substance alcohol, and drug agency directors from across the country. NASADAD's mission is to promote effective and efficient State substance use disorder treatment, prevention and recovery systems. The Association promotes best practices, shares information about State systems, and collaborates with federal and non-governmental stakeholders from its Washington, D.C. location. NASADAD is led by Robert Morrison, Executive Director, and houses a Research Department and Public Policy Department.

Federal support of, and coordination with, State-based groups focused on the opioid crisis - including the National Governors Association (NGA): Since 2012, NGA's Center for Best Practices has worked with 13 states to help States develop and implement comprehensive plans for reducing prescription drug and heroin abuse. States that participated in NGA's two policy academies have passed legislation, developed public awareness campaigns, launched cross-agency and regional initiatives, and established critical relationships with universities and the private sector. We applaud NGA, led by Scott Pattison, for their leadership on this issue and look forward to our continued collaboration on this and other related efforts.

I also wish to recognize the work of the Association of State and Territorial Health Officials (ASTHO) led by Dr. Michael Fraser. We also wish to recognize ASTHO's current President, Dr. Jay Butler from Alaska, for identifying substance misuse and addiction as his top presidential priority. ASTHO has been working with NGA and NASADAD on these issues, participating in the NGA policy academies, and leading its own set of meetings on the topic. Over the years, the two Executive Directors of ASTHO and NASADAD have joined together to engage in joint presentations at meetings and conferences in order to ensure our efforts are coordinated.

I also recommend coordinating with other State-based groups that are working on this topic. For example, the National Alliance of State and Territorial AIDS Directors have been leaders on issues such as Hepatitis C and other matters related to intravenous drug use. The Safe States Alliance is another important group focused on injury and violence prevention. Close coordination between the federal government and State-based organizations does have an impact on our respective memberships on the ground level.

Conclusion: I sincerely appreciate the opportunity to present testimony before the Subcommittee. I look forward to working with Congress on these important issues. I also encourage the Subcommittee and Congress to work with NGA, NASADAD and ASTHO as well as other partners to leverage the collective knowledge and expertise of State alcohol and drug agency directors and public health departments across the country.

Mr. COLE. Thank you very much.

We will next go to Mr. Guy for your opening statement.

Mr. GUY. Chairman Cole, Ranking Member DeLauro, and members of the committee, thank you so much for this opportunity to speak to you today.

It was an unexpected phone call on September the 26th, 2016, that brought the news that our 34-year-old son Chris had died 2 days before from an injected dose of heroin. Incomprehensible. Just one brief phone call could evoke such utter grief and pain. But it is a call that is replicated thousands and thousands of times every year following the deaths of those who die from drug overdose in America. Multiplied missives of misery, thousands and thousands of times.

Yet, years earlier, on December the 21st, 1981, it was also an unexpected phone call from the adoption agency that brought us incredible, exhilarating news. Just 4 days before Christmas, we were given the best present we could have imagined, William Christopher Guy.

Chris became a daddy's boy. You would most often find him either on my lap or in my arms. He loved all creatures, great and small, puppies, kittens, rabbits, and much to the chagrin of his mom, frogs, lizards, and snakes.

Chris was a gifted artist. He studied graphic arts. But for most of his adult life he worked as a cook in good restaurants in Portland, Boston, Nashville, Oklahoma City. Chris was a bright and beautiful soul. He was kind, caring, compassionate. He was raised in church. He was adored by an extended family. He had such potential, such hope for a bright future.

But unbeknownst to us, Chris was also a drug addict. For more than 20 years he was trapped in a terrifying house of mirrors, hoping that this twist or that turn might bring relief from crippling anxiety and depression, but more often finding sorrow and pain, guilt and shame.

And for far too long, feeling guilt and shame ourselves for not being aware of his plight and then not knowing how to help him, we unwittingly provided financial support that only perpetuated the misery. We were at a loss, not knowing how to find help for him or for ourselves.

Finally, with grace, and the help of programs like Al-Anon and Parents Helping Parents, his mother and I came to realize that Chris' addiction was an illness, part of an eviscerating epidemic sweeping this Nation.

On any day in Oklahoma some 700 addicts who need rehabilitative treatment cannot get it. Waiting lists are long for State-assisted treatment and there are not even enough placements for those who can pay for them. For those who work in jobs with little or no health insurance or who cannot work because of their illness, the despair can be debilitating.

Chris' addiction was something that he could no more overcome without professional help than he could self-cure a cancerous tumor. He tried desperately to get well. He sought treatment many times, only to be told that it could be days or even weeks before a placement might become available. On the streets, with no viable support, he couldn't get the help he needed, and we couldn't get it

for him. It was an abject nightmare. I cannot begin to describe to you the depths of despair.

Often compounded by mental health issues, the disease of addiction is a life-and-death struggle, made even more debilitating by guilt and shame. Relying on short-term emergency room care and the incarceration of the addicted and the mentally ill, without hope of long-term professional treatment, can doom them to lifelong cycles of disease and their families to unmitigated agony.

Meanwhile, all of society is paying for it, either monetarily or emotionally or both. Surely it makes sense, even if only economic sense, to increase the availability of preventive education and treatment programs, and isn't it also the compassionate thing to do?

I join the many families afflicted by this insidious disease of addiction who are heartened by the bipartisan passage of the Comprehensive Addiction and Recovery Act and the CURES Act, but there is much work left to do. In the words of Saint Francis of Assisi, start by doing what is necessary, then do what is possible, and soon you may find you are doing the impossible. Thank you.

[The information follows:]

Bill Guy
Advocate
Parents Helping Parents

Something just as simple or as profound as an unexpected phone call can make all the difference. It can bring unsurpassed joy. Or, it can evoke unspeakable grief.

It was September 26, 2016. I had just arrived at my elderly parents' home in the Dallas/Fort Worth area after taking them back from a delightful visit with us. That's when I got an unexpected phone call from our eldest son. He struggled to speak. Only with great difficulty was he finally able to articulate his message, "Dad . . . Chris is dead!" My heart heaved in violent pain. The blood drained from my face. I staggered and had to sit down. Our 34-year-old son had died two days before from an overdose of injected heroin. It took the medical examiner's office that long to identify him and find a close relative to notify.

That unexpected call is one no parent, family member or friend ever wants to get. Yet it's replicated thousands of times to fathers, mothers, children, siblings, grandparents, aunts, uncles, cousins and friends, resulting from the deaths of the estimated 144 people who die every day in our country from drug overdose. That's almost 53,000 loved ones per year – more than the number of American's killed during the Vietnam War in the 1960s and early '70s.

Just one unexpected phone call, but repeated thousands upon thousands of times . . . multiplied missives of misery.

Yet, it was also an unexpected phone call that carried the incredible, but exhilarating news that we had become the parents of a week-old baby boy. It was December 21, 1981, four days before Christmas. While others made their last-minute holiday gift purchases, we scrambled to buy diapers, bottles and baby blankets. The adoption agency had told us that though we were approved, we should not get our hopes too high. We already had a three-year-old son. But

exactly nine months later, an unexpected phone call gave us the best Christmas present imaginable . . . William Christopher Guy. How could we have known then that our beloved, sweet Chris would grow up to become enslaved by the disease of addiction?

Chris was one of the most beautiful babies I have ever seen. He had a full head of abundant brown hair, the face of a cherub and bright blue eyes that radiated health and charm.

A bit introverted and shy around groups of people as a toddler, he was a daddy's boy. At church or even at large family events, you'd generally find him in my arms or on my lap.

Nothing thrilled him more than to be around any creature, great or small. Puppies, kittens, rabbits, and much to the chagrin and horror of his mother, frogs, lizards and especially, snakes. He loved the outdoors and was much happier at the fishing pond than just about anywhere else.

Chris was a gifted artist. He could take a scrap of paper and some pencils, and within minutes perfectly replicate an object of intricate complexity. For a time, he studied to become a graphic artist, but he spent most of his adult life in the food industry. He worked his way up to responsible positions as a cook in good restaurants in Portland, Boston, Nashville and Oklahoma City.

Chris was a bright and beautiful soul . . . kind, caring and compassionate. He had been raised in church. He was adored by an extended family. He had such hopes for his future, such potential. But unbelievably, our beloved son was also a drug addict.

For more than twenty years, Chris was trapped on a ride through a macabre house of mirrors, never knowing which twist or turn might bring him sorrow or pain, guilt or shame. He kept trying to escape, but never could find the way out. And for too many of those years, feeling guilty and desperate ourselves for not being aware of his plight sooner, and then not knowing how to help him, we unwittingly kept buying him "ride tickets" in the form of well-meant

financial support that only perpetuated his tragic journey. Isn't that what good parents do? Try to help their children when they are mired in pain and horror? We were at a loss, and Chris even more so.

Finally, it was grace, and the help of programs like Al-Anon and Parents Helping Parents, we came to realize that Chris' addiction was an illness, part of an eviscerating epidemic sweeping the nation. Something he could no more overcome without professional help than he could cure an affliction of diabetes or cancer.

Addiction is a disease. Who would willfully choose to inflict such repeated suffering upon themselves and those they love if it was a merely a matter of choice? I have witnessed Chris in the throes of sweaty, feverish, painful agony, but there's no way I can comprehend the compulsion to repeat it, time after time after time. Not even the addicted can do so.

Chris so desperately tried to win his fight. But tragically, the professional help he needed was extremely difficult or often even impossible to get. For those who work in jobs where there is scant or no health insurance, or who cannot work, or who lose their jobs because of the ravages of the illness, the despair is manifold. Often compounded by mental health issues, the disease of addiction is a life and death struggle made even more desperate by its attendant guilt and shame. Despite heroic efforts to overcome their despair enough to truly seek help, they too often find that there is no place available for them to get it.

On any day in Oklahoma, there are between 600 and 800 addicts who need rehabilitative treatment unavailable to them. The waiting lists are lengthy for the state-funded programs, and there are not even enough slots in private pay facilities for those who have insurance or other financial means to pay for them.

On numerous occasions, Chris tried to get a rehabilitative treatment placement, only to be told that it could be days or even weeks before one might become available. On the streets and with no viable means of support, he had to take his pitiful chances, hoping his luck might change, but knowing the odds were against him. And we were left to shuffle an incomplete deck, hoping for a full hand, trying to support him without enabling him.

Relying on short-term emergency room treatment and the incarceration of non-violent addicts and the mentally ill without hope of rehabilitation and treatment, can doom them to a life-long cycle of disease and despair. Meanwhile, all of us are paying for it, either monetarily or emotionally or both. Surely it makes sense, even if only economic sense, to increase the availability of preventative education and rehabilitative treatment programs. And isn't it also a compassionate thing to do.

While we still have much work to do to increase access to treatment in Oklahoma and the United States, I join the many families afflicted by this insidious disease who were so heartened by the bipartisan passage last July of the Comprehensive Addiction and Recovery Act (CARA).

I'm here today to honor our beloved son's struggle and ultimate death from drug addiction, and to represent the thousands upon thousands of individuals like him and families like ours. In the words of St. Francis of Assisi, "Start by doing what is necessary; then do what is possible; and suddenly, you find you are doing the impossible."

Just maybe, we can cut the frequency of those heart breaking, unexpected phone calls.

Mr. COLE. Thank you very much.

Ms. Pacula, we will next go to you for your opening statement.

Ms. PACULA. Chairman Cole, Ranking Member DeLauro, and the other distinguished members of the subcommittee, thank you very much for allowing me the opportunity to testify to you today. As was said earlier, I am a senior economist at the RAND Corporation and I co-direct RAND's Drug Policy Research Center.

RAND's mission as a nonprofit, nonpartisan research organization is to produce and disseminate objective information that can be used to help solve our Nation's most pressing challenges. Along with my colleagues at RAND, we have evaluated the effectiveness of various drug control strategies, and I will share with you today some of the lessons we have learned that might help inform the Federal response to this opioid crisis.

First, it is important to say that the strategies involved take a mix of strategy. No one single strategy will be a silver bullet for any epidemic. The most effective and cost-effective mix of strategies, however, depend on where you are at a particular point of time in an epidemic.

Unfortunately, it is hard to determine exactly where we are today in the opioid epidemic because it is fueled by two very different classes of opioids, prescription opioids and then the illicit heroin and Fentanyl opioids, and these trends are moving in different direction.

However, it does seem absolutely clear in light of the level of overdose fatalities experienced today that we are in the territory where treatment must be part of the policy mix. And, thankfully, this is where we have the strongest evidence base regarding the effectiveness and cost effectiveness.

Opioid addiction is, as stated clearly already, a chronic medical condition that is receptive to treatment, and the use of medication-assisted therapies, or MAT, including methadone, buprenorphine and naltrexone, have been demonstrated to be among the most effective forms of opioid treatment. Research shows a number of policies have been effective at expanding access to this MAT, including insurance parity, expanding the patient limits buprenorphine-waivered physicians are allowed to treat from 30 to 100, and State Medicaid policies that provide coverage for buprenorphine and place it on preferred drug formularies.

Just expanding access to MAT, though, is not enough. Strategies must encourage delivery of high quality treatment. Policies and programs that improve training of providers in the delivery of this therapy, such as those currently being considered by the Centers for Medicare and Medicaid as well as ARC, appear promising and could improve the quality of care received.

When it comes to the other drug control strategies undertaken by the agencies under the purview of the subcommittee, the evidence base demonstrating effectiveness is still developing. In the case of naloxone distribution, there is solid evidence that naloxone can be safely administered by first responders and laypersons who are properly trained and educated in its administration, resulting in a saved life in that episode.

Questions remain, however, about whether the general distribution of naloxone leads to a rise in overall overdoses and there the evidence is thin. I can speak to it more later.

Prescription drug monitoring programs have been evaluated quite a bit, but the results are mixed. It appears the effectiveness of these programs can be influenced by certain elements that are either present or not present, including mandatory participation of all prescribers and pharmacies, inclusion of all scheduled drugs, and real-time access and updating of the system. Recent studies that evaluate the effectiveness of these more enhanced PDMPs suggest that they can be powerful at reducing the supply of opioids as well as the demand and harm associated with them.

Policies emphasizing the adoption of clinical guidelines for safe opioid prescribing are also frequently advocated, although usually implemented in combination with other initiatives, making it hard to understand their effectiveness alone. In the VA's Opioid Safety Initiative, which was undertaken in 2013, there they implemented it with aggressive education of the providers, risk management tools, pain management strategies for patients in chronic pain, and improved access to MAT therapy, and substantial reductions in inappropriate prescribing, total prescribing of opioids, as well as cutting in half overdose mortality of veterans occurred from this comprehensive approach.

Given the availability of both legal and illicit opioid products in many communities, we have to be cautious about policies focused on solving just one part of the opioid problem, for example just focusing on prescription opioids, or just within one particular health system, like the VA, because people can move to other health systems and do.

The complexity of the opioid epidemic requires a thoughtful, comprehensive approach to access of all opioids and careful evaluation and monitoring to avoid the unintended consequences of any singular policy approach.

Thank you for inviting me to testify, and I am happy to answer any questions.

[The information follows:]

Funding Considerations in the Fight Against the Opioid Epidemic

What the Science Tells Us

Rosalie Liccardo Pacula

CT-469

Testimony presented before the House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies on April 5, 2017.



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Funding Considerations in the Fight Against the Opioid Epidemic: What the Science Tells Us

Testimony of Rosalie Liccardo Pacula, Ph.D.¹
 The RAND Corporation²

Before the Committee on Appropriations
 Subcommittee on Labor, Health and Human Services, Education, Related Agencies
 United States House of Representatives

April 5, 2017

Chairman Cole, Ranking Member DeLauro, and other distinguished members of the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, thank you very much for the opportunity to testify before you today. I am a senior economist at the RAND Corporation, where I also serve as the co-director of RAND's Drug Policy Research Center and the director of the BING Center for Health Economics. RAND's mission, as a nonprofit, nonpartisan research organization, is to produce and disseminate objective information that can be used to help solve our nation's most pressing challenges. I was asked to speak to you today about the effectiveness of various programs that have been funded by this committee in the country's efforts to end the opioid epidemic. This is something that my RAND colleagues and I have spent considerable time evaluating in recent years, thanks to research support provided by the National Institute on Drug Abuse, the Office of the Assistant Secretary for Planning and Evaluation, and the Centers for Disease Control and Prevention.

Congress has made considerable investments to address the opioid crisis, most recently with the Comprehensive Addiction and Recovery Act and 21st Century Cures Act. While it is too soon to determine the effect of these laws on the opioid epidemic, I will speak to the existing evidence examining policies to stem opioid diversion and misuse and why it might be worth continuing to support some of them until clear evidence emerges related to the effectiveness and relative cost-effectiveness of each intervention.

In this testimony, I will begin by providing some general insights about what we know about drug epidemics more generally, and the relative effectiveness of different types of drug policy

¹ The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

² The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

strategies at different stages in drug epidemics. Such background is important because there are some broad lessons that should be considered when thinking about the effective allocation of society's resources in tackling the opioid problem today. I will then discuss what science tells us about the effectiveness of some of the current strategies supported by funding this subcommittee provides that combats the opioid epidemic. Specifically, this testimony will discuss the value of treatment, particularly medication assisted treatment, expanded availability of naloxone, enhancing prescription drug monitoring programs, and establishing guidelines for safe opioid prescribing. Many more strategies than these exist, including important supply reduction strategies that are undertaken by law enforcement. Given the limited time, I have narrowed my focus in today's remarks to specific strategies funded by the agencies under the jurisdiction of this subcommittee.

Relative Effectiveness of Drug Control Strategies During Phases of a Drug Epidemic

In the mid-1990s, RAND did groundbreaking work modeling the interaction between the supply and demand for cocaine, which enabled us for the first time to be able to consider the relative effectiveness and cost-effectiveness of alternative supply side strategies (e.g. crop eradication, local law enforcement) versus demand-side (e.g. prevention or treatment).³ Scholars continued to build on this work, developing dynamic models of other drug epidemics.⁴ A few scholars have begun modeling the specific dynamics of the opioid epidemic, and the general models provide several important insights for prioritizing opioid epidemic funding.⁵

1. Early in the development of a drug epidemic, when prevalence of use is increasing very rapidly, primary prevention and public awareness campaigns that deter new users are especially effective, as they reduce the pool of "susceptibles"—i.e., those who are at risk of using. Because of a phenomenon we refer to as "social contagion," prevention policies early in an epidemic have the added benefit of deterring more than just the one person they reach. Similarly, traditional law enforcement that aims to shrink the market through

³ S.S. Everingham and C.P. Rydell, "Modeling the Demand for Cocaine," Santa Monica, Calif.: RAND Corporation, MR-332-ONDCP/A/DPRC, 1994.

⁴ J.P. Caulkins, "Models Pertaining to How Drug Policy Should Vary over the Course of an Epidemic Cycle," in B. Lindgren and M. Grossman, eds., *Substance Use: Individual Behavior, Social Interactions, Markets, and Politics, Advances in Health Economics and Health Services*, Bingley, UK: Emerald Publishing, Vol. 16, 2005, pp. 407–439; D. Winkler, J.P. Caulkins, D.A. Behrens, and G. Tragler, "Estimating the Relative Efficiency of Various Forms of Prevention at Different Stages of a Drug Epidemic," *Socio-Economic Planning Sciences*, Vol. 38, No. 1, March 2004, pp. 43–56; G. Tragler, J.P. Caulkins and G Feichtinger, "The Impact of Enforcement and Treatment on Illicit Drug Consumption," *Operations Research*, Vol. 49, pp. 352–362, 2001.

⁵ W. Wakeland, A. Nielsen, and P. Geissert, "Dynamic Model of Nonmedical Opioid Use Trajectories and Potential Policy Interventions," *American Journal of Drug and Alcohol Abuse*, Vol. 41, No. 6, 2015, pp. 508–518; R.L. Pacula, S.B. Hunter, A.J. Ober, K.C. Osilla, R. Vardavas, J.C. Blanchard, E.F. Drabo, K.J. Leuschner, W. Stewart, and J. Walters, *Preventing, Identifying, and Treating Prescription-Drug Misuse Among Active-Duty Service Members*, Santa Monica, Calif: RAND Corporation, RR-1345-OSD, 2016.

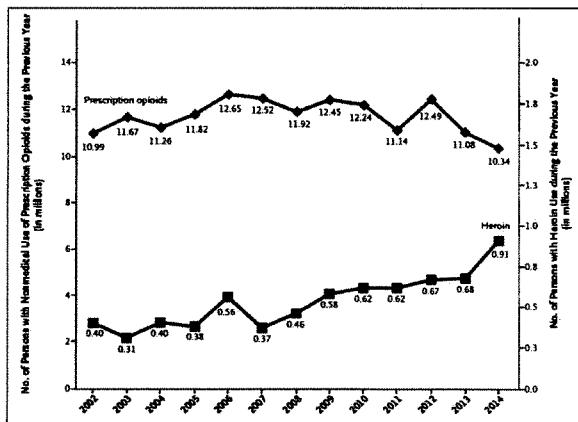
supply disruptions can also be quite effective during this phase, as it can tip the momentum of the upswing in use through “enforcement swamping.”

2. After new drug use peaks, secondary prevention (aimed at deterring existing users from transitioning to heavy use) and awareness campaigns focusing on the negative consequences associated with heavy use can be particularly effective. Treatment is also particularly important at this point, to help heavy users quit or reduce the harms experienced by heavy use.
3. The harms from an epidemic usually peak later than the peak in initiation and prevalence of use, as the greatest harms come from the stock of heavy users. Therefore, even if initiation rates or prevalence rates start to fall, sustained investment in treatment is key for reducing the overall harm of the epidemic and transitioning heavy users safely to nonuse. Law enforcement can also support efforts to divert people to treatment at this stage, by keeping prices high in the drug market and/or diverting heavy users to treatment.

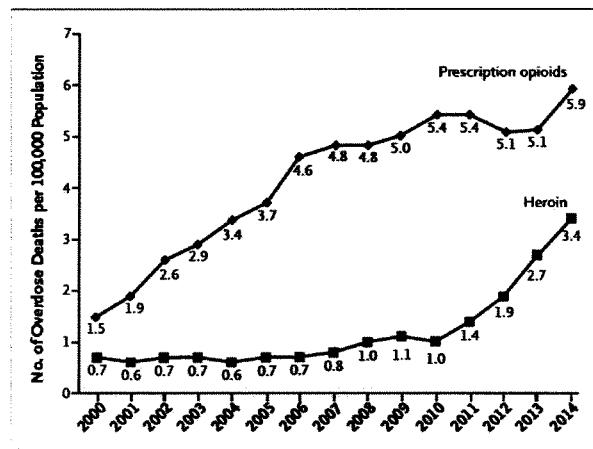
What does this suggest for the current opioid epidemic? One might think that by looking at trends in new initiates, annual prevalence rates and heavy use rates we could see where we are in the opioid epidemic. However, as Figure 1 demonstrates, this epidemic is complicated by the fact that it is fueled by the consumption of two types of opioids, prescription opioids and heroin, whose trends seem to be moving in very different directions.

Figure 1: Trends in Past Year Use and Mortality for Opioids

Part A: Millions of Persons Reporting Nonmedical Use of Prescription Opioids and Heroin in Past Year



Part B: Trends in Age-Adjusted Mortality Related to Prescription Opioids and Heroin



SOURCE: W.M. Compton, C.M. Jones, and G.T. Baldwin, "Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use," *New England Journal of Medicine*, Vol. 374, No. 2, 2016, pp.154–163.

That makes it challenging to say exactly where we are in the opioid epidemic as a whole. As shown in Part A, in the past year, nonmedical use of prescription opioids appears to be declining from what may have been a leveling off between 2006–2012, while heroin use is clearly still on a rise (albeit at a lower absolute level than prescription opioids). Unfortunately, data past 2014 cannot be compared to prior years due to changes in how the data were collected in 2015, making it hard to know at this point of whether trends persisted or changed past 2014. Moreover, we cannot tell from these trends whether the two populations are independent or related. Given recent compelling evidence suggesting that they are not independent, it is hard to say definitively whether annual prevalence rates overall are rising or not.⁶ Harms from each group of opioids are clearly on the rise, however, as shown by mortality data in Part B. This means that for the population of users, there is a pretty high rate of transition from regular use to harmful use.

Effective Strategies to Combat the Opioid Epidemic Now

Without the luxury of knowing exactly where we are in this opioid epidemic, particularly if prescription opioid analgesics and heroin are considered together, it is hard to know what mix of

⁶ A. Alpert, D. Powell, and R.L. Pacula, "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids," National Bureau of Economic Research Working Paper #23031, 2017; Compton, Jones, and Baldwin, 2016; T.J. Cicero, M.S. Ellis, and H.L. Surratt, "Effect of Abuse-Deterrent Formulation of OxyContin," *New England Journal of Medicine*, Vol. 367, No. 2, 2012, pp. 187–189.

strategies would be most effective overall. Moreover, law enforcement data, opioid prescribing data, and mortality data all confirm substantial geographic variation in the availability of and harm from both opioid analgesics and heroin, even across counties within the same state, suggesting that local communities are at different epidemic stages.⁷ A recent National Association of State Alcohol and Drug Abuse Directors study summarized what states were doing to combat the opioid epidemic as recently as May 2015, largely with support from federal dollars.⁸ Here is what we know about the effectiveness of some of the strategies that have been supported by the agencies this subcommittee funds.

Expanding Access to Treatment, Particularly Medication-Assisted Treatment

Opioid addiction is a chronic medical condition that is receptive to effective treatment.⁹ Pharmacotherapies, which predominantly include methadone, buprenorphine, and injectable naltrexone, are among the most effective interventions for opioid use disorders.¹⁰ Before 2002, the main opioid pharmacotherapy available was methadone, which can only be dispensed in a licensed opioid treatment program. The approval of buprenorphine, a partial opioid agonist that can be prescribed by waivered physicians in their offices as well as in traditional opioid treatment programs, greatly increased access to medication-assisted treatment (MAT).¹¹ Options

⁷ D.C. McDonald, K. Carlson, and D. Izrael, "Geographic Variation in Opioid Prescribing in the U.S.," *Journal of Pain: Official Journal of the American Pain Society*, Vol. 13, No. 10, 2012, pp. 988–996; L.M. Rosen, D. Khan, and M. Warner, "Trends and Geographic Patterns in Drug-Poisoning Death Rates in the U.S. 1999–2009," *American Journal of Preventive Medicine*, Vol. 45, No. 6, 2013, pp. e19–e25; National Drug Intelligence Center, *National Drug Threat Assessment 2014*, Jonestown, Penn., 2010.

⁸ S. Wickramatilake, J. Zur, N. Mulvaney-Day, M.C.V. Klimo, E. Selmi, and H. Harwood, "How States Are Tackling the Opioid Crisis," *Public Health Reports*, Vol. 132, No. 2, 2017, pp. 171–179.

⁹ A.T. McLellan, D.C. Lewis, C.P. O'Brien, and H.D. Kleber, "Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation," *Journal of the American Medical Association*, Vol. 284, No. 13, 2000, pp. 1689–1695; National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, "Effective Medical Treatment of Opiate Addiction," *Journal of the American Medical Association*, Vol. 280, No. 22, 1998, pp. 1936–1943.

¹⁰ N.D. Volkow, T.R. Frieden, P.S. Hyde, and S.S. Cha, "Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic," *New England Journal of Medicine*, Vol. 370, No. 22, 2014, pp. 2063–2066; National Institute on Drug Abuse, *Principles of Effective Treatment for Criminal Justice Populations*, Rockville, Md., 2006; R.P. Mattick, J. Kimber, C. Breen, and M. Davoli, "Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence," *Cochrane Database Syst Review*, Vol. 6, No. 2, 2014; D.A. Fiellin, M.V. Pantalon, M.C. Chawarski, B.A. Moore, L.E. Sullivan, P.G. O'Connor, and R.S. Schottenfeld, "Counseling Plus Buprenorphine-Naloxone Maintenance Therapy for Opioid Dependence," *New England Journal of Medicine*, Vol. 355, No. 4, 2006, pp. 365–374; J. Kakko, K.D. Svanborg, M.J. Kreek, and M. Heilig, "1-Year Retention and Social Function After Buprenorphine-Assisted Relapse Prevention Treatment for Heroin Dependence in Sweden: A Randomised, Placebo-Controlled Trial," *Lancet*, Vol. 361, No. 9358, 2003, pp. 662–668; P.J. Fudala, T.P. Bridge, S. Herbert, W.O. Williford, C.N. Chiang, K. Jones, J. Collins, D. Raisch, P. Casadonte, R.J. Goldsmith, W. Ling, U. Malkerneker, L. McNicholas, J. Renner, S. Stine, and D. Tusel, "Office-Based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone," *New England Journal of Medicine*, Vol. 349, No. 10, 2003, pp. 949–958.

¹¹ E.M. Oliva, J.A. Trafton, A.H. Harris, and A.J. Gordon, "Trends in Opioid Agonist Therapy in the Veterans Health Administration: Is Supply Keeping up With Demand?" *American Journal of Drug Alcohol Abuse*, Vol. 39, No. 2, 2013, pp. 103–107; A.W. Dick, R.L. Pacula, A.J. Gordon, M. Sorbero, R.M. Burns, D. Leslie, and B.D. Stein,

increased even further with the 2010 Food and Drug Administration approval of extended-release opioid antagonist naltrexone (XR-NTX).¹²

Recent federal legislation and many state policies have been shown to be effective at increasing MAT use.¹³ Research by RAND and others has shown that insurance parity, expanding the limits on patients a waivered buprenorphine physician can treat from 30 to 100, and state Medicaid policies providing coverage of buprenorphine and placement on preferred drug lists have over time influenced MAT utilization and the locations in which it is provided.¹⁴ This is not enough, however. Much work still needs to be done to better understand why the majority of waivered physicians do not come close to treating the number of patients allowed by their waiver.¹⁵ Moreover, expanding MAT utilization alone, without paying attention to the quality of the treatment received, might not generate a net public health gain if, for example, substantial numbers of newer providers are not adequately prepared or sufficiently incentivized to provide the quality, comprehensive care essential for safe and effective MAT treatment.¹⁶ Improving MAT quality may be particularly important for improving outcomes for historically underserved or high-risk populations, such as racial/ethnic minorities, individuals with HIV, and individuals in rural counties, who may not receive effective treatments for opioid use disorders at the same rate as nonminority individuals. Policies and programs that improve *delivery* of this

¹²“Growth in Buprenorphine Waivers for Physicians Increased Potential Access to Opioid Agonist Treatment, 2002-11,” *Health Affairs (Millwood)*, Vol. 34, No. 6, 2015, pp. 1028-1034; B.D. Stein, R.L. Pacula, A.J. Gordon, R.M. Burns, D.L. Leslie, M.J. Sorbero, S. Bauhoff, T.W. Mandell, and A.W. Dick, “Where Is Buprenorphine Dispensed? The Role of Private Offices, Opioid Treatment Programs, and Substance Abuse Treatment Facilities in Urban and Rural Areas,” *Milbank Quarterly*, Vol. 93, No. 3, 2015, pp. 561-583; B.D. Stein, A.J. Gordon, A.W. Dick, R.M. Burns, R.L. Pacula, C.M. Farmer, D.L. Leslie, and M. Sorbero, “Supply of Buprenorphine Waivered Physicians: the Influence of State Policies,” *Journal of Substance Abuse Treatment*, Vol. 48, No. 1, 2015, pp. 104-111.

¹³E. Krupitsky, E.V. Nunes, W. Ling, D.R. Gastfriend, A. Memisoglu, and B.L. Silverman, “Injectable Extended-Release Naltrexone (XR-NTX) on Opioid Dependence: Long-Term Safety and Effectiveness,” *Addiction*, Vol. 108, No. 9, 2013, pp. 1628-1637; E. Krupitsky, E.V. Nunes, W. Ling, A. Illeperuma, D.R. Gastfriend, and B.L. Silverman, “Injectable Extended-Release Naltrexone for Opioid Dependence,” *Lancet*, Vol. 378, No. 9792, 2011, p. 665; author reply 666.

¹⁴Stein et al., 2015a; Stein et al., 2015b; R.M. Burns, R.L. Pacula, S. Bauhoff, A.J. Gordon, H. Hendrikson, D.L. Leslie, and B.D. Stein, “Policies Related to Opioid Agonist Therapy for Opioid Use Disorders: The Evolution of State Policies from 2004 to 2013,” *Substance Abuse*, Vol. 37, No. 1, 2016; American Society of Addiction Medicine, “State Medicaid Reports,” 2015; L. Ducharme, and A. Abraham, “State policy influence on the early diffusion of buprenorphine in community treatment programs,” *Substance Abuse Treatment Prevention Policy*, Vol. 3, No. 1, 2008, pp. 17-27; T.L. Mark, R. Lubran, E.F. McCance-Katz, M. Chalk, and J. Richardson, “Medicaid Coverage of Medications to Treat Alcohol and Opioid Dependence,” *Journal of Substance Abuse Treatment*, 2015.

¹⁵Dick et al., 2015; Stein et al., 2015a; Stein et al., 2015b; Ducharme and Abraham, 2008.

¹⁶B.D. Stein, M. Sorbero, A.W. Dick, R.L. Pacula, R.M. Burns, and AJ Gordon (). “Underutilized Physician Capacity to Treat Opioid Use Disorder with Buprenorphine Opioid Agonist Medication Assisted Treatment,” *Journal of the American Medical Association*, Vol. 316, No. 11, 2016, pp. 1211-1212.

¹⁷J.D. Baxter, R.E. Clark, M. Samnaliev, G. Aweh, E. O’Connell, “Adherence to Buprenorphine Treatment Guidelines in a Medicaid Program,” *Substance Abuse*, Vol. 36, No. 2, 2015, pp. 174-182; A.J. Gordon, W. LoCiganic, G. Cochran, W. Gellad, T. Cathers, D. Kelley, and J. Donohue, “Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program,” Vol. 9, No. 6, 2015, pp. 470-477; American Society of Addiction Medicine, *The National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use*. Chevy Chase, Md., 2015.

therapy, such as those currently being considered by CMS and AHRQ, could be just as important as expanding treatment.¹⁷

Expanding Availability of Naloxone

Naloxone is a medication that, when used immediately following an opioid overdose, can counter the life-threatening effects caused by depression of the central nervous system. Despite a push by the prior administration to expand access to naloxone as part of its opioid initiative, there remains considerable debate amongst clinicians, policymakers and researchers about whether providing education and naloxone kits does in fact save lives or instead discourages treatment and causes harm (by reducing interactions with emergency health care providers and/or encouraging increasing risky behavior).¹⁸ There is a growing body of evidence that naloxone can be safely administered by first responders and laypersons who are properly educated and trained in its administration, resulting in a life saved from a specific overdose episode.¹⁹ However, what remains unclear due to limited evidence is whether these programs lead to an increase or reduction in overall rates of opioid overdose, including fatal overdoses, within a community.²⁰ I

¹⁷ R. Chou, P.T. Korthuis, M. Weimer, C. Bougatsos, I. Blazina, B. Zakhari, S. Grusing, B. Devine, and D. McCarty, *Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings*, Technical Brief No. 28, Rockville, Md.: Agency for Healthcare Research and Quality, December 2016; P.T. Korthuis, D. McCarty, M. Weimer, C. Bougatsos, B. Zakhari, S. Grusing, B. Devine, and R. Chou, "Primary Care-Based Models for the Treatment of Opioid Use Disorders: A Scoping Review," *Annals of Internal Medicine*, Vol. 166, 2017, pp. 268–278.

¹⁸ Assistant Secretary of Policy Evaluation, *Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths*, Washington, D.C., 2015; A.J. Ashworth and A. Kidd, "Take Home Naloxone for Opiate Addicts. Apparent Advantages May Be Balanced by Hidden Harms," *BMJ*, Vol. 323, No. 7318, 2001, p. 935; D. Mountain, "Take Home Naloxone for Opiate Addicts. Big Conclusions Are Drawn from Little Evidence," *BMJ*, Vol. 323, No. 7318, 2001, p. 934, author reply 935; A.R. Bazazi, N.D. Zaller, J.J. Fu, and J.D. Rich, "Preventing Opiate Overdose Deaths: Examining Objections to Take-Home Naloxone," *Journal of Health Care of the Poor and Underserved*, Vol. 21, No. 4, 2010, pp. 1108–1113.

¹⁹ A.K. Clark, C.M. Wilder, and E.L. Winstanley, "A Systematic Review of Community Opioid Overdose Prevention and Naloxone Distribution Programs," *Journal of Addiction Medication*, Vol. 8, No. 3, 2014, pp. 153–163; R. Fisher, D. O'Donnell, B. Ray, and D. Rusyniak, "Police Officers Can Safely and Effectively Administer Intranasal Naloxone," *Prehospital Emergency Care*, Vol. 20, No. 6, 2016, pp. 675–680; D.P. Wermeling, "Review of Naloxone Safety For Opioid Overdose: Practical Considerations For New Technology And Expanded Public Access," *Therapeutic Advances in Drug Safety*, Vol. 6, No. 1, 2015, pp. 20–31; M. Doe-Simkins, E. Quinn, Z. Xuan, A. Sorenson-Alawad, H. Hackman, A. Ozonoff, and A. Walley, "Overdose Rescues by Trained and Untrained Participants and Change in Opioid Use Among Substance-Using Participants In Overdose," *BMC Public Health*, Vol. 14, No. 297, 2014.

²⁰ D.P. Wermeling, "Review of Naloxone Safety for Opioid Overdose: Practical Considerations for New Technology and Expanded Public Access," *Therapeutic Advances in Drug Safety*, Vol. 6, No. 1, 2015, pp. 20–31; S.M. Bird, A. McAuley, S. Perry, and C. Hunter, "Effectiveness of Scotland's National Naloxone Programme for reducing opioid-related deaths: A before (2006–10) versus after (2011–13) comparison," *Addiction*, Vol. 111, No. 5, 2016, pp. 883–891; A.Y. Walley, Z. Xuan, H. H. Hackman, E. Quinn, M. Doe-Simkins, A. Sorenson-Alawad, S. Ruiz, and A. Ozonoff, "Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis," *BMJ*, Vol. 346, 2013, p. 174; A. McAuley, J. Boutil, L. Barnsdale, D. Mackay, J. Lewsey, C. Hunter, and M. Robinson, "Evaluating the Impact of a National Naloxone Programme on Ambulance Attendance at Overdose Incidents: A Controlled Time-Series Analysis," *Addiction*, Vol. 112, No. 2, 2017, pp. 301–308.

am aware of only two U.S. studies that have looked at the impact of naloxone distribution on overall opioid mortality as an outcome. One of the studies looked narrowly at a training and distribution program adopted within specific communities in Massachusetts, and found the program did in fact reduce annual community levels of opioid-related mortality with no statistical increase in the rate of acute care hospital utilization, suggesting the program was effective at reducing overall harm.²¹ However, the study did not have a within-state control group, making it unclear if the findings were truly attributable to the program and not to broader aggregate trends. A very recent National Bureau of Economic Research working paper used a much more-sophisticated, quasiexperimental design, exploiting variation in state laws providing legal protections for naloxone prescribing and/or administration²². The authors of this study found that state adoption of naloxone laws was associated with a 9- to 11-percent reduction in opioid-related deaths overall. Findings from this study are perhaps the most supportive of an overall positive effect, but more research is needed to evaluate if these findings can be replicated in other data.

Enhancing Prescription-Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) have been promoted by the federal government to improve safety in opioid analgesic prescribing; help identify diversion of these medications; and reduce the harm associated with opioid analgesic abuse, including fatal and nonfatal overdoses.²³ As such, evaluations of their effectiveness have considered a variety of different behaviors and outcomes, including physician prescribing, patient behavior (doctor and pharmacy shopping), and broader population health outcomes, including fatal and nonfatal overdoses and admissions to substance abuse treatment.

While several studies have demonstrated the utility of proactive PDMPs at changing physician prescribing, the effectiveness of PDMPs at reducing the misuse and harm associated with prescription opioids continues to be assessed, as the current literature remains inconclusive about their effects.²⁴ There are a variety of legitimate reasons why previous studies have failed to

²¹ Walley et al., 2013.

²² D.I. Rees, J.J. Sabia, L.M. Argys, J. Latshaw, and D. Dave, *With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths*, Cambridge, Mass.: National Bureau of Economic Research, 2017.

²³ Centers for Disease Control and Prevention, “Prescription Drug Monitoring Programs (PDMPs),” March 2017; Government Accountability Office, “Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion,” May 2002; Executive Office of the President, “Epidemic: Responding to America’s Prescription Drug Abuse Crisis,” 2011.

²⁴ Y. Bao, Y. Pan, A. Taylor, S. Radakrishnan, F. Luo, H.A. Pincus, and B.R. Schackman, “Prescription Drug Monitoring Programs Are Associated With Sustained Reductions in Opioid Prescribing by Physicians,” *Health Affairs (Millwood)*, Vol. 35, No. 6, 2016, pp. 1045–1051; D.F. Baehren, C.A. Marco, D.E. Droz, S. Sinha, E.M. Callan, and P. Akpunonu, “A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors,” *Annals of Emergency Medicine*, Vol. 56, No. 1, 2010, pp. 19–23; C. Ringwalt, M. Garretson, and A. Alexandridis, “The Effects of North Carolina’s Prescription Drug Monitoring Program on the Prescribing Behaviors of the State’s Providers,” *Journal of Primary Prevention*, Vol. 36, No. 2, 2015, pp. 131–137; G.G. Franklin, J. Sabel, C.M. Jones, J. Mai, C. Baumgartner, C.J. Banta-Green, D. Neven, and D.J. Tauben, “A

generate conclusive results, particularly at the population level. First, while there has been wide adoption of state PDMPs, early state adopters were fundamentally different than the programs that exist today. For example, many early states did not require real-time updates or reporting of the system, making the timely dissemination of information or utility for identifying physician and pharmacy shopping limited.²⁵ Similarly, states tend not to require PDMP participation; as of May 2016, only 29 states require prescribers to register.²⁶ Moreover, only 34 of the states with PDMPs mandate their use by prescribers or dispensers who are registered in the state.²⁷ Thus, it is not surprising to see that in a recent nationally representative survey of primary care providers, only 54 percent made use of their state's PDMP program despite a much larger share actually being aware of them.²⁸

Research on the differences between state PDMP programs will help us understand the impacts of different PDMP programs and identify how to enhance existing programs. Recent scientific evaluations are starting to do just that, and findings from these studies suggest that PDMPs can be effective at achieving their goals of reducing prescription opioid misuse and harm.²⁹

Establishing Guidelines for Safe Opioid Prescribing

Overprescribing of opioids—providing more days' supply or much-higher dosages than what is commonly required to manage pain in most people, or prescribing opioids before trying alternative methods of pain control—has been shown to be a major risk factor for the

Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned," *American Journal of Public Health*, Vol. 105, No. 3, 2015, pp. 463–469; T.M. Haegerich, L.J. Paulozzi, B.J. Manns, and C.M. Jones, "What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose," *Drug and Alcohol Dependence*, Vol. 145, 2014, pp. 34–47; J.E. Brady, H. Wunsch, C. DiMaggio, B.H. Lang, J. Giglio, and G. Li, "Prescription Drug Monitoring and Dispensing of Prescription Opioids," *Public Health Reports*, Vol. 129, No. 2, 2014, 139–147; L.J. Paulozzi, E.M. Kilbourne, and H.A. Desai, "Prescription Drug Monitoring Programs and Death Rates from Drug Overdose," *Pain Medicine*, Vol. 12, No. 5, 2011, pp. 747–754; L.M. Reifler, D. Droz, J.E. Bailey, S.H. Schnoll, R. Fant, R.C. Dart, B. Bucher Bartelson, "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?" *Pain Medicine*, Vol. 13, No. 3, 2012, pp. 434–442; R. Simeone and L. Holland, "An Evaluation of Prescription Drug Monitoring Programs," 2006.

²⁵ S.W. Patrick, C.E. Fry, T.F. Jones, and M.B. Buntin, "Implementation of Prescription Drug Monitoring Programs Associated with Reductions in Opioid-Related Death Rates," *Health Affairs*, Vol. 35, No. 7, 2016, pp. 1324–1332.

²⁶ National Alliance for Model State Drug Laws, "States that Require All Licensed Prescribers and/or Dispensers to Register with the State PDMP," May 2016.

²⁷ National Alliance for Model State Drug Laws, "Mandated Use of State Prescription Drug Monitoring Programs: Specified Circumstances Requiring Prescribers/Dispensers to Access PMP Data," November 2017.

²⁸ L. Rutkow, L. Turner, E. Lucas, C. Hwang, and G.C. Alexander, "Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, but Many Find the Data Difficult to Access," *Health Affairs* (Millwood), Vol. 34, No. 3, 2015, pp. 484–492.

²⁹ B. Pardo, "Do More Robust Prescription Drug Monitoring Programs Reduce Prescription Opioid Overdoses?" *Addiction*, 2017; Patrick et al., 2016; M.M. Ali, W.N. Dowd, T. Classen, R. Mutter, and S.P. Novak, "Prescription Drug Monitoring Programs, Nonmedical Use of Prescription Drugs, and Heroin Use: Evidence from the National Survey of Drug Use and Health," *Addictive Behaviors*, Vol. 69, 2017, pp. 69–77; Simeone and Holland, 2006.

development of an opioid use disorder.³⁰ Potentially inappropriate prescribing, which includes prescribing overlapping opioid analgesics and benzodiazepines, has also been verified in studies of both publicly and privately insured populations.³¹

Efforts to reduce these problems have largely emphasized the adoption of clinical guidelines for safe opioid prescribing. I am aware of only a couple of studies that focused on evaluating the impact of just adopting these sorts of guidelines, and both studies focused on effects within a single state. One study shows that implementation of these tools in Washington's workers' compensation system led to a 27-percent reduction in the morphine equivalent doses per day and a 35-percent reduction in the proportion of workers on high doses.³² Another study evaluated the state's adoption of a PDMP and showed that the guidelines alone helped reduce opioid related fatalities by 27 percent between 2008 and 2012.³³

However, a recent evaluation of the Veterans Affairs (VA) Health Administration Opioid Safety Initiative demonstrated that system-wide adoption of clinical guidelines, including directives for stepped pain treatment and the adoption of a risk management tool to hold clinicians accountable for their prescribing practices, when coupled with other strategies for managing chronic pain patients and improving access to opioid treatment, led to a 25-percent decline in the number of veterans prescribed an opioid within the VA system, a 36-percent reduction in patients receiving inappropriately high opioid doses, and a 47-percent reduction in simultaneous, inappropriate prescription of opioids and benzodiazepines.³⁴ Perhaps even more significantly, there was a 50-percent drop in the rate of overdose deaths among veterans prescribed an opioid after program adoption. This strongly suggests that system-wide adoption of clinical guidelines, when coupled with effective education and training, can be very effective at changing physician practice, reducing inappropriate prescribing, in a manner that might actually improve patient health.

³⁰ M.J. Edlund, B.C. Martin, J.E. Russo, A. DeVries, J.B. Braden, and M.D. Sullivan, "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Noncancer Pain: The Role of Opioid Prescription," *Clinical Journal of Pain*, Vol. 30, No. 7, 2014, pp. 557-564.

³¹ B.D. Stein, J. Mendelsohn, A.J. Gordon, A.W. Dick, R.M. Burns, M. Sorbero, R.A. Shih, and R.L. Pacula, "Opioid Analgesic And Benzodiazepine Prescribing Among Medicaid-Enrollees with Opioid Use Disorders: The Influence of Provider Communities," *Journal of Addictive Diseases*, Vol. 36, No. 1, pp. 14-22; K.M. Dunn, K.W. Saunders, C.M. Rutter, C.J. Banta-Green, J.O. Merrill, M.D. Sullivan, C.M. Weisner, M.J. Silverberg, C.I. Campbell B.M. Psaty, and M. Von Korff, "Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study," *Annals of Internal Medicine*, Vol. 152, No. 2, 2010, pp. 85-92; J. Logan, Y. Liu, L. Paulozzi, K. Zhang, and C. Jones, "Opioid Prescribing in Emergency Departments: The Prevalence of Potentially Inappropriate Prescribing and Misuse," *Med Care*, Vol. 51, No. 8, 2013, pp. 646-653; L.J. Paulozzi, G.K. Strickler, P.W. Kreiner, C.M. Koris, Centers for Disease Control and Prevention, "Controlled Substance Prescribing Patterns—Prescription Behavior Surveillance System, Eight States, 2013," *MMWR Surveillance Summaries*, Vol. 64, No. 9, 2015, pp. 1-14.

³² G.M. Franklin, J. Mai, J. Turner, M. Sullivan, T. Wickizer, and D. Fulton-Kehoe, "Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline," *American Journal of Industrial Medicine*, Vol. 55, No. 4, 2012, pp. 325-331.

³³ Franklin et al., 2015.

³⁴ W.F. Gellad, C.B. Good, and D.J. Shulkin, "Addressing the Opioid Epidemic in the United States: Lessons From the Department of Veterans Affairs," *JAMA Internal Medicine*, 2017.

Concluding Remarks

Under ideal circumstances, decisions are made based on solid evidence related to effectiveness, including cost-effectiveness calculations. However, at this time it is impossible to apply such strong criteria to funding decisions for the opioid epidemic. So much more information is needed regarding where we actually are in the opioid epidemic and how the use of heroin and opioid analgesics interact. Additionally, we need to better understand the true effectiveness of various programs in light of the changing state and local environments in which they are implemented. What works in some communities may not be particularly effective in others, due to demographic differences, epidemic stage, and/or existing policies that are already in place. Much scientific work is needed to disentangle these things before firm recommendations based on strong science can be offered. Nonetheless, budgetary decisions need to be made today.

My remarks are intended to provide insights regarding the probable effectiveness of key strategies already undertaken by agencies funded by this subcommittee. There are many other strategies to consider as well. In general, we know that demand-side interventions, including treatment and prevention, are cost-beneficial.³⁵ Moreover, as these strategies generally apply to use of any opioid, they provide the least risk of unintended consequences in terms of pushing individuals into black markets. We also know that many supply-side strategies, at least those targeting diversion of prescription opioids, have reduced the amount of opioids available in the market, although these strategies possibly have unintended consequences when they target only specific opioids (e.g., Schedule II opioids only included in PDMPs, rather than all opioids; abuse-deterrant formulations of OxyContin).³⁶ A combined approach that considers both demand and supply seems justified. Harm reduction strategies, such as naloxone distribution, should not be ignored. While they may come with some risk (e.g., engaging in more opioid abuse because of less risk of overdose), those hypothesized effects have not yet been scientifically demonstrated, and studies suggest the opposite may in fact be the case.

When making budgetary decisions, bear in mind that some policies, including prevention and treatment, take time before their effects are fully observed in aggregate prevalence numbers. Moreover, natural dynamics influence these epidemics beyond the policies we adopt to try to influence them. Given the availability of both legal and illicit opioid products in many communities, we must be particularly concerned about policies that target just one part of the opioid problem (e.g., prescription opioids) in one particular system (e.g., the VA or Medicaid); singular approaches that only target one of these products or in one health system could generate

³⁵ G.A. Zarkin, L.J. Dunlap, K.A. Hicks, and D. Mamo, "Benefits and Costs of Methadone Treatment: Results from a Lifetime Simulation Model," *Health Economics*, Vol. 14, No. 11, 2005, pp.1133–1150; J.P. Caulkins, R.L. Pacula, S. Paddock, and J. Chiesa, "What We Can—and Cannot—Expect from School-Based Drug Prevention," *Drug and Alcohol Review*, Vol. 23, No. 1, 2004, pp.79–87.

³⁶ D. Powell and R.L. Pacula "Prescription Opiates and Opioid Abuse: Regulatory Efforts to Limit Diversion from Medical Markets to Black Markets in the United States," in E. Savona and M.A.R. Kleiman, eds., *Dual Markets—Comparative Approaches for Regulation*, New York: Springer, forthcoming.

substitution across drugs or across health systems.³⁷ Moreover, some highly restrictive supply side strategies, such as those that limit opioid prescriptions to five- or seven-day dosages, may make it very difficult for patients with legitimate needs to obtain medication. Supply strategies, whether implemented through the medical system or through law enforcement, must consider all of these things. That is why it is truly difficult to find the right balance of policies for managing the opioid epidemic.

Thank you for inviting me to testify before you today, and I welcome the opportunity to answer any questions you may have.

³⁷ Alpert, Powell, and Pacula, 2017; Cicero, Ellis, and Surratt. 2012; W.F. Gellad, X. Zhao, C.T. Thorpe, J.M. Thorpe, F.E. Sileau, J.P. Cashy, M. Mor, J.A. Hale, T. Radomski, L.R. Hausmann, and M.J. Fine, “Overlapping Buprenorphine, Opioid, and Benzodiazepine Prescriptions Among Veterans Dually Enrolled in Department of Veterans Affairs and Medicare Part D,” *Substance Abuse*, Vol. 38, No. 1, 2017, pp. 22–25.

Mr. COLE. I want to begin by thanking all of our witnesses, because I have got to tell you, you do a much better time of staying within your 5 minutes than any of my colleagues up here do on either side of the aisle. So thanks for setting such a high standard.

In the interim, we have been joined by the former chairman of the full Appropriations Committee and the current chairman of the State and Foreign Operations. And if I may say, the guy, as both sides of the aisle recognize, has done more to focus Federal attention on this problem and done more to bring resources to bear to try and help Americans not just in his district or his State but all across the country than anybody else.

So it is my privilege to recognize my good friend and colleague and mentor for any opening remarks he cares to make.

Mr. ROGERS. Well, thank you, Mr. Chairman, for those wonderful words. You went on a bit too much. But like Mae West once said, too much of a good thing is simply wonderful.

And, Ranking Member DeLauro, thank you for letting me sit in on your subcommittee. I will be brief, hopefully, and keep myself out of your way.

I am delighted to see my great friend Nancy Hale here today. You have heard from her already. But you have heard me ad nauseam, I think, praise the work of Operation UNITE back in Kentucky and now across the country, helping us take back our communities from the grip of drug traffickers and addiction.

And Nancy is a big reason why they have been so successful in Kentucky. She was a part-time volunteer for UNITE and worked her way up to be president and CEO, and she keeps the momentum going in this seemingly never-ending fight.

You have heard me tell the story of UNITE. It stands for Unlawful Narcotics Investigations, Treatment and Education, a holistic approach. We can't arrest our way out of this, we can't educate our way out of it singly, and we can't treat our way out of it singly. We have to do all of that at the same time, endlessly and permanently, and that is what UNITE was organized to do.

Thirteen years ago, we had a horrendous problem in my eastern Kentucky district, one of the first ground zeros for OxyContin, people dying and kids in the emergency rooms and so on. It was new at that time, new to really the world.

So I called together people from all walks of life and we brainstormed and brainstormed and finally came up with a concept of this holistic approach. And since that time, for example at the outset they had 35 undercover agents to cover about a one-third of the State, 30 counties. They had 35 undercover agents, very professional. And so far they have put in jail 4,400 pushers just in that part of Kentucky.

We have treatment centers, we have UNITE clubs in schools, most of the schools that do after-school things make it fun, drug courts in every county, and so on. It is a holistic and successful approach. But we are a long way, as Nancy has said, from being perfect. We have got a long ways to go.

But I am especially grateful that Nancy has taken the time, especially now, to share her experience. It is a busy time for UNITE because 6 years ago UNITE decided to take their operation national and they called a prescription pain drug summit in Orlando.

Started out with around 1,000 people there. It has now grown. We will be holding the sixth annual summit week after next in Atlanta. We will have upwards of 3,000 people there from every walk of life, every nook and cranny of the country and the world. We will have congressmen and senators and governors and attorneys general and treatment experts and medical experts and NIH and CDC and DEA and ABC at this conference.

Last year, the President came. He has been invited again, a different President. So we are hoping that he and/or the Vice President will join us there.

But it is the only place where all of the disciplines that make up this fight that we are in come together in a single place under one roof, because the treatment people need to understand what the prosecutors are doing and the judges need to know what the attorneys general think about it and so on. And it is a great place for sharing of ideas and learning from each other and taking best practices and spread them across the country. That is what these summits are doing.

And I hope that each one of you will be there. I am looking our panelists in the eye and I am looking Members of the House in the eye, hoping that all of you can be there for the annual prescription drug summit in Atlanta.

What is the date, Nancy?

Ms. HALE. April 17th through the 20th.

Mr. ROGERS. Are you taking reservations?

Ms. HALE. Yes, I have forms in my packet here.

Mr. ROGERS. Thank you, Mr. Chairman, for letting me be here with you.

The fight goes on. It is getting worse, it seems. And we have got new drugs coming at us like crazy. We have got a government that must be resilient and adept to switch with the times and the attack and where it is coming from. That is no small chore.

But this subcommittee, Mr. Chairman, Ranking Member, you are on the front line, and we are looking to you as we have in the past for great leadership. I thank you for letting me speak.

Mr. COLE. I thank the chairman. And thanks, when you put us on the front line, you were never shy about giving us bullets. So thank you very much. The country owes you a lot in many regards, but particularly in this regard.

Ms. Hale, let me start with you, and then I am just going to work across quickly.

You know, the late President Lyndon Johnson used to say doing the right thing isn't hard, knowing the right thing to do is. And you each have had vast experience in this area, but from very different points of view, and have had a chance to look at some of the things that we fund from a Federal level.

And, again, as I told you in the back, I am not going to ask you to name losers, unless you want to, but I am going to ask you to try and give us—because we will have tough decisions to make, even with the resources that we have available, and I share my friend the gentlelady from Connecticut's concern about that.

But whatever, there is never enough, and this is an area where we really need to make sure that whatever resources we have we direct where people that are actually working the problem think

this can make a difference. So I would really like your opinions for the record on two or three initiatives, whatever number you care to pick out, that you think Federal dollars really matter in.

Ms. HALE. I think definitely you have to have that holistic approach. And we have been very reactionary in this epidemic. We had to start out really strong in southern and eastern Kentucky with an emphasis on law enforcement, those undercover investigations that Congressman Rogers mentioned.

Over the years, we have seen what he was telling us to be true, that we cannot arrest our way out of the problem. And I think what we are seeing now is that we have got to move prevention to the forefront. We have got to be proactive where we have been reactionary in the past.

And I firmly believe that we are seeing a generation of young people that need a K through 12 prevention curriculum in their schools that builds consistently, that is developmentally appropriate, culturally appropriate.

Two years ago I was in one of our counties doing a program, On The Move! It is a mobile prevention unit. I was in our trailer with eighteen 16-year-old boys, going through the PowerPoint, sharing all the information about gateway drugs, and we had a great discussion.

And as the boys were leaving to go out of the trailer, one young man stopped and his body language was very angry. And he said, "I have two things to say, two things to ask you."

And I said, "Okay."

And he said, "One, I want you to know that I have smoked pot before, but I am not going to anymore, because my goal in life is to get smarter, not dumber." And he said, "But what I want to ask you is why no one has told me this before."

And so I began—we all began to see these young people want to make good choices. They want to be given the facts, the information. And that is how we are going to build on people who make those choices.

So I think our prevention programs are ones that we need to replicate, that we need to fund definitely, but then providing vouchers for the treatment programs.

When Congressman Rogers helped establish Operation UNITE, there were very few treatment facilities in Kentucky, and now we have many who are opening their arms. We are working with law enforcement to initiate programs such as the Angel Initiative, where people can go into the State police post in crisis and ask for help, and our treatment facilities are accepting them, and then UNITE is helping to provide them vouchers.

Those are two.

Mr. COLE. I am going to try to move quickly here or I will come back to this question because I don't want to rush anybody.

But, Ms. Cimaglio, the same question.

Ms. CIMAGLIO. I think you have heard from all of us in one way or another that the important element is a comprehensive approach. We aren't going to get ahead of this problem by just doing a single strategy. And for Vermont it does include prevention, intervention, treatment, recovery, support, and others.

Some of the elements of our comprehensive strategy have focused on public information and messaging. It is critically important that we have messages that speak to people throughout the community and throughout our States.

Pain management and prescribing practices. We have guidelines similar to the CDC guidelines in our State and have done education with our medical community, because we know that we have to change the practices of the physicians on the ground and also be there to support them with how to address addiction when a person comes into their office and is struggling. What do I say? Where do I send them? How do I give them help? So having clear guidelines and education for physicians.

Prevention and community mobilization is critical and I will leave that there. I think you have heard a lot about that.

Drug disposal. Safe disposal practices on the Statewide level is something that we have been working on, gearing up for Drug Take Back Day on the 29th. It has to be easy for people to dispose of these substances.

Mr. COLE. I am going to have to ask you to stop there because I can't be tough on the rest of these guys if I am not tough on me. I will come back to our other two witnesses in my next round of questioning. I want to go to my good friend, the gentlelady from Connecticut.

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

And thank you all very, very much for your testimony.

I just will say to you, Mr. Guy, there is no way that we can replace the hole in your heart, but I am hopeful that this sub-committee can help alleviate some of that pain.

Mr. GUY. Thank you, thank you.

Ms. DELAUBRO. Ms. Cimaglio, just a series of questions very quickly because I want to try to get to a second question as well. This has to do, Ms. Cimaglio, with Medicaid and it serving as the most significant source of coverage and funding for prevention and for treatment, which you have highlighted as well as Ms. Hale has.

In some places Medicaid is paying up to 50 percent of the cost of medication-assisted treatment. Healthcare experts estimate that 1.6 million individuals with substance abuse disorders gained health insurance through Medicaid expansion.

So is Medicaid responsible for expanding access to medication-assisted treatment in Vermont?

Ms. CIMAGLIO. Yes, it is. We actually had Medicaid expansion before the Federal Government acted, but it has been significant. As many as 70 to 80 percent of folks are getting treatment because of the support of our Medicaid program, and that has allowed us to expand our Hub and Spoke model.

Ms. DELAUBRO. Which I want to get to later on, Hub and Spoke, right.

If the Affordable Care Act is repealed, the States forced to scale back Medicaid programs, impact on Vermont in terms of treatment for substance use disorder?

Ms. CIMAGLIO. Well, as I said, since a high percentage of people are supported through the Medicaid program, it would be a challenge and a disaster, I think, if we had to pull back all of the work that we have done to develop the system.

Ms. DELAUR. In your experience, if you have to interrupt the treatment because of loss of health insurance, what is the outcome, what does that mean? If you are on, then you have no insurance coverage, and then you are off, and then you go you go back, what is interrupted to your process here?

Ms. CIMAGLIO. Well, I think there are two outcomes. To the individual, it disrupts treatment, which is not a good thing, and we wouldn't want to see that happen. But then that means that the State picks up the cost. So through our block grant we would then support to the extent we could, and that is the Substance Abuse Prevention Treatment Block Grant that is the foundation of state-wide system.

Ms. DELAUR. So let me just see if this is accurate. If we repeal this Medicaid expansion, it does not continue in some way, if we cut back dollars to Medicaid, yes or no, would it worsen the crisis in your State of Vermont? Would it affect it first and would it worsen the crisis?

Ms. CIMAGLIO. If it cut back access to services it definitely would affect it and worsen it. And I think each State has their own approach, but our approach has been very comprehensive. And we appreciate the talk of flexibility so that each State can do what they need to do.

Ms. DELAUR. One of the things that has concerned me about this is that something that you used, you would have to then deal with how you would adjust to dealing with an affected population. In my mind, in instances of when I have seen block granting in this area, has been when a State is forced to choose who. And that is a Sophie's choice. You begin to take a look at rationing. Would that not be the case in this instance?

Ms. CIMAGLIO. It certainly could be, depending on the extent of the reductions. But as I said, we worked very hard to get to where we are today in a very comprehensive way and we would not want to see having to go backwards.

Ms. DELAUR. And if I might add to Ms. Hale and Ms. Cimaglio, I will ask the question quickly. The Institute of Medicine has called for 10 percent of public funds to be spent on young people to be directed toward effective prevention interventions to promote healthy behaviors. You have talked about prevention, you have talked about K through 12, or maybe even preschool.

Does that sound right to you with the IOM, the Institute of Medicine, say, 10 percent? Would you support that kind of an effort, 10 percent of public funds spent, directed at young people?

Ms. HALE. Well, when you have had nothing—

Ms. DELAUR. Ten percent is better than nothing. Okay. I hear you. I hear you.

I guess I am out of time, but I want to come back in terms of your prevention programs. You talked about what works and doesn't. And the SAPT Block Grant, if that were cut by 18 percent. So think about that, what that would mean to you.

Thank you, Mr. Chairman.

Mr. COLE. I thank you.

We next, as tradition dictates, go to the gentlelady. The ranking member of the full committee from New York is recognized.

Mrs. LOWEY. Thank you, Mr. Chairman. And I want to apologize in advance because after I ask the questions I have to go to another hearing.

Mr. COLE. That is why I am going to you next.

Mrs. LOWEY. Thank you. But I want to thank you. And I want to thank Chairman Rogers because we have been working together and you have done such an extraordinary job.

And to the whole panel, and especially you, Mr. Guy. Thank you so much for being here today. As a grandmother and a mother we all feel for the difficult time you went through. Thank you very much.

Mr. GUY. Thank you.

Mrs. LOWEY. Since 1999 sales of opiates in the United States have quadrupled. I am so concerned about this increase, particularly as there is no data to support Americans are facing more physical pain than they did two decades ago. And as opioids are not intended to treat chronic pain, I cannot fathom how nearly 300 million prescriptions are written each year. There is clearly a vast over prescription of opioids. And a staffer of mine was just telling me as we were preparing for this hearing, she had a sprained ankle and the doctor gave her a 1-week prescription for vicodin, for her sprained ankle.

The CDC has been taking steps to provide best practices for physicians, but much more must be done. And if whoever would like to respond, or in the time I have a few of you could respond, what steps should the Federal Government take to work with providers to prescribe opioids only when necessary for the health of the patient or in more limited doses? Clearly they are not doing it now.

Thank you.

Ms. PACULA. So it is absolutely necessary to educate prescribers, all prescribers, and it is not just physicians. Dentists can prescribe opioids as well. Vets can prescribe opioids as well. And opioid-seeking patients know these things. We need as active an education of our prescribers as we have in the advertising of the effectiveness of the drugs at treating pain.

One of the successful elements of the VA strategy was the pharmacists who are part of this situation being the ones educating the prescribers, the doctors, the ER people, on how much needs to be distributed and why it might not be appropriate to give two overlapping opioids to a patient because they aren't sure which one they want. Give them one. Make it restricted. If it doesn't work, have them turn it in and give them the second one.

There is effective strategies to doing this. They just need to be disseminated. When we talk about education, this is an area where it is not just educating our kids—although that is extremely important—educating the medical community, and by that I mean it as broadly as dentists and vets as well, about the risks, about the abuses, and how to identify potentially patient-seeking behavior and participation in this prescription drug monitoring programs.

While many physicians are aware of them, States do not mandate that all prescribers participate. They don't know that this patient has already received a prescription from another provider because they don't have access to that information because their State system is not set up to do that.

Enhancing prescription drug monitoring programs enables physicians to have access to that information, providers. Vets can participate, dentists can participate if it is part of the policies. Let's make it part of the policy.

Mrs. LOWEY. I would just—since I have just a minute, little less than a minute left, I just don't get it. Because if you are a physician or if you are a dentist, you don't know what these drugs can do? What does your research show?

Ms. PACULA. I don't know that it is—

Mrs. LOWEY. I had a tooth pulled recently, and I said, no, thanks, and I didn't—well, I didn't take anything. But I don't get it.

Ms. PACULA. There is a problem in our system in that physicians and hospitals are ranked in the quality of care that they are given, and part of that measure of quality is if the patient believes their pain was effectively managed.

So there is actually in our system a financial incentive to provide patients with too much medication because the patient is more likely then to respond that their pain was effectively managed. We need to educate patients as well as providers, but there is, unfortunately, misaligned incentives in our healthcare system today.

Mrs. LOWEY. Thank you very much, Mr. Chairman. And I apologize for having to go off to another hearing.

Mr. COLE. Just a point of information before we move the next member for my friend. I actually had an interesting conversation with Dr. Collins at the NIH recently. You may want to bring this up. Because they are beginning to find—to look for medicines that don't have opioids that can achieve the same results.

So we are actually—and I think Mr. English is actually working on something similar to that. So this is an area we may want to explore when the NIH comes up here to testify because it could be a real contribution.

Mrs. LOWEY. Thank you very much. And thank you all.

Mr. COLE. Thank you.

We next go to the vice chairman of the subcommittee, the distinguished gentleman from Arkansas.

Mr. WOMACK. Thank you, Mr. Chairman. And what a riveting discussion that we are having here concerning what I consider to be one of the—if not the most important issue facing our country today, insofar as the impact it has on young people and their future development and progress.

I don't know what would be more important. I will say this up-front, that I believe in my heart that addiction is a disease and not a moral failing of an individual. And our country needs to recognize that it is a disease and not a moral failing.

Mr. GUY, when I heard and read your testimony, it became apparent to me that you, as a parent, became overwhelmed with the inability to fix a problem.

Mr. GUY. Absolutely. Absolutely.

Mr. WOMACK. I don't know—short of people having a similar experience, I don't know what more we can do. There has got to be some things we can do to help people understand that, as has been mentioned, that a holistic approach is the only solution; that you can't just fix certain elements of it; that there is a progression of these diseases; and that, you just can't lock them up and throw

away the key and hope that the situation per individual is going to be fixed. Can you?

Mr. GUY. No, you can't. And I would advocate for greater opportunities for people who are experiencing these kinds of things to be able to network with each other and to—and, you know, you addressed a significant part of it, is that there is still—there is still some degree of stigma and shame, you know, related to this issue.

And I think that there are some people who are reticent to reach out, and that is one of the reasons that I have gotten involved with the program called Parents Helping Parents, because it is a peer group. The purpose of it—the primary purpose of it is to provide opportunities for people who are experiencing this in their families, to be able to come together to share information, to share resources.

In the Norman Chapter, we provide a lending library. We got a grant from the United Way to provide a lending library. We have a comprehensive lending library. We are working with the police department in Norman because the police department has told us that they are often on the frontline, if someone overdoses or if someone is arrested; that they have parents that were in the situation that we are in that they don't know what to do. And the police department in Norman has been very forthcoming in working with us because now they have a resource to refer people to.

You know, I think preventive education—I think not just education for children but education for parents as well. And I think anything that we can do to help people feel like that they are—I was talking to someone earlier, it is a huge club, and it is a club nobody wants to join.

But I think the more that we can do to help people see that even people who are not affected by this personally are open to helping the people that they are. I think that would go a long way.

Mr. WOMACK. There has been some discussion in this briefing so far about naloxone and its use in the emergency rooms on an overdose. It just makes sense to me that once an individual has been treated in an ER setting, that to just—because a lot of these folks are just going to be released—

Mr. GUY. Right.

Mr. WOMACK [continuing]. Back out on the street. And those demons will call again, and those individuals are going to be back in need.

Mr. GUY. Right.

Mr. WOMACK. It would seem to me that it would be very appropriate and worthwhile to get these folks in some treatment program upon an incident like this. I don't know who might want to take that for just a moment. I have only got about 20 seconds left in my time.

Ms. CIMAGLIO. One of the things that Vermont has proposed in our 21st Century Cures application is exactly that, expanding partnerships with emergency departments to make those linkages with peer support workers that can help link individuals and families to help and support. That is one of the most frequent comments we hear in the community, that people need help from other people. And I agree 100 percent that that is a missing link often.

Mr. COLE. Thank you.

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

Ms. ROYBAL-ALLARD. First of all, Mr. Guy, I want to join my colleagues in thanking you for being here and helping to put a human face on this crisis of opioid addiction.

Mr. GUY. Thank you.

Ms. ROYBAL-ALLARD. Ms. Pacula, in your written testimony, you say the following: "Improving the quality of medication-assisted treatment may be particularly important for improving outcomes for historically underserved or high-risk populations, such as racial, ethnic minorities, individuals with HIV, and individuals in rural counties who may not receive effective treatments for opioid use disorders at the same rate as non-minority individuals. Policies and programs have improved delivery of this therapy, such as those currently being considered by CMS, and AHRQ could be just as important as expanding treatment."

As you may be aware, the administration has proposed eliminating AHRQ next year. Given your emphasis on the need to improve delivery of medication-assisted treatment, do you think that AHRQ provides valuable research to help improve the delivery of services in healthcare settings, and in your view, is it important to continue to support AHRQ research in this area?

Ms. PACULA. I can tell you, they absolutely deliver valuable research. As RAND does receive funding from AHRQ, I think I have to be honest in disclosing that we do receive funding from AHRQ to do—and we do find this funding to be unique, filling holes that are not necessarily filled by the other funding agencies and have enabled important research on the effectiveness of not just MAT but other important activities.

For example, one of the things I was referring to in my testimony is the integration of primary care and medication-assisted treatment. In order to administer buprenorphine, you have to get a waiver from the Federal Government. And those that do are not necessarily treating all the patients they could treat under those waivers.

How do we educate more providers to get those waivers in areas where we have need, and how do we help them understand how to do this in a way that helps the patient? There is resistance, because these are difficult patients. And now these patients are—then become part of your patient mix that are going to rate your quality. That is not attractive to some practices. But there are successful strategies and AHRQ has been at the forefront of trying to evaluate those and disseminate them.

Ms. ROYBAL-ALLARD. Thank you.

Ms. Cimaglio, as was mentioned earlier, despite the fact that the majority of doctors and other members of the medical community are licensed to prescribe opioids and other narcotics to treat patients with pain, most American physicians receive little or no training during medical school regarding evidence-based prescribing substance-use disorders and pain management. And currently, only five States require all or nearly all physicians to obtain continuing medical education on these topics.

As my colleague, Ms. DeLauro, mentioned, CDC released guidelines for prescribing opioids for chronic pain last year. However,

one of the concerns that I have is that not all medical professionals know of or are even adhering to these guidelines.

What should be done to—nationally to standardize CME requirements for all medical professionals prescribing opioid medications? And should States require that patients receive multiple ongoing opioid prescriptions, that they should see a specialty in pain management, such as a pain management physician or CRNA?

Ms. CIMAGLIO. Thank you for the question. In Vermont, we actually have passed State law with basically the CDC guidelines and probably a little bit more than that in ours. And all of our physicians have to meet those guidelines, and that is what our medical practice board uses to evaluate how the physicians are doing.

We have also increased the number of hours that they need to receive. So clearly, we do believe that that is an important aspect. We also require all physicians to enroll and use the prescription monitoring program. So I think where the States have the ability to increase their own guidelines and regulations, I think that is a tool.

I don't know that across the board the Federal Government can do that. I am just not versed enough to know whether that is a possibility, but I think anything that can be done through the associations, through training, through guidelines, is critical.

We have to change the culture. That is what we are really talking about here, is using a variety of tools to change the culture. And make it clear that opioids are not the first choice, that when you are prescribing opioids to a patient, there need to be checks and balances to ensure that they are being monitored carefully.

Ms. ROYBAL-ALLARD. What about requiring someone to see a pain management specialist as part of the process for a cure?

Ms. CIMAGLIO. Yes. I think if a patient is experiencing chronic pain, definitely going to see a specialist is an important element. There aren't enough of them. We struggle with having access to pain management and pain specialists, but also alternative and complementary approaches are important. And so making sure we have the choices and the support for managing pain that isn't just based on taking a pill.

Ms. ROYBAL-ALLARD. Thank you.

Mr. COLE. Next, we will go to my good friend, the gentleman from Tennessee, Mr. Fleischmann.

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And to each and every one of the panelists, I want to echo the sentiments of folks on both sides of the dais. This has really been a very important testimony for us as policymakers, and I thank each and every one of you for your participation in this national epidemic.

Ms. Pacula, your testimony, you addressed that it is too soon to have an evaluation of the impact of programs in the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. As we begin to provide a framework for these programs, what factors should we keep in mind as to import the assessing programs as to their effectiveness?

Ms. PACULA. I think that requiring data collection of implementation as well as outcomes is vitally important, and providing broad access to that is important. A lot of work was stalled on the effec-

tiveness of some of the medication-assisted therapies because of the redaction of information of patients who had mental health and addiction diseases from general health care.

In CMS data, we were not able to get combined data sets that had both their healthcare utilization and mental health and addiction until just last year. It was redacted because of concerns over privacy for people who had these conditions. That is a legitimate concern. But the inability to do analyses to see where—primary care prevention is where we need to be doing addiction therapy. If they are not integrated, we can't evaluate it.

So I emphasize the need for data on both implementation and outcomes in order to assess. I think documenting as many—SAMHSA has done effective programs in getting information out immediately to the State agencies. And the medical agencies on those effective programs are also extremely valuable and useful at this point in time. But I also think that research, continued research and dissemination of that research is very important.

Mr. FLEISCHMANN. Thank you.

Ms. Cimaglio, can you discuss some of the efforts you undertook at the State and local level to develop a strategy that met the needs for ground, and what factors should States consider when developing a plan?

Ms. CIMAGLIO. Well, clearly, having a good plan is an important part of our approach, and what we started with is the need to have a comprehensive plan. We gathered information from around the State. We used data. Our work is data driven. We look at the National Household Survey, the Youth Risk Behavior Survey. We look at where the local needs are. We listen to people in the communities.

So it is a combination of things. But we also are driven by our healthy people 2020 goals, and our legislature actually requires that all of the State programs set their own goals and have measures. And we actually have a dashboard. I can send you a link to our website. But accountability is a big part of what we are held to in our State, and we feel it actually has really helped us improve the quality.

Back to the AHRQ question, we are also asking our medication-assisted treatment specialty providers to meet the AHRQ standards for specialty care. Because any tool we have that shows us how we are doing and how people are measuring up against standards help us deliver a more high-quality product.

Mr. FLEISCHMANN. Thank you.

Ms. Hale, your work with AmeriCorps and education efforts seem to be a key aspect of your approach to crisis based on your testimony. Can you discuss in more detail how you use volunteers to reach out to young people to keep them drug free? The reason I ask that, I would go out and I would talk to students in high schools all the time, and I said, “Don’t do drugs. Don’t smoke pot.” You know what, sometimes I get booed. I get booed.

Then I say, well, let me tell you some stories about some lawyers I knew or I practiced with. They are no longer practicing law because they have lost their law license due to addiction or they are dead now and things like that, and then it gets silent. So please, tell us how you work with your volunteers?

Ms. HALE. Well, with those, we have 54 AmeriCorps volunteers in our elementary schools, 54 elementary schools. But one of the things that they have done is to bring in volunteers into the school, particularly from the recovery community. It is important for these young people to hear their stories. It is important for them to hear—like Mr. Guy's story, that is how they identify.

And so I think working with the—bringing the volunteers into the communities. Our community coalitions, we have a coalition in every one of our counties, and their input—we were founded on community input and providing programs. Someone mentioned, you know, not only educating our children but educating the adults as well.

Our volunteers, we train them to teach programs such as “Accidental Dealer,” because many of our students, our young people are getting their first prescription drug out of their own medicine cabinets or grandmother's medicine cabinets. And so using our AmeriCorps members who are trained to pull volunteers from those communities, the communities know what is their greatest need.

And they respond. They want to be trained. So in that aspect—and we are bringing in a lot of volunteers into our school system to work with our young people who had very bad experiences when they were in school, in that very same building, perhaps. And they are beginning to see what they can do to change the culture for their children.

Mr. FLEISCHMANN. Thank you.

And to each and every one of you all, please continue to do your great work. I appreciate that so much.

Mr. Chairman, I yield back. Thank you, sir.

Mr. COLE. Thank you very much.

We will next go to my good friend, the gentleman from Wisconsin, Mr. Pocan.

Mr. POCAN. Great. Thank you, Mr. Chairman and Ranking Member.

Thank you to the panel for your testimony, and Mr. Guy, for sharing your very personal story. I appreciate it. The one thing, I guess, I would add is, we keep referring to the 33,000 people who died from overdoses.

But, you know, I had—one of my very first employees, almost 3 decades ago, is a family friend, went for about 20 years, worked at a law firm, did very well in New York, kept moving up, family member died, he wound up, you know, doing opiates along with alcohol. Finally, after falling down a flight of stairs and getting \$100,000 titanium shoulder, got some treatment, but it was like a 3 or 4-week treatment, not the comprehensive treatment you are referring to.

He stayed with my husband and I immediately after that for a week, because we live out in the country. So he was very broken. And within a week, he was back to using, and within 2 months, he died from arrhythmia at his house alone in New York, and they found his body like 10 days later.

There is no question that that death was also caused by an addiction to opiates. And I think, you know, the more we can share those numbers, I think that is important too. Because it is not just the overdose; it is the other actions due to the addictions.

So the question I have, and it kind of follows up with what Mrs. Lowey was saying, specifically Dr. Pacula, you are talking about the VA program. And the VA in Tomah, Wisconsin, is a facility that was overprescribing opioids, to the point that it got called Candy Land up there. And we had a lot of issues. We had a couple deaths related to it. There is inspectors general report that didn't do a good job, so we didn't quite get to things in time.

But now they have this opiate safety initiative that you brought up that is seeming to work really, really well. It takes a non-prescription approach towards veterans' pain through variety of things, and they have had a 48 percent reduction in the amount of veterans receiving opiates and other similar type drugs.

And nationally, I think it is about a 16 to 24 percent reduction, depending on the intensity of the drug, we have seen out of this program. Can you just talk about those kind of programs, and specifically if—because they have a single, unified medical system they can keep track of people better as opposed to people who patient shop at various hospitals and clinics and dentists and veterans.

Could that approach be used perhaps with Medicare and Medicaid, and some other ways that we could try to find that. I am just really curious on the success they have had?

Ms. PACULA. You highlight exactly the feature that made it very successful by having a unified system as well as a very comprehensive approach.

One of the things I failed to say earlier is that in dealing with this, you have to deal with the patients who are already addicted to the pain medication and figure out how best to treat them while also preventing new patients from becoming addicted and dealing with people who obtain them outside the community. And those strategies differ in a given community.

Implementing what the VA did, aspects of it could be done in any healthcare system. The extent to which a State prescription drug monitoring program is made available State-wide to all prescribers, elements of it can be implemented regardless of the system because then the physician has knowledge. You have to provide—of what the patient is getting.

You also have to instill in that physician and any provider the other options that might be available. VA actively provided alternative forms of chronic pain management. That was part of what they were educating their doctors about and what they were doing in the system.

Private insurance companies are starting to do this. Medicare with the disabled population is definitely starting to do this. I can say to you though that only having a certain number of physical therapy or chiropractic visits covered leaves you short in the sense that chronic pain is, by definition, not going to last—is going to last past those 20 or 30 visits.

So thinking about those other options. I think NIH has done a lot of work to look at alternative strategies that can be effective in long term. We need much more work. And there are more people who are more knowledgeable than me who can speak to—

Mr. POCAN. And just a quick followup, because I have less than a minute, for you or for anyone who can address. The other thing is, you know, I look at this as it is a prescription drug—or pre-

scribed, overprescribed, and then it is prescription drugs that can help you. And at some point, I know there is a lot of other natural things including plants.

I know that one of the things we dealt with recently was kratom, for example, where they are finding that it doesn't have the same—it has some of the pain-relieving effects for people, and they have used it around the world, but not the receptors that give you the high. So it is a way to try to deal with it naturally.

Is there other work on that, and should we be doing more to figure out what else is out there naturally?

Ms. PACULA. There are lots of—there is lots of work that is going on. The evidence of the science—the science base is very, very difficult, particularly for plants, because dosages vary in a plant. You don't know how much is being received. So the gold standards for doing research on these alternative medications, when they are plant based, is very, very difficult.

Mr. POCAN. Thank you.

Mr. COLE. I thank the gentleman.

We next go to my good friend from Maryland, distinguished gentleman, Mr. Harris.

Mr. HARRIS. Thank you very much, and obviously, a very important topic. I am an anesthesiologist, and both my subspecialty and just physicians in general have some role to play. Unfortunately, they had a role to play, I think, in getting people into this addiction problem, and hopefully they have a role to play getting people out.

But let me just get up to a little higher view of what goes on. I do think that the message that comes from the government about drugs is important. And, you know, we chuckle, you know, just say no to drugs, but, you know, we should tell our children just say no to drugs, bottom line.

I don't know. I was disturbed that the last President was, for all we know, the first President we ever had who used cocaine and marijuana and wrote about it. Didn't say it was wrong, wrote about it. Now, honestly, thank goodness we have a president who says don't do drugs because of a personal tragedy in his family of addiction. No question about it.

And we have other issues now because, you know, we have another trend going on nationwide that I think does—and I know it is controversial, but I think it does contribute to it, and that is the spread of recreational use of marijuana, legally.

And, you know, Dr. Volkov, who just presented to the Doctors Caucus a couple days ago, does believe it is a gateway drug. Not for everybody, not one-to-one, not exclusive, you know, every person who uses marijuana is going to go on to have a more serious addiction.

But because of its interaction with the dopamine systems, just like nicotine and alcohol, I mean, all these things that do this, that have cross-sensitization, it actually makes sense that someone who has used these substances actually might be more liable to be an addict.

And, you know, we have discussions now going on about whether or not to enforce Federal drug law. I mean, it is stunning. I mean, our Federal laws are pretty good. We should—in my opinion, we

should enforce them. But I am going to ask your opinion, all three of you, about something.

And, oh, by the way, on the subject of marijuana, the strangest thing that has come up now is—I know because we just—actually, we just defeated the act in Maryland—is to say that medical marijuana somehow is good for treating opioid addiction. You know, maybe in a couple of cases it is, but I have got to tell you, this is dangerous, when we start talking about using an addictive drug to somehow think we are going to treat another addictive drug with no scientific evidence for it.

Anyway, the surgeon general wrote a report on addiction. You know, it is about an inch thick. I don't know if any of you have read it. I doubt anybody has read through the whole thing. But I was particularly interested, because when I was in the Maryland legislature, I sat on the Health Committee, and this was a problem, you know, 10 years ago, 12 years ago. Now it is an acute crisis, but it was a problem for a long time.

And the debate that went on was whether or not the States should fund faith-based treatment. And it was stunning to me as a physician that there are actually people who say, no, we know it works, we know it actually has a pretty good record; in fact, relative to other methods, a lot of people believe it actually has some of the best outcomes. But, nope, we can't touch it because it has the word "faith" in it. It is faith based in some way.

That bothers me, because if we are really serious about doing this and doing everything we can, and we are going to bring the government in to help solve this problem, I think we have to get over this.

So I am going to ask all your opinions. Do you think that we should include—and oh, by the way, to get back to the surgeon general's report, it doesn't mention faith-based programs in it. And I pointedly asked them, why doesn't it mention faith-based programs? Well yeah, you know, we should—you know, it is an all inclusive—everything should be included. And I say, well, how come you didn't mention the one that some people think worked the best?

So I am going to ask your opinion, this panel, what do you think about faith-based programs? Do they have a role? And should we seriously consider getting over the fact that it has the word "faith" in it if we want to treat this problem seriously?

Ms. HALE. I will begin with that, if you don't mind. Yes, I think faith-based programs should be definitely included. I have a son who is 9 years into recovery, a daughter-in-law who is 10 years into recovery. And one of the things that both of them have told me is that in their recovery process, and they both went through an abstinence-based program, is that they know that there has to be something between them and that next pill, that next drink, whatever. And for them, they have realized, after, you know, 19 combined years, that that faith provides that element.

You know, when I go home this afternoon, there are a lot of roads that I can take back to Mount Vernon, Kentucky. But if you block one of—the road that I am taking, because it was my choice, because I felt like it was the best route, then that is going to make me detour or it is going to cause me to be very frustrated.

And I think that is probably what we have done with the faith-based treatment programs. We have tried to vilify them and undeservingly. I think that those programs that worked, you know, there are other roads to take to Mount Vernon, but if I choose that one for faith based, I think that we should have that support.

Mr. COLE. I am going to allow all of you to respond to Dr. Harris' question, but I would just ask you to be short, given the time.

Ms. CIMAGLIO. I can go next. Being a State official, we support a variety of programs, especially community prevention programs. And I know there are people involved in faith-based approaches that are participants and part of managing those. So we say there are many paths to recovery, and one size doesn't fit all.

So I think whatever we do at a policy level we need to be open to a variety of paths that people choose.

Mr. GUY. I would just quickly say that I think that we should—anything should be considered as long as it works. If there is research that says it works, it should at least be considered.

Ms. PACULA. And there is research that suggests that it does work.

Mr. HARRIS. Thank you.

Mr. COLE. Thank all of our witnesses.

Next, I want to go to my good friend, a new member on the committee, distinguished lady from Massachusetts, Ms. Clark.

Ms. CLARK. Thank you so much, Mr. Chairman.

And thank you to the panel and the work that you do and for being here, and especially to Mr. Guy—

Mr. GUY. Thank you.

Ms. CLARK [continuing]. For reliving the very worst day and phone call to help other families. As a parent of three boys, I thank you from the bottom of my heart—

Mr. GUY. Thank you.

Ms. CLARK [continuing]. For sharing your story and your work.

And in Massachusetts, this is a terrible crisis, much like Vermont and Kentucky and other States. We have this terrible bond together.

Two thousand opioid, fatal overdoses in 2016, in Massachusetts, and it is trending very young. We are really taking out a younger generation. If you are age 25 to 34, one-third of all deaths in that age group are opioid fatal overdoses. And if you are a young man, that is 40 percent of all deaths in that age group. We have to do better. And we have to listen to Mr. Guy when he quoted St. Francis by starting by doing what is necessary.

And Dr. Pacula, as I looked through your testimony, you talked about medical-assisted treatment expansion of narcan prescription, drug monitoring, guidelines for safe prescribing, and talking about prevention and education and hopefully getting to these young people before they are in the throes of substance abuse disorder.

Can we do this on less financial support from the Federal Government? Can it be done with less dollars?

Ms. PACULA. Not right now. If we knew that there were a few key strategies that were the special sauce, I would say, yes. But the science isn't there to know what few strategies are the most effective, and I think we have to take a comprehensive approach to discover what is.

Ms. CLARK. Thank you.

And I wanted to ask Ms. Cimaglio—

Ms. CIMAGLIO. Cimaglio.

Ms. CLARK. Cimaglio. Sorry, I should know this. I too am from New Haven, so I should know this. Come on. But I wanted to—we had Secretary Price in last week, and he would not directly answer my questions, but seemed to be doubtful about mandating under essential benefits that treatment for substance abuse disorder and mental health treatment, that we keep that mandate, instead that we go to more of a cafeteria-style approach.

So you can purchase for—a variety of different things, including substance abuse treatment from, you know, your insurer as need arises. So this is, I guess, in his opinion, some sort of liberty that you would be able to not pay for this if you did not opt to.

How do you see an insurance system like that, cafeteria style, working from what you have seen in Vermont and the need for comprehensive care?

Ms. CIMAGLIO. Well, in our State, we have been inclusive of all of the elements of the plan as it is right now, and we would not want to go backwards. Behavioral health, mental health, addiction treatment, is health, and it belongs in health care just as fixing a broken arm. And it has been too long, you know; it has been too long that we have had to fight to have coverage for these afflictions in the package.

And so we absolutely believe that we should continue to support behavioral health, mental health, addiction treatment as part of the essential benefit. It is part of what we cover in our State, and we want to continue to cover it.

Ms. CLARK. And I guess, my question—maybe Dr. Pacula, you could—do you see families who are in the throes of this crisis, you know, in dealing with this incredible, devastating epidemic, would they be able to go out and purchase, do you think—do you see that as a system that would work? Mr. Guy, maybe you want to address that. I see you shaking your head.

Mr. GUY. No.

Ms. CLARK. I have 29 seconds.

Mr. GUY. No, because, you know, although it would have been difficult for us, we could have perhaps paid for some kind of treatment. But when you are dealing with an adult son who has mental health issues, you can't force them, you know, to do something.

And as I said in my testimony, we are paying for this. We are paying for it in the most expensive way, and it makes much more sense to do it by education and prevention and treatment.

Ms. PACULA. If I could add one other point, we are pushing really hard to get mental health and substance abuse treatment and education done at the primary care level. And if primary care physicians aren't reimbursed for that care, they don't know when the patient walks in, necessarily, unless the nurse tells them, what coverage the person has.

But if they have to worry about, oh, the patient is going to have to pay for this or they can't pay for this, should I deliver it, that shouldn't be part of that decision. It should be the physician taking the needs of the patient and considering the needs independent of ability to pay.

Ms. CLARK. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. I thank the gentlelady.

I am going to arbitrarily lower us to 3 minutes, just so that if anybody hangs around, they have got a chance for a second shot, because we don't have that much time left.

Let me begin with you, Mr. Guy. And obviously, all of us felt the power of the story and all of us appreciate you being willing to share it. And not to ask you to relive it in any difficult way, but you must, like any of us in a situation, try to think back, what would have made a difference at a critical time.

I was so struck by your testimony about, you know, struggling to, you know—what can we do. Just an average person, average family that gets hit with something like this. So as you think back, what do you wish you knew that you didn't know at the time? What do you wish your government or community could have done for you that we didn't do at the time?

Mr. GUY. Well, that is a really difficult question to answer. I guess, I wish that there had been some more comprehensive education programs in school. As you well know, we have high schools in Oklahoma that have 1,400 to 2,000 students that may have two counselors, you know.

So I think education would have been vital. And I think—you know, it is not that we were reticent to do anything that we could do for our child. But if it had been—if it had just been part of our health insurance coverage that there were no questions asked, I think that that would have been an avenue that was open to us that we would have maybe pursued more vigorously, you know.

You know, we do ask ourselves that question many times. But I think—again, taking away the stigma, taking away the shame, providing opportunities for people to network around these issues, I think that would be beneficial.

Mr. COLE. Well, you are doing your part and doing that just by being here and making that testimony and being public, and so we thank you for that.

Mr. GUY. Thank you for the opportunity.

Mr. COLE. You bet.

Let me go quickly—I don't have a lot of time left—Ms. Hale, to you, because I think you have exactly the same perspective, having been a classroom teacher and seeing some of these things unfold and now your activity. What can we do, again, ahead of time to try and help people before they get hit this way?

Ms. HALE. I think what Mr. Guy said would be what I would reiterate for us. We were seeing it in the school system. We were averaging in our small county of 16,000 a death a week, according to our coroner. And we did not know how to react in the school system. Then it came to our own doorstep, and we were never educated, we were not told. We went to our family doctor. He was like, I don't know what to tell you. I will try and call and find some information and things.

So I think, you know, the prevention, making people aware, there has to be a comprehensive approach, and the support for families. But I think having people share those stories and having a greater awareness within our communities, preparing our fami-

lies, not only how to prevent but how to support when that person moves into recovery.

Mr. COLE. Well, we all want to thank all of you today because that is precisely when you are doing, is sharing stories that really make a difference.

With that, I go to my good friend, the gentlelady from Connecticut.

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

Just a couple of pieces. I think, Ms. Pacula, you will be interested to know that there is a piece of legislation, which is Promoting Responsible Opioid Prescribing Act; in fact, it was introduced in the last session of Congress by Representatives Mooney and former Chairman Rogers. It is about removing the link between patients' satisfaction surveys about pain management and physician hospital reimbursement.

So if you think that is a worthy cause, it hasn't yet been introduced. It is something that I have cosponsored. I am hoping my colleagues do, but push people to cosponsor this, because I think you are absolutely right.

I am just going to make this comment. Ms. Hale, you talked about the value of your AmeriCorps volunteers. I am going to plead with you to make your voice heard on that because we are looking at the potential possibility of seeing the elimination of AmeriCorps and the Senior Corps, which, as I hear from you—and it is just a yes or no from you—that has made a real difference for what you can do.

Ms. HALE. It has, because of their prevention curriculum that they are teaching.

Ms. DELAUBRO. Fabulous. Please speak up.

Let me just ask a question with regard to naloxone, and that is, Vermont has a standing order on naloxone. Some States have similar processes. I am not going to go through all the information here, but basically my question is, given that the experience of a standing order, do you think that this kind of access should be available in all States? Why are States not doing this? And do you think naloxone should be reclassified as over the counter? I am going to ask you, please.

Ms. CIMAGLIO. Yes. We do have a standing order. We have tried to spread naloxone throughout the whole State through emergency responders, police departments, recovery centers, treatment centers, needle exchanges, et cetera. So I think it should be available.

I think it is one of the reasons we have been—of all the New England States, we are the only one that isn't seeing a statistically significant rise in our overdoses. And I think it is because of naloxone and our increased access to treatment.

Ms. DELAUBRO. Over the counter?

Ms. CIMAGLIO. Yes.

Ms. DELAUBRO. Over the counter, Ms. Hale, naloxone?

Ms. HALE. I think every life is worth, you know—we have not really dealt with that that much.

Ms. DELAUBRO. Okay. Ms. Pacula.

Ms. PACULA. Yes.

Mr. GUY. Absolutely.

Ms. DELAUBRO. Okay. Thank you.

Do you think—I have just got 27 seconds here—should we require physicians to follow the CDC guidelines for prescribing? CDC, understanding, is not a regulatory agency, but should we require physicians to follow these guidelines? Yes or no from you guys.

Ms. PACULA. It depends on the patient.

Ms. DELAUBO. Okay. Mr. Guy.

Mr. GUY. I don't really—I am not able to comment on that, but I think it is good to think about.

Ms. DELAUBO. Okay.

Ms. CIMALGIO. Yes.

Ms. DELAUBO. Yes.

Ms. HALE. I think it depends on the patient as well.

Ms. DELAUBO. Okay. Thank you.

Mr. COLE. Just for the record, I am tough, but I am not mean. I would give you the time.

Ms. DELAUBO. Well, thank you. If we have any more time, I will take it later, Mr. Chairman.

Mr. COLE. Okay. Well, we have been joined by one of our distinguished members, Ms. Herrera Beutler, from Washington. And in this case, she will get the full 5 minutes because she did not have an opportunity to participate in the first round.

Ms. HERRERA BEUTLER. Thank you, Mr. Chairman.

Thank you, all, for being here.

I am going to read my first question because I want to get it out. And this is for Ms. Cimalgio—am I saying it right? Great.

Our Nation's opioid epidemic has particularly been devastating for infants, among others. Recent data suggests that there has been a fivefold increase since 2000 in infants experiencing drug withdrawal after birth. I have actually seen this happen in certain instances and a NICU situation. And this is known as neonatal abstinence syndrome.

We hear gaps about access in treatment across the board, but I want to ask specifically about pregnant women and parenting women. The GAO conducted a review of programs and stated in their 2015 report that the program gap most frequently cited was the lack of available treatment programs for pregnant women. And we know this population is incredibly vulnerable, but also often-times extra motivated to seek treatment, for obvious reasons.

So can you speak to the treatment gaps for pregnant women and parenting women in both residential and nonresidential settings, and what would be needed to close that gap? And in addition, how can we ensure that the States receiving Federal funds are addressing and prioritizing treatment for pregnant and parenting women with substance abuse disorders?

Ms. CIMALGIO. Well, first of all, pregnant and parenting women are a priority for our Federal block grant funds, so we do have to prioritize them, just to be clear on that.

However, I think we, particularly in rural States, struggle with the availability of specialized programs that serve women and families. So I think we need more resources that can really help us provide those specialty programs that cannot only focus on the addiction but also on the comprehensive needs of those families in treatment.

In terms of the neonatal abstinence and all that comes with that, I think a close collaboration with the child welfare system so that we are reaching the highest risk families and making sure that we get them into treatment. And also specialty neonatal units and physicians who have that expertise at our largest medical center in Vermont, we do have a special program, and it has been lifesaving.

We are seeing for those moms in treatment who deliver babies with neonatal abstinence syndrome, those in the program are experiencing fewer days in the NICU, better outcomes. And so NAS is not negative if we are doing all the right things, but we need the resources to make sure that we can deliver evidence-based treatment.

Ms. HERRERA BEUTLER. Great. Thank you.

And I have a couple—I have one more, one about drug take-back that I wanted to ask, but I kind of wanted to throw this one open to the group because it is something I have been pondering on. I did a roundtable this summer with a—it was DEA-type folks, it was law enforcement, it was former—or addicts who have been overcoming their disease. It was a pretty good, robust group. It was medical providers.

And it was really, for me, a learning experience, what should I be considering in this epidemic that we are trying to fight. And it was actually the gentleman to my—who sat next to me who had been exposed at a very young age, had been overcoming a pretty serious addiction, but had gone through the whole—I mean, he went to the end and back.

And he—I am from Washington State. And he commented at one point because some—I don't know who brought it up, but Washington State has legalized marijuana for recreational purposes, not for medical purposes. I draw that distinction. And he jumped in to comment on it and said it was—he was—and I am paraphrasing but it was a big mistake, as someone who had been down a pretty tough road. And he elaborated on that.

And I was just wondering if anybody who has been impacted by this, if anybody on the panel had any comments on that?

Mr. COLE. I would ask you all to be brief.

Ms. HERRERA BEUTLER. Oh, yes. I have 48 seconds.

Ms. PACULA. We are currently doing research to evaluate the impact of adoption of these—we have looked at medical marijuana laws, the recreational laws on the opioid epidemic. There appears to be a correlation, but the question is who is changing use. And to the comment about whether it is useful for opioid treatment, there is no science at all.

To the question of whether or not it could help as an alternative form of chronic pain management for certain types of pain, there is suggestive evidence, depends on the products. Again, it should be done with physician oversight, but it is—

Ms. HERRERA BEUTLER. I am interested in that report when it comes out. And that is probably all I have got.

Thank you.

Mr. COLE. Thank you very much.

I want to next go to the gentlelady from California for 3 minutes.

Ms. ROYBAL-ALLARD. Ms. Hale, the drug-free communities program has been an essential, bipartisan component of our Nation's

substance abuse prevention since its passage in 1998. And over the years, the number of grantees has increased from 92 original grantees to more than 2,000. However, despite growth of the program, there has only been enough money over the years to fund 32.7 percent of the communities that applied for funds.

I understand that Operation UNITE is part of Carter County's DFC grant, and that you told us your community has been—or has seen massive reductions in youth drug use and improvements in college career readiness and even in graduation rates.

What do you consider to be the reasons for the success of the DFC program in your community? And based on your experience, do you believe we should be putting more emphasis on investing in effective prevention programs like the DFC program and Operation UNITE?

Ms. HALE. Yes, I do. I do believe that we need more funding. Carter County is one of several of our counties in the Fifth Congressional District that has a DFC community grant.

I think the success to it has been with those coalitions, that organization of people within that community, within that county, having the funding to do those education programs, to provide the awareness, the treatment. It has made a world of difference in having people who can go into the school system, who can go into the civic organizations, who can go out into the community because of the funding that they are able to provide to bring in programming, to bring in training.

And so the drug-free community grants have been invaluable in rural Kentucky in helping those communities that are most hard hit.

Ms. ROYBAL-ALLARD. Okay. Thank you.

I yield back.

Mr. COLE. I thank the gentlelady.

We next go to Ms. Clark for 3 minutes.

Ms. CLARK. Thank you, Mr. Chairman.

Dr. Pacula, we know that frequently substance use disorder starts in adolescence, and there are unique brain development issues continuing on into a person's 20s that can be impacted. Has RAND studied the particular challenges of looking at understanding and treating substance use disorder in adolescence and young adults?

Ms. PACULA. Actually, we have done a lot of work on that, and we have found that therapies and strategies to some extent differed than adults in some ways. But indeed, treatment can be very effective with adolescents, as well as with some adults. It may need to be a coerce treatment. Not everybody goes into treatment willingly, with acknowledging a problem, and coerce treatment can be effective.

Ms. ROYBAL-ALLARD. Have you looked at MAT particularly with adolescence? Have you looked at medically assisted treatment?

Ms. PACULA. I don't know. I can get back to you on that.

Ms. ROYBAL-ALLARD. You mentioned it in your testimony, and part of the figures we were looking at was that as of 2014, a study was done, 89 percent of people struggling with substance use disorder did not receive treatment. And you mentioned that some-

times there is a cultural or perception of a practice that may be driving part of that.

Can you give us a better sense of why doctors aren't taking advantage of MAT as an population for their patients? Is there a structural, a regulatory, a cultural problem?

Ms. PACULA. There is a concern about replacing one addictive good with another addictive good. Because medication-assisted therapy is not something that everybody can go off of. It is for some. It is a life-long medication, just like some people need to have blood control medication. And depending on the nature of the product, it could have similar effects on the body.

Our methadone in the U.S. is different than the methadone delivered in, say, Australia, which actually still has psychoactive properties. Our methadone does not. So the long-term implications are not as severe. But there has to be, obviously, a willingness to consider for certain patients. The right form of therapy will depend on their own beliefs about their willingness to initiate this therapy.

We use these things for detox all the time. The question is whether or not we maintain it for long-term therapy. The struggle with treatment, why treatment sometimes doesn't work, is it is too short. They leave and they overdose. Medication-assisted therapy can reduce those cravings, but there is the concern about being tied to another substance.

Ms. CLARK. And in my last 15 seconds, do you think it is helpful to be working with doctors, in particular, to identify and address substance abuse disorders and dealing with pain prescriptions? It seems like it is an area in medical school that isn't as covered as much as we might think.

Ms. PACULA. Absolutely.

Ms. CLARK. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. You bet. Thank you.

We next go for our last questions to the gentlelady from Washington, Ms. Herrera Beutler.

Ms. HERRERA BEUTLER. Thank you, Mr. Chairman.

Obviously, we are inundated with prescription medications. And what I have seen in this whole conversation and have heard so much about is people have leftovers, and they put them in their medicine cabinet. And in a family, you have all members of a family coming in and out of those rooms where those are stored.

And I think there are—you know, I have seen some stewardship models that are great. I think the biggest challenges are at the county level in some areas, in some States. And there is no State-wide take-back program. I mean, there is a 1 day—or there is an event, but there is nothing big picture that is ongoing, because you don't know when you are going—you know, when you don't need it anymore and what you are going to do with it. It may not coincide with that 1-day event.

So beyond the DEA's take-back event, where can the Federal Government invest resources efficiently to ensure that the unused medications are safely disposed of? That is for anybody.

Ms. CIMAGLIO. Yeah. I can say, in our State, we have done a lot of work on this. And the biggest question we get is why can't pharmacies take back unused medication. They have the permits to

hold and dispense; why can't they be the ones who also take it back?

Because for law enforcement, they are worried about amassing large quantities and the security of their evidence rooms and so forth. So that is the biggest question that I get is, why can't the Federal Government do something about the pharmacy's responsibility.

Ms. HERRERA BEUTLER. Any other thoughts on that?

Ms. HALE. One of the things that we have with Operation UNITE is going through our coalitions. We have a take-back box in every county in the sheriff's office, but we did a great deal of educating with the sheriffs, with the community on how important it was to dispose of those medications properly. It has been extremely successful.

Our detectives are the ones who go in and empty those and work with the DEA in keeping track and everything of that. But it has taken a great deal of education to help people realize the importance of proper disposal and working in the communities.

Ms. HERRERA BEUTLER. And with my last 46 seconds, on my last question about marijuana use, I didn't know if anybody else had any thoughts?

Ms. HALE. You know, I think when it comes to marijuana, I have to go back to what Yoda said in Star Wars: "Mind what you have learned. Save you it can." And I think we can look back at the history of tobacco, we can look at the history of alcohol. And, you know, knowing what we have learned from Dr. Volkov, from NIH and things, you know, do we need a third legal drug that can do the damage that we now are realizing, like tobacco and alcohol did.

Ms. CIMAGLIO. And we come back to the importance of prevention. Whatever we do, we have to keep our focus on the prevention.

Mr. GUY. I will tell you that we know now that our son started smoking marijuana when he was twelve. I don't know whether that led to his subsequent death, you know, nobody knows, but that is fact.

Ms. PACULA. And it can be tied with tobacco. I spoke to high schoolers just last year, and they were completely unaware that there was marijuana in vape pens. They thought they were just doing flavored oils and possibly nicotine, not realizing that some of them do, in fact, contain marijuana. So educating adults and children on how this is getting to them is also very important.

Ms. HERRERA BEUTLER. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. Anytime you have run a hearing where the figures quoted range from St. Francis to Yoda, you know you have covered a lot of ground. I want to congratulate you, but I want to call on my friend, the ranking member, to offer any final observations or comments that she cares to.

Ms. DELAURO. Thank you again, Mr. Chairman.

I was struck by this headline, and it is a story that appeared in my local papers, but it is about Milwaukee. And it is, "Youngest Opioid Victims Are Curious Toddlers," which is—this is a staggering article.

Sorry we did not get to talk about hub and spoke, but maybe we can do that offline. And just to mention that I think what you have

said is that there is the importance of the substance abuse prevention and treatment block grant. That is critically important. Please make your voices heard. There may be an attempt to cut that program by about 18 percent. That would be devastating.

Mr. Chairman, there is this article St. Louis Post-Dispatch: "Social Change and Economic Disappointment Create an Epidemic of Deaths by Despair." Sometimes we lose track of what the effects of potentially economic despair have in people's lives.

I just think, this is a study that has been done by two Princeton University economists. They found that between 1999 and 2014 middle-age, 45 to 54 white Americans with a high school education or less died at a rate never before seen in a modern industrial society. Suicides, drug overdoses, liver disease caused by alcohol poison, and that is what they have classified as death by despair.

What they—in the report to Brookings, they suggest that while income inequality and wage stagnation may play a background role, it is a lifetime of cumulative disadvantage catches up with the demographic.

A slice of the population hit the job market as low-skilled jobs were being mechanized, computerized, globalized. They grew into adulthood as cohesion-building social institutions like marriage, family, and churches became weaker. They didn't have spouses often, pastors, work buddies, or kids to back them up. They did have opioid painkillers that added fuel to the flames making the epidemic much worse than it would have otherwise been. They found that among men in the labor force, nearly half are taking pain medication most often by prescription.

Mr. Chairman, I just say that if we do not begin to understand the economic issues that people face in their lives, and oftentimes the disasters that are not of their making and that relationship to what we are seeing today in drug overdoses, suicides, and other ways in which people's lives are—and health ways being affected, then we are not going to be able to do the job that we were tasked to.

These problems are all related and interconnected. And you have to address all of them. And you have got to walk and chew gum at the same time if we are going to help to try to make a difference in people's lives.

You are really, truly remarkable individuals that we have heard from today. Thank you so much.

Mr. COLE. Would the gentlelady like to submit the article for the record?

Ms. DELAUBRO. I would very much like to do that.

Mr. COLE. Without objection.

Ms. DELAUBRO. Thank you very much.

Mr. COLE. I just want to conclude again by thanking each and every one of you. In many cases, you have come from a long way away and you have got very important stories and very important expertise to share with this committee and the Congress as a whole and, frankly, through them, beyond that to the American people.

I appreciate more than I can say the fact that you were willing to do that. Believe me, your testimony—as you could see, the committee was awfully engaged and awfully moved by what you had to say.

I also want to tell the committee members how proud I am of them, because I can tell you, they all did their homework. I don't know how many times, I read your testimony, I did that. And, again, that is a sign of the seriousness, and it is also a sign of how respectful they are of your expertise your contribution here today.

So, again, thank you, very, very much.

Mr. Guy, in particular, thank you. All this testimony was helpful. Yours was probably the most personally difficult to deliver but probably the most important for us all to hear, because we all know, there for the grace of God go I.

And we all know somebody else or some other family that has walked this same very difficult journey. And it is important that the personal dimension here be put on this because I think that is the most compelling thing to get people to act and to change.

As Ms. Hale said, stories make a lot of difference. And anecdotes and, you know, and humanizing something so it is not just statistics and policy, you know, is a powerful motivation for political change.

Again, I want to thank my good friend, the ranking member. This was a great hearing. And with that, we are adjourned.

WEDNESDAY, MAY 17, 2017.

OVERSIGHT HEARING—ADVANCES IN BIOMEDICAL RESEARCH

WITNESSES

DR. FRANCIS COLLINS, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DR. ANTHONY S. FAUCI, DIRECTOR, NIH, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
DR. GARY H. GIBBONS, DIRECTOR, NIH, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
DR. JOSHUA A. GORDON, DIRECTOR, NIH, NATIONAL INSTITUTE OF MENTAL HEALTH
DR. DOUGLAS R. LOWY, ACTING DIRECTOR, NIH, NATIONAL CANCER INSTITUTE
DR. NORA D. VOLKOW, DIRECTOR, NIH, NATIONAL INSTITUTE ON DRUG ABUSE

INTRODUCTIONS

Mr. COLE. Good morning. We will go ahead and bring the committee to order because I want to try and stay on time. There seem to be other activities this morning that seem to be distracting people, but we are going to do our work.

Anyway, good morning. It is my pleasure to welcome you to the Subcommittee on Labor, Health and Human Services, and Education to discuss the National Institutes of Health and the recent advances in biomedical research. We are looking forward to hearing the testimony of Dr. Collins.

And I would like to publicly thank Dr. Collins and the staff at the NIH for hosting our subcommittee members and myself for our annual briefing and tour at the NIH campus in February. As usual, all the members learned a lot about the important work that you do every day to improve the health of Americans and people around the world.

Investment in NIH has been the key driver in making the United States the world leader in biomedical research and has led to vast improvements in life expectancy and the quality of life. The NIH is the primary source of funding for basic medical research not only on the NIH campuses, but also at 2,500 universities and research institutions in every State.

I am very proud that Congress increased NIH funding by \$2,000,000,000 in the fiscal year 2017 omnibus spending bill. Congress also passed the 21st Century Cures Act last December, which will build upon and greatly enhance the efforts to find cures for diseases such as cancer and Alzheimer's.

I was, therefore, especially disappointed to see a proposed budget cut to the National Institutes of Health this year. I am concerned

that the reductions in the request would stall progress that our recent investments were intended to achieve and potentially discouraging promising scientists from entering or remaining in biomedical research.

Personally, I believe that continued investment at the NIH is extraordinarily important to bending the cost curve on healthcare in general for the American people. It is also the key to protecting the American people from pandemics like Ebola and Zika, which will certainly happen again in the future.

And finally, I think keeping America at the forefront of this is not only important for us in terms of our healthcare, it is important for our economy and, frankly, it is important for American global leadership. It is something this country can be extraordinarily proud of as a contribution, not only to the well-being of its own citizens, but to people all over the world.

We have been a very blessed country and we have responsibilities, honestly, in accord with those blessings, and this is one of the areas in which I think our country can be proud, wherever you are on the political or ideological spectrum, of the contributions we have made as a people to the well-being of all of humanity.

I look forward to hearing about the recent progress in biomedical research as well as about how the NIH will focus resources on its top priorities in the upcoming fiscal year. I intend to work with you going forward to maintain momentum towards developing new treatments and cures for diseases while achieving efficiencies and being a responsible steward of taxpayer dollars.

I welcome, of course, Dr. Francis Collins, the NIH director, to the subcommittee. Dr. Collins is accompanied by five of his institute directors, who can assist answering specific member questions. They are Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases; Dr. Doug Lowy, the acting director of the National Cancer Institute; Dr. Gary Gibbons, the director of the National Heart, Lung, and Blood Institute; Dr. Joshua Gordon, director of the National Institute of Mental Health; and 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.

Before we begin, I would like to yield the floor to my good friend, the ranking member, the gentlelady from Connecticut, for any opening remarks she cares to make.

REMARKS BY REP. DELAURO

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

And I too want to welcome Dr. Collins, director of the National Institutes of Health, as well as Dr. Lowy, Dr. Fauci, Dr. Gordon, Dr. Gibbons, Dr. Volkow. Thank you. Thank you so much for being here this morning to discuss the future of funding for the National Institutes of Health.

The sheer talent on your side of the table cannot be overstated. You and the work that you do with the NIH represent the power to do more good for more people than anything else within the purview of our government.

The NIH is the leading biomedical research entity in the world, and my colleagues on the subcommittee have often heard me say

that medical research is special. A breakthrough at the NIH saves not just one life, but potentially millions over generations to come. That breakthrough can improve the life of not just a sick individual, but the lives of their loved ones, caretakers, and friends. That is what the NIH represents. As a survivor of ovarian cancer, this is personal to me.

Everyone on this committee recognizes the importance of restoring purchasing power for the NIH, and I want to say a thank you to Chairman Cole and all of the members of the subcommittee for their bipartisan work to support NIH research in the past. Last year Congress showed once again that the NIH is a bipartisan priority by providing an additional \$4,800,000,000 over 10 years through the 21st Century Cures Act.

The Trump administration's budget proposal, however, would eliminate that entire amount in just 1 year by cutting \$8,000,000,000 from the NIH. This would decimate the NIH, reducing the agency's research purchasing power to a level not seen since the 1990s.

We cannot turn back the clock on lifesaving biomedical research. This is not just theoretical. When we face a public health emergency, NIH research is often our best tool to combat the tragic loss of life. You take Ebola. Just Friday, the World Health Organization declared an outbreak in the Democratic Republic of the Congo, which is why the work that you are doing to develop a vaccine remains critically important, not just for public health, but for global security. It is clear that the Ebola crisis is not over.

Last week, one of my committee staff members visited Puerto Rico to meet with the principal investigator of a phase II clinical trial of the Zika vaccine candidate. The vaccine candidate was developed by the NIH. Those are NIH dollars at work.

The administration's budget proposal would also completely eliminate the Fogarty International Center. This program represents only a sliver of the NIH's budget, yet it has an outsized impact on the prevention and the mitigation of outbreaks abroad. Their work helps to ensure that diseases are quickly contained and never reach our country.

The Fogarty Center has actively increased capacity in countries facing health crises like Ebola, they have trained some of the best practitioners on the ground, accelerating discoveries and building essential infrastructure. As we have seen with the diseases like Ebola, Zika, HIV/AIDS, public health emergencies know no borders.

In fiscal year 2016, the NIH funded 35,840 grants. In 2017, under the omnibus we passed just 2 weeks ago, the NIH should be able to fund an additional 1,500 grants. This is the direction that we need to be moving in. But a cut of \$8,000,000,000, like the administration has proposed, could eliminate approximately 5,000 to 8,000 grants. In Connecticut, a cut of the NIH magnitude could result in our State losing our \$100,000,000 or over 250 grants.

Sixteen years ago, NIH funded about one in three meritorious research proposals, but today that rate has fallen to about one in five, a slight improvement over recent years, but still low by historical standards. We are missing opportunities to work toward cures for life-altering diseases that affect far too many people. Those un-

funded grants translate to medical discoveries not being made, lives not being saved.

We are choosing to hamper our progress as a Nation, we are choosing to ravage our medical community, and it makes you just wonder why we would move down that road. And even without this proposed cut, NIH's budget has declined by nearly \$6,500,000,000 since 2003 when you adjust for inflation.

While the NIH is now funded at an all-time high of \$34,100,000,000 thanks to the \$4,000,000,000 of increases over the last 2 years, funding has not kept pace with the rising cost of biomedical research. Think about the choice we would be making if we cut already insufficient funding even further.

In the last Congress, I introduced the bipartisan Accelerating Biomedical Research Act, which would reverse the devastating funding cuts to the NIH and attempt to provide stable, predictable growth for years to come. It would untie the hands of the committee, it would allow us to go above the caps. This is the same mechanism that we use for the healthcare fraud and abuse account. This would set us on the path of doubling the NIH budget, as we did in the late 1990s under Chairman John Porter.

Investing in the NIH creates jobs, because biomedical research is a driver of economic growth. And diminishing the NIH's ability to conduct basic science research would result in fewer discoveries, which would lead to fewer cures and therapeutics being developed by the private sector because of basic science research that the NIH does.

I am almost inclined to dismiss the administration's budget, but I cannot ignore it. It would be a disservice to the American people to pretend that it does not exist. It does exist. In fact, senior officials like HHS Secretary Tom Price and OMB Director Mick Mulvaney have tried to defend it.

There is no defending cutting thousands of research grants. The budget would inflict immeasurable harm on one of the jewels of our scientific research. This proposal should be dead on arrival. We should be talking about increasing the NIH's budget by \$8,000,000,000, not cutting it by \$8,000,000,000.

I thank all of you. I look forward to your testimony and I look forward to your new discoveries today and your new discoveries in the future. Thank you for the work that you do.

Thank you, Mr. Chairman.

REMARKS BY REP. LOWEY

Mr. COLE. I thank the gentlelady.

And we have been joined by the ranking member of the full committee, and we will move to her. Just for purposes of announcement, we may well be joined by the full committee chairman, and if that is the case, I will certainly recognize him when he arrives for whatever opening remarks he cares to make.

So with that, it is my great pleasure to yield to the gentlelady from New York for whatever remarks she cares to make.

Mrs. LOWEY. Well, a lot going on this morning.

Thank you very much to my friend Chairman Cole and Ranking Member DeLauro for holding this hearing. I would also like to

thank our distinguished panelists, Dr. Fauci, Dr. Gibbons, Dr. Gordon, Dr. Lowy, Dr. Volkow, and Dr. Collins for joining us today.

I never thought I would be troubled by a hearing on Federal funding for the NIH. Ordinarily, this is one of the best hearings of the year with the leading scientists in the world on groundbreaking medical breakthroughs, and partisan politics usually falls by the wayside as we marvel at the advances your work is making to improve the lives of Americans.

And I must say at the outset, I look forward to working with our distinguished Chairman and Ranking Member and all the members of the committee in a bipartisan doubling of the money to the NIH, because I remember I served with John Porter. I don't know what that wonderful smile is, but I thank you, Mr. Chairman. I am not going to read your mind. I will leave that for anybody else. But I look forward to working together, because we have done it before and I hope we do it again.

So it is with this spirit that this committee negotiated an increase of \$2,000,000,000 for the fiscal year 2017 spending bill, and yet a dark cloud hangs over us today. The Trump administration has proposed an \$8,000,000,000, or 24 percent, cut to the NIH budget. I barely can say it. This would result in 5,000 to 8,000 fewer annual research grants, a direct assault on universities' research centers by targeting so-called indirect costs, and the elimination of the Fogarty International Center.

These cuts would decimate biomedical research and the economy. According to a recent study, it would amount to losses of nearly 90,000 jobs, more than \$15,000,000,000 in economic activity. In my home State of New York, nearly 6,500 jobs would be lost and communities would take a \$1,300,000,000 hit economically.

As for medical research under the Trump budget, America would cede our global stature, medical advances could be stalled, suffering would increase, and for many, the cure that is right around the corner would now be out of reach.

At a time when the NIH is taking the lead on the Cancer Moonshot, precision medicine, the BRAIN Initiative, and so much more, we must commit to increasing funding, not abiding by arbitrary and misguided attacks on the NIH and science itself.

Earlier this year, members of this subcommittee met with researchers at the NIH. We heard from scientists devising new, more effective ways of targeting prostate cancer and researchers doing groundbreaking work on understanding the working of the human brain. We capped off our day meeting with a group of young researchers. These men and women will lead medical advances for a generation if we continue to invest in their impressive work.

And I do want to say, because I visit schools and labs all the time, and we don't want to see these young researchers decide, "Hmm, I am going to be out of work next year. I better go to Yahoo and Google." I don't want to say there is anything wrong with Yahoo and Google, but we want to make sure there are continued incentives so they work on your absolutely essential lifesaving investments.

The Trump budget signals that the United States will no longer be the leader in biomedical research, that these young researchers should look abroad to pursue their careers. If a budget is a state-

ment of our values, then this one is a slap in the face to the scientific community and, frankly, to the men, women, and children depending on research to save and improve their lives.

I do hope my colleagues will join me in defeating the Trump proposal. We have a responsibility on this committee to do so. We cannot slash these vital healthcare and economic engines.

And thank you again for all you do to improve the lives of Americans. And I look forward to your testimony.

Mr. COLE. I thank the gentlelady. And just so she knows, I was smiling at your opening remarks because you reminded me so much of my mother, who used to, any accomplishment, would say, "Oh, that was wonderful," and then nudge me and say, "But I think you could do a little better." So it is always good to have my friend with us.

Mrs. LOWEY. I just have to say that I have confidence in my friend, the chairman. And I know as we move forward, not as his mother, but as a good friend—at least he didn't say grandmother—I know, as a good friend, we will work together, because this committee has always been on the lead. And thank you for your kind words. I love my mother.

STATEMENT OF DR. COLLINS

Mr. COLE. You would have loved mine. She would have loved you as well, by the way. But, again, I thank the gentlelady for her comments.

And, Dr. Collins, we want to go to you for any opening statement you care to make to the committee.

Dr. COLLINS. Well, good morning, Chairman Cole, Ranking Member DeLauro, distinguished member Mrs. Lowey, and all of you distinguished members of this subcommittee. It is an honor for my colleagues and me to be here before you today.

I especially want to thank you for the recent appropriations increase for fiscal year 2017, which built on your fiscal year 2016 investment. And I promise you, your sustained commitment to NIH will ensure that the U.S. remains the global leader in biomedical research, with all that means for human health.

I am going to ask you to turn your attention to the screen. Today I would like to highlight several areas of exceptional opportunity, including a few patients whose lives depend on advances, along with some young investigators who are working hard to make these dreams come true.

INVESTING IN BASIC SCIENCE

Let's start with an opportunity that shows the transformational power of investing in basic science at NIH. Imagine you could determine the precise molecular structures of proteins targeted by pharmaceuticals and see exactly how they interact with each drug. This is starting to happen thanks to a new technology called cryo-EM.

This image you see here shows in atomic-level detail the structure of a protein channel of great interest. The channel is indicated in gray mesh here. And this channel regulates salt and water bal-

ance in the lungs so that it can travel through that channel from inside to outside of the cell.

1. CYSTIC FIBROSIS

This protein is a famous one, but we just learned its structure 2 months ago. It is the one that is miscoded in people with cystic fibrosis, or CF, our Nation's most common fatal genetic disease.

New structural information is key to designing better drugs to help patients with CF, like little Evelyn Mahoney, who will be celebrating her second birthday in just a few weeks. Evelyn's life hasn't been easy. She required surgery for an intestinal blockage shortly after birth. But she is doing pretty well now. Just a few decades ago, she probably wouldn't have been able to make it past her teens, but no longer. Today, we have two FDA-approved targeted drugs for cystic fibrosis and much more to come, all building on NIH-supported basic research. And we are not done. Our goal is to turn CF into a 100 percent curable disease.

For that, we need the next generation of scientific talent. Among those early stage investigators tackling this challenge is Stephen Aller of the University of Alabama. Trained in both computer science and biology, he plans to transform, using cryo-EM, in fundamental ways how we design and deliver drugs for all kinds of conditions.

2. SICKLE CELL

A second case. Treatments only exist for 500 of the 7,000 diseases for which a molecular cause is known. Among those in desperate need of breakthroughs is sickle cell disease, a life-threatening disorder in which red blood cells are deformed in a way that clogs small blood vessels. Sickle cell disease is caused by a genetic misspelling. It was understood 60 years ago, but we still can only cure this by a bone marrow transplant from an unaffected donor.

Now, that can work really well for some patients, like Chris Sweet, who is shown here with his family. Chris received a transplant at the NIH Clinical Center 6 years ago and is now essentially cured. But unfortunately, most patients with sickle cell disease don't have a well-matched bone marrow donor, and it is too risky otherwise.

So what if we could actually correct that genetic sickle misspelling in a patient's own blood cells. A few years ago, I would have said that is just not likely, but no more. NIH's Courtney Fitzhugh is seeking to use a new gene editing system called CRISPR to modify the bone marrow stem cells in people with sickle cell disease. The goal is to fix the underlying genetic defect and make the patient's own cells healthy.

If Courtney and other young scientists can get this to work for sickle cell disease, and I believe they can within a decade, just imagine what they might do for thousands of others still awaiting a cure.

3. CANCER

Another tough challenge is cancer. Imagine a world in which we could consistently and reliably cure this long-time foe. In your vis-

its to NIH, you have met folks with advanced cancer who are enrolled in clinical trials of immunotherapy. One of them shown here is Judy Perkins Anderson, here meeting with Secretary Price and researcher Steven Rosenberg. Judy came to NIH with breast cancer that had already spread to her liver, the dreaded stage 4. All efforts at chemotherapy had failed. Her only hope was a trial that sought to activate her own immune system to attack the cancer, yet this approach had never worked before for breast cancer.

First, one of Judy's tumors was removed. The immune cells in it were examined. It turned out those immune cells were asleep and not going after the cancer as they should. So Dr. Rosenberg's team grew these cells up in a lab dish and took them to school, taught them what to look for, and those educated cells were then infused back into Judy, and a battle raged.

Now, a year and a half later, it is clear Judy's immune system won. She has no signs of disease. She appears to be cured from metastatic breast cancer. What an amazing story.

But sadly, immunotherapy doesn't always work this way. We have miraculous outcomes and then we have disappointments. We need to understand why, and for that, we need to better understand the human immune system.

4. YOUNG INVESTIGATORS

So enter Matthew Spitzer of the University of California San Francisco, who is creating a detailed atlas that will help reveal the many ways in which human immune cells can be activated. If young scientists like Matt succeed, they will expand the promise of immunotherapy, not only for cancer, but potentially for other conditions as well.

So all of us here are motivated by a sense of urgency to help patients in need of breakthroughs. The next generation of innovative and passionate young researchers will be the most critical part of achieving that brighter future. Our Nation's health and well-being depend on your strong support for them.

So thank you, Mr. Chairman, and we welcome your questions.
[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

The Transformative Power of Biomedical Research

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

Anthony S. Fauci, M.D.

Director, National Institute of Allergy and Infectious Diseases

Gary H. Gibbons, M.D.

Director, National Heart, Lung, and Blood Institute

Joshua A. Gordon, M.D., Ph.D.

Director, National Institute of Mental Health

Douglas R. Lowy, M.D.

Acting Director, National Cancer Institute

Nora Volkow, M.D.

Director, National Institute on Drug Abuse

May 17, 2017

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, and it was a pleasure to host many of you at NIH in February.

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 the life sciences and advances in human health.

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 believe passionately in our mission. This extends equally to the tens 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.

I would like to provide just a few examples of the depth and breadth of the amazing research being supported across the Institutes and Centers of NIH.

The core of our mission remains basic biomedical science. Given the exploratory and, hence, unpredictable nature of fundamental discovery, basic science is generally not supported in the private sector – but it provides the critical foundation for advances in disease diagnosis, treatment, and prevention through future clinical applications. Virtually none of the substantial gains in reducing human suffering and extending longevity over the last century would have happened without basic science. NIH's emphasis on fostering innovation to understand

fundamental biological processes has led to no fewer than 149 Nobel Prizes to our grantees, and is leading year by year to new and more effective ways to treat complex medical conditions.

As a current example, the emergence of “cryo-EM,” a new form of electron microscopy, has dramatically sped up the time needed to visualize the exquisite details of biological structures including protein-protein and protein-drug complexes. This is a major revolution in structural biology that already is transforming drug design.

Basic research is also fueling new advances in our understanding of the brain, which will be critically important for treating diseases such as Alzheimer’s disease, Parkinson’s disease, autism, epilepsy, traumatic brain injury, and others. Through the Accelerating Medicines Partnership (AMP), a public-private partnership between NIH, the Food and Drug Administration (FDA), 10 biotechnology companies, and nonprofit organizations, we have joined ranks across sectors to expand our understanding of Alzheimer’s disease. In one component of AMP, researchers are analyzing large-scale molecular data from thousands of affected and unaffected human brain samples, including genomic, gene expression, and protein measures. With this information, NIH and our partners are building new molecular pathways to understand the cause of Alzheimer’s, and charting a course for entirely new ways to detect and treat this devastating disease that go beyond the previous understanding of the amyloid and tau proteins. By working with industry and sharing data widely in the scientific community, NIH aims to shorten the time between these discoveries and the development of new strategies for Alzheimer’s disease treatment and prevention.

Rare diseases also represent an area of great need and great opportunity, one which NIH continues to be uniquely positioned to address. Though such diseases are individually rare, collectively an estimated 25 to 30 million Americans are affected. Great advances have been made through genomic science in uncovering the cause of rare diseases, and that has led to

dramatic improvements in diagnosis. But of the 6,500 identified rare and neglected diseases for which the molecular cause is now known, only about 500 have approved treatments. The private sector generally finds it difficult to mount expensive initiatives for such small markets – the risks are too high. Finding new treatments thus requires NIH to play a lead role – by investing in the early stage of therapeutic development to “de-risk” such projects. While almost all Institutes and Centers at NIH work on rare diseases, the National Center for Advancing Translational Sciences (NCATS) has a particular focus on this area of opportunity.

As an example, autoimmune pulmonary alveolar proteinosis (aPAP) is a rare, potentially fatal disease marked by a build-up of lipids and proteins in the lungs, and leads to respiratory failure. The current treatment for severe aPAP is whole-lung lavage, whereby both lungs are repeatedly filled and washed with a salt solution. This procedure is complicated, dangerous, and must be repeated throughout a patient’s entire life. NCATS has supported efforts to develop an inhaled treatment for aPAP, providing support and expertise to the basic research, pre-clinical research and testing, and early-phase clinical trials.

Other transformative technologies are offering dramatic new approaches to achieving a truly molecular cure of rare diseases. For example, experts are now testing genetic therapy in bone marrow stem cells as a curative treatment for sickle cell disease, the first human disease understood at the molecular level and the most common inherited blood disorder in the United States, affecting over one hundred thousand Americans at a yearly cost of hundreds of millions of dollars.

As a final example, consider how fundamental research over many years now promises to transform medicine for patients with advanced cancer: immunotherapy. For decades, basic scientists have worked to understand how the immune system functions at the molecular level. Now, thanks to a series of dramatic advances, we can not only watch the immune system at

work, we can instruct it – “send it to school.” In a recent breathtaking example, a young woman with widely metastatic breast cancer, whose cancer had failed to respond to several rounds of chemotherapy, enrolled in an experimental protocol at the NIH Clinical Center as a last hope. Her tumor genome was sequenced, and rare immune cells in her body with the potential to seek and destroy those cancer cells were identified. After those immune cells were massively expanded in the laboratory, and then unleashed to go after the cancer, her tumors started to recede within days. Now more than a year later, there is no evidence of any remaining cancer in her body. She is part of a revolution in cancer treatment, all made possible by years of dedicated basic research in fields like immunology and genomics.

So the future has never been brighter for advances in biomedical research than right now. Imagine what this feels like for a talented and curious new investigator. Early-stage investigators are responsible for many of the advances I’ve told you about today, and our future depends on them and their bright ideas. Those young men and women are thrilled by the prospect of exploration, and driven to help people. NIH is responsible for training these scientists, and for making sure that our investment in their careers, and the potential advances they will bring to patients, are sustained into the next stage. They are our most important resource. If advances in medical research are to continue, if research is to lead to breakthroughs that can reduce health care costs, if the considerable economic return on research is to continue, and if America is to continue its global leadership in biomedicine, we need to be sure this next generation has the confidence that there will be support for them. This is a priority for me.

NIH is preparing to implement a new measure to allow a broader number of meritorious investigators, particularly those in early- and mid-career, to receive NIH funding through new and renewed grants. A number of recent studies have demonstrated that while NIH support is essential to ensure the productivity of an investigator, there is a point of “diminishing returns” if

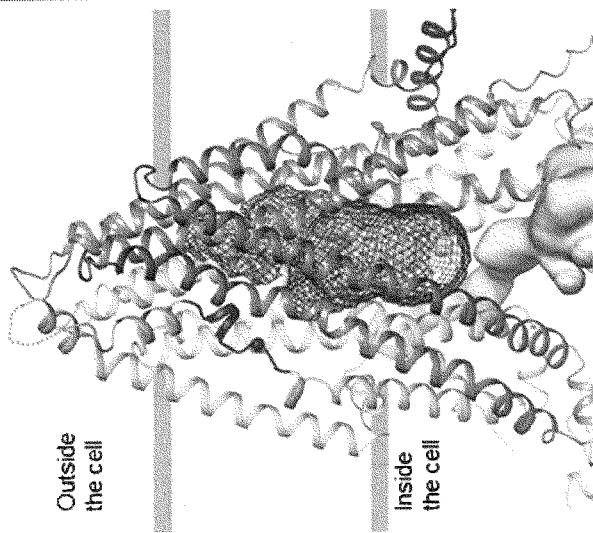
an investigator becomes overextended. Quality science and fiscal stewardship require time and effort, and it stands to reason that a person can be stretched too thin. We are therefore proposing to work with NIH grant applicants and their institutions to limit the total NIH support that any one principal investigator may receive through research currently funded by NIH, allowing NIH funds to be more broadly distributed. Opening up opportunities for highly meritorious investigators at all stages of career development will ensure that NIH will remain a good steward of trusted public dollars, and strengthen the biomedical research workforce for the future. We are working with stakeholders now to determine the best way to move forward on this important goal.

I have provided you with examples of how investments in bright new ideas in biomedical research are advancing human health, spurring innovations in science and technology, stimulating economic growth, and laying the groundwork for the future of the United States biomedical research enterprise. We have never witnessed a time of greater promise for advances in medicine than right now. Your support has been critical, and will continue to be.

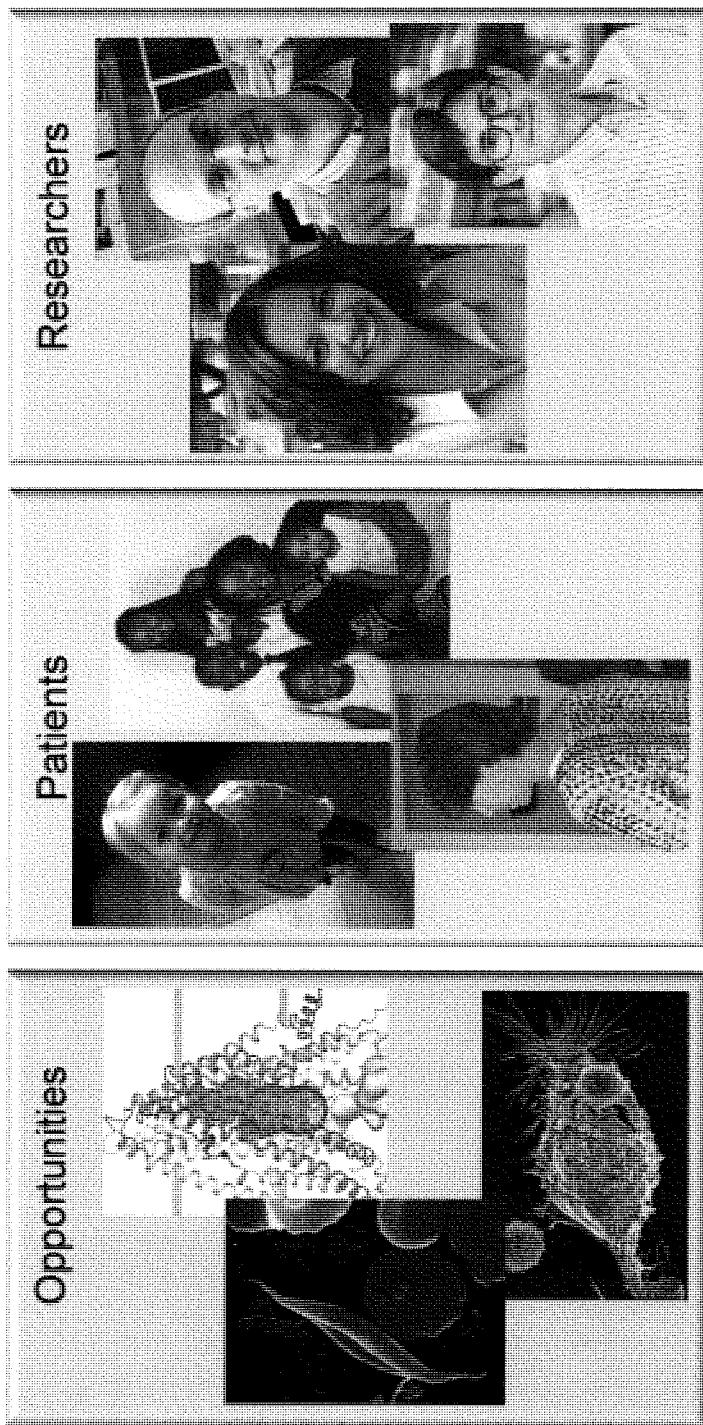
This concludes my testimony, and I look forward to answering your questions.

Leveraging Basic Science for Medical Advances

Cystic Fibrosis drugs are working



NIH and Advances in Biomedical Research



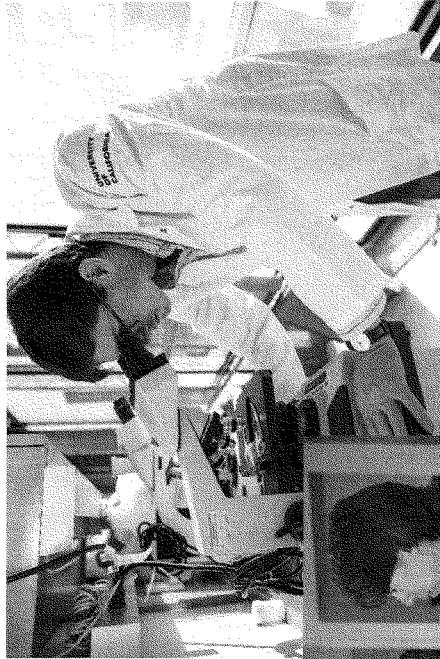
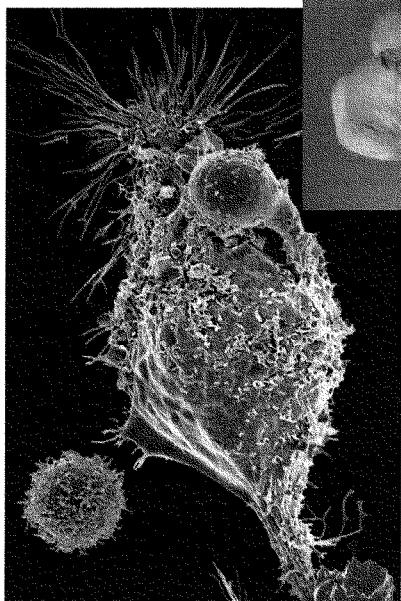
Pursuing Treatments for Rare Diseases

Sickle cell disease needs a molecular cure



Advancing Cancer Immunotherapy

Going for the cure, not just a remission



Encouraging Young Investigators
America's most important research resource



CONTRIBUTIONS OF BIOMEDICAL RESEARCH IN BENDING COST ON MEDICARE AND MEDICAID

Mr. COLE. Thank you. And let me begin by, number one, congratulating you on your distinguished stewardship there, Dr. Collins. And every member of this committee is supportive of you and appreciative of the way in which you have interacted with all of us.

I have got a question, because these cures individually are startling and they are wonderful and they are inspiring, quite frankly, but we also live in a time with very tight budgets and have to make very tough choices on this committee.

And I think one of the compelling arguments, and I would like you to expand on this if you care to, for this is actually the ability to bend the cost curve on some of these awful diseases. Everybody up here knows how much money we spend through Medicaid, for instance, on Alzheimer's. It is literally \$250,000,000,000-plus a year. And it is the right and appropriate thing to do, looking after Alzheimer's patients.

But if we could do something that either slowed or positioned us in a way that we could ultimately reach a cure, not only would human life be incomparably better, but, honestly, it would be a huge boom to the Treasury and a pretty strained budget as well.

So I would like you to talk about some of the ways in which some of the things you do at NIH not only help us individually and cure these awful diseases, but also contribute longer term to bending the cost curves on Medicare and Medicaid.

Dr. COLLINS. Well, thank you for the question, because that is one of our major goals and part of our mission, and we are making headway in a substantial way. When we talk about cancer, it may come up that the death rate from cancer is dropping by about 1 percent per year, and that has been happening now for almost 20 years. That is slow and we wish it was faster, but the progress is happening, based upon molecular understanding of this disease. Each 1 percent drop in cancer deaths is estimated by economists to be worth \$500,000,000,000 to our economy. So just that small part of what we do has a big impact.

Look at what has happened with heart attack and stroke. Deaths from heart attack and stroke now are down by 70 percent over where they were 40 years ago, much of that based upon NIH research followed by good implementation of our discoveries across the board.

And you mentioned Alzheimer's disease. I just want to show you this diagram of just how serious it is that we have to attack this problem.

So here we are in 2017, the cost to our Nation is estimated at \$259,000,000,000 right now in taking care of the roughly 5 percent of people who have that condition, with all that means for their caregivers and lost economic benefits from those folks being able to work. And in 2050, the estimates are that it will be over \$1,000,000,000,000. It will absolutely break our budget if we don't come up with something.

Thank you to the Committee, because the fiscal year 2017 Omnibus added an additional \$400,000,000 to our Alzheimer's disease research budget, which is in the green bar, but you can see it is

still modest compared to what we are facing. We promise you every dollar of that will go into identifying ways to prevent and treat this disease to try to bend that cost curve, which is one of the scariest ones around.

I could also mention diabetes. It is now costing us \$300,000,000,000 a year in our healthcare, and we need to come up with better ways. And with things like the artificial pancreas, just for the first time getting to the point of an FDA-approved version of that, we are on the way. But it takes that kind of focus. And it is a long-term investment. It is not a sprint, it is a marathon.

INVESTMENT IN YOUNG INVESTIGATORS

Mr. COLE. Well, thank you for that. And as my good friend the gentlelady from Connecticut suggested during her remarks, we went a dozen years without significant increases at the NIH, and in the last 2 years have reversed that trend.

Let us know, if you can—we often talk about—my friend from New York always likes to set the goal of doubling. My goal has always been just sustained regular increases. And what sort of difference would it make in your long-term planning if you could think forward and know, okay, every year we are going to sort of make this modest investment and keep these research dollars coming? And what would it do in terms, in your opinion, of decision-making of younger people thinking about long-term careers in biomedicine?

Dr. COLLINS. Well, I really appreciate your question, because we think about that a lot. And you are right that young people right now are particularly concerned, because they are under stress. What was traditionally a one chance in three of getting funded, now it is down to one out of five is putting a lot of stress on those new careers. Are they going to be able to get up and going?

For me, as the NIH director, what we would most like to plan on would be a stable, predictable trajectory of research. The roller-coaster model is really destructive both for our trying to plan projects and for people staying in the field, who wonder: Is there a career path for me?

What you have done the last two years, which is essentially inflation plus about five percent, has been a wonderful recovery from what was a long, difficult time since 2003. And for NIH to be able to stay on that kind of trajectory would be enormously beneficial for all of medical research.

Mr. COLE. Well, I thank you.

And with that, I want to go to my good friend the gentlelady from Connecticut for whatever questions she cares to ask.

FOGARTY CENTER'S ROLE IN BIOMEDICAL RESEARCH

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

Just on that note, I would hope that we could have a discussion about what is now the bipartisan Accelerating Biomedical Research Act, which deals with predictability of growth for years to come, and that is the opportunity to look at going above the caps the way we do, as I said, for the healthcare fraud and abuse account. We do this. This is not something that would be new. And that way we would be set on that path to make sure that we are dealing

with inflation every year as we move down the pike. So I hope we can have a conversation about that.

Dr. Fauci, I wanted to ask you—first of all, let me say, your point on cystic fibrosis was very touching, because I was in school with, one of my college classmates, with a brother and sister who both died with cystic fibrosis. Their dad was a physician and could do nothing to prevent their deaths. So thank you for that work.

Dr. Fauci, again, interested in understanding the impact of eliminating the Fogarty International Center. It is my understanding that to stop infections with a pandemic potential in their tracks, whether we are looking at flu from Southeast Asia, MERS from Saudi, hemorrhagic fevers from Africa, Zika from the Americas, other kinds of potential pathogens in animal reservoirs, that it requires global investment that includes scientists and labs.

So can you talk about the Fogarty Center, the role that it has played in your work when you are dealing with emerging infectious diseases? Is it value added? And let me just follow that up with what, the Fogarty trainees, what role have they had in administering the Zika vaccine trial that NIAID is now running and what would happen to that research?

Thank you, Doctor.

Dr. FAUCI. Well, thank you for the question, Ms. DeLauro.

The last part of your question really is the fundamental basis of the answer, which is the people that the Fogarty International Center trains. If you look just historically at what we have been experiencing over the last many years and even as recently as the last few years, from A to Z, from HIV/AIDS to Zika, all of the things that are threats to us here in the United States, but that are global issues that need to be addressed at the global level. And virtually all of the collaborations that we have, starting from the HIV clinical trial units that we have in South Africa, if you look at the leadership of those individuals, almost all of them have been trained in one way or another at the Fogarty International Center.

If you look at the situation with Ebola, there were some very difficult times that you might remember, because we discussed this at a committee hearing, where individuals who were infected in West Africa traveled to places like Mali, but the outbreak was completely suppressed there because the people who were in charge of managing the outbreak were Fogarty-trained people. The same occurred when the epidemic went to Nigeria, the people in charge were Fogarty-trained people. These are people that are our brothers and sisters in what we do.

And your last part of the question regarding Zika, we now, as I have mentioned to you before, have a network to implement our Phase II clinical trial of Zika, which is going on right now predominantly in the Americas, in South and Central America. Several of the investigators who are leading that Phase II in country on the ground, for example, in Peru, are people who were trained by the Fogarty International Center.

So the Fogarty International Center is really part of our army of defense against diseases that will ultimately have an impact right here in our own country. Even though they are foreigners, they are helping us to be protected from disease.

Ms. DELAURO. I would just say, at the same time the Fogarty Center is working to build an infrastructure in those countries, that without that infrastructure there would be a greater burden on us to engage. But we are building the capacity of these countries to be able to deal with infectious diseases or any crisis.

Dr. FAUCI. An example of that is Mali. If you look at the Malaria Research and Training facility in Mali, it is developed by, run by, and implemented by people who were Fogarty trained.

Ms. DELAURO. Thank you.

Let me just if I can—maybe we have to come around again—this is about a vaccine update, Dr. Fauci, on your efforts to develop an Ebola vaccine and treatment, the Zika vaccine candidates. And you may have to come around at the next go-round here. And I am interested in the longer-term efforts to develop a universal flu vaccine, as well as a vaccine for HIV/AIDS, and I would like to have you update us on those kinds of efforts that you have been engaged in over the years.

So I think my time has run out, so I will get you on the next go-around.

Dr. FAUCI. I will get back to you on that.

Ms. DELAURO. Thank you.

Mr. COLE. I thank the gentlelady.

Before I go to my good friend, the ranking member of the full committee, just a quick history lesson, which I just got from late Representative Fogarty's daughter, who came to visit us. I did not know this, but he was, I guess, elected when he was 27, that the institute is named after, served until he died of a heart attack at 53.

Well, there you go. Of course, there is never anything my ranking member doesn't know.

Ms. DELAURO. Mr. Public Health.

Mr. COLE. Yeah. But served on this committee for 20 years, 16 as chairman, the longest-serving person ever to serve on this committee. So we probably ought to have one picture up here somewhere. I am going to talk to my chief clerk.

Ms. DELAURO. That would be great.

Mr. COLE. It would be right up there.

With that, let me go to my good friend, the ranking member of the full committee.

BENEFITS OF GOVERNMENT'S INVESTMENT IN BIOMEDICAL RESEARCH

Mrs. LOWEY. I want to thank my good friend again for conducting this hearing and an opportunity to meet with such a distinguished panel.

As you can tell, I am very upset with the 24 percent cut requested by the Trump administration, because it will result in more human suffering and more lives lost that could have been saved. And yet the administration is dismissive of the impacts, arguing that the private sector can pick up the slack and that advances in innovation would not suffer. I am worried that not only would the U.S. Government and research institutions be decimated as a result of these cuts, but the private sector itself, which relies on NIH research, would also be harmed.

Dr. Collins, is it even feasible for the private sector to invest enough to bridge this funding cliff, and what would these cuts do to private sector research and economic development?

Dr. COLLINS. Well, it is very interesting. Just two weeks ago the White House convened a meeting of leading CEOs in the biotech and pharmaceutical company arena, as well as leading academics from some of our Nation's most highly regarded institutions, as well as NIH and FDA. That was attended by very high-ranking people in the White House, including a brief visit with the President. And for the two hours of that meeting, the conversation was very much along the lines of what you are talking about.

America's efforts to develop new medicines and prevent disease is the envy of the world. Clearly, we have led in this space for decades. And yet, the leaders from the private sector were quick to say that is in large part because of the success of this ecosystem where NIH, through support from your committee and from the taxpayers, carries out the basic science, makes those discoveries that allow light bulbs to go off that something might then be brought to clinical benefit. But if we were not doing the basic science, the companies were quite clear, they would not be able to, their stockholders would not necessarily appreciate them putting money into things that are not going to be connected to a product.

So between the industry effort, the academic effort supported by NIH, venture capital, philanthropy and advocacy groups, the conclusion of that group was we have an amazing engine for discovery, something that was called in an op-ed by Eric Schmidt and Eric Lander a "miracle machine," because it produces miracles.

But you don't want to put some sand in the gears or find that there is some part of the machine that has sort of run out of its particular maintenance. And they were quite clear that anything that would reduce the inputs from industry or from academia or from NIH would put this country at risk. And they were very clear about the potential of losing our lead to China, given the massive investments that are happening in China in this very space. China has read our playbook. They want to become us, and I don't blame them, but we should be sure that we are still us.

E-CIGARETTE RISKS

Mrs. LOWEY. Okay. You noted the popularity of e-cigarettes has led to more kids getting hooked on nicotine and that e-cigarettes meet the criteria for an addictive substance.

Dr. Collins, Dr. Volkow, what are the health risks associated with e-cigarettes? What makes e-cigarettes particularly dangerous for children and adolescents? If you could answer that quickly.

Dr. VOLKOW. There is limited research with regard to e-cigarettes, but what we do know from that limited research is that it appears that, first of all, if they are used to deliver nicotine, they are addictive. Nicotine is an addictive substance. And what we are observing is teenagers that otherwise would have no transition into smoking combustible tobacco are doing so after they get first exposed to electronic cigarettes.

So we are concerned that all of the advances we have made on prevention of smoking may be lost by the accessibility of these electronic cigarette devices.

Mrs. LOWEY. So since I have 45 seconds left, it is no question in your mind that it is a gateway to cigarettes?

Dr. VOLKOW. For teenagers when they use it with nicotine, yes.

Mrs. LOWEY. Otherwise they wouldn't be calling it Yummy Bummy and pretending with all these names that you attribute to candies that they put on cigarettes.

Thank you very much.

And thank you, Mr. Chairman.

Mr. COLE. Absolutely.

We will next go just on the basis of arrival to my good friend the gentleman from Tennessee, Mr. Fleischmann.

UPDATE ON NEW "GRANT SUPPORT INDEX" (GSI)

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And, Dr. Collins, and to your entire panel today, I am the eternal optimist, so I am going to say thank you for all of your past successes and your current endeavors to really address all of the medical maladies that affect human beings. So thank each and every one of you all for your great efforts.

This committee and the Medical Research Committee have continued to voice concerns over the pipeline for the next generation of researchers. This is a question for Dr. Collins, sir. I am interested to learn more about the new Grant Support Index you are considering. While I know the process is early, I do have some basic questions I would like to see addressed and would appreciate you keeping my staff informed as you move forward.

First and foremost, should the GSI be implemented, what follow-up actions are you considering to ensure it has the desired effect of funding and sustaining more early career investigators? Second, are you considering steps to ensure we do not inflict unintended harm on current scientific progress? And, thirdly, in the interest of time, sir, finally, are you considering mechanisms that might allow exceptions on the caps for situations where they might hamper or roll back progress or where they do not align properly with some of the unique research structures that are out there?

Thank you, sir.

Dr. COLLINS. Thanks for those questions. This is a topic of intense conversation right now amongst all the institute directors and our biomedical research community.

The basis for this proposal that we might consider using this Grant Support Index is the graph that you see here. This tells you what happens in terms of productivity per dollar by the best metric we have got, which depends on publications and their impact, as a function of how many grants a particular investigator is currently holding. And on the Y axis is that measure of impact, and on the X axis there is the number of grants.

So you can see the curve actually kind of flattens out. As one goes above, about three grants per year, it gets pretty flat. And that says that those dollars are not giving us as much of an impact as if they were perhaps given to somebody who had no grants or maybe one and was going for two. This is new data. It is based upon a whole lot of metrics that we have developed and analytics that we now have. That is our motivator.

Now, we have to be very careful in making broad, sweeping conclusions from that, but it does suggest that if we are going to be good stewards of the taxpayers' money, which is our charge, we ought to look at those individuals who are in that flatter part of the curve. They are still producing great science, but dollar for dollar, perhaps not quite at the same level. It could be that we redistribute those funds to younger investigators or mid-level investigators who are not as well funded but still have a lot of potential.

So we want to be sure that if we do this, and it is still under discussion, that we follow carefully to see what happens, where do the dollars end up, that we don't cause harms, and we will need to have an exceptions process to be sure that there is no harm done to exceptional individuals. One of the things we are figuring out, is we don't want to penalize people who are doing public service, for instance, with a training grant or running a center, which maybe isn't that much benefit to them personally, but helps the whole community.

So we are deep into that kind of sophisticated conversation. Every one of our advisory councils is discussing this issue. This month, we had a stakeholders conference call. It will be a topic for my Advisory Committee to the Director coming up in just two weeks. And ultimately, then, we will figure out what makes the most sense here. But we are determined to take some action now that we have this data.

Mr. FLEISCHMANN. Thank you, Doctor.

With that, Mr. Chairman, I will yield back.

Mr. COLE. Wow. That is unexpected. Thank you. But Ms. Lee thanks you even more.

Ms. LEE. Thank you very much.

Mr. COLE. I recognize the gentlelady from California, my good friend.

UPDATE ON HEALTH DISPARITIES AND HIV/AIDS

Ms. LEE. Thank you. Good morning. And thank you all for being here and for your great work. Really, we are looking at an institute and individuals who are really making a difference in terms of saving lives and extending lifespans for so many people. So thank you.

I have to agree with my ranking member in terms of doubling the budget. That is what I want to see. And I will tell you why. And I will try to ask all my questions very quickly.

The Office of Minority Health, for example, has been critical in identifying racial and ethnic health disparities, which have existed since the beginning of time really. And that is why we need more money, to really begin to close that gap—those gaps—and you have been critical in creating and implementing programs that address health disparities. Without the National Institute on Minority Health and Health Disparities, I don't know where we would be.

And, so, I would like to just ask you what some of the efforts are at this point as it relates to health disparities research and applied research, and with a focus on social determinants of health and how is that going to be carried out.

Secondly, with regard to HIV and AIDS, I know the office had been flat funded for a while now, and you know that the global fight against HIV and AIDS, it is really at a tipping point in terms

of the critical window that we have now to turn the tide of the epidemic. And I am wondering where we are in terms of the development of vaccine and what really the effects of a stagnant program would mean in terms of future progress in this area.

And also, of course, the National HIV/AIDS Strategy, where are we on that? I haven't heard back from the administration on how we are proceeding. I would like to know that.

Thank you again.

Dr. COLLINS. Thanks for the questions.

In terms of NIMHD, we are very fortunate to have recruited a leader of that effort, Eliseo Perez-Stable, who has come in with a lot of really good ideas to try to increase our focus on health disparity research, including bringing more actual research projects into the Institute, which we are pretty excited about.

I am going to ask Dr. Gibbons to say a quick word about a particular study that has very recently happened that looks at this issue of health disparities in terms of cardiovascular disease, and then I will ask Dr. Fauci to answer your question about HIV/AIDS and vaccines.

HEALTH DISPARITIES AND STROKE

Dr. GIBBONS. Well, thank you for that question.

Certainly we have made tremendous progress in reducing cardiovascular disease, over 71 percent over the last 50 years. But with that progress, we recognize that not all communities have benefited from the fruits of those research investments and we have to do more. Indeed, there are a lot of disparities that relate to race and ethnicity, in which those communities lagging behind, particularly African Americans, who have hypertension, and are predisposed to stroke.

We are also noting geographic disparities. A recent report came out this week that indicated there are certain parts of our country where, in fact, maybe things are going the wrong direction. In fact, life expectancy may be shortening. And it is particularly disturbing, because it is affecting America's heartland. There appears to be a swath in the middle of the country from the hills of Appalachia, western Virginia, Kentucky, Tennessee, Arkansas, over to Oklahoma, Mr. Chairman, and down the Mississippi River Valley, Louisiana, Mississippi, and Alabama.

And this is really a call to action, I believe, that if we are going to reverse that trend, we have to address some of the challenges those communities are facing, and a lot of those relate to both social determinants, as well as adopting and getting access to healthy lifestyles.

HIV AIDS RESEARCH

Dr. FAUCI. The microphone is not working. We are all flashing, but I can speak loud.

There are two aspects of HIV/AIDS research that you asked about: one, the status of an HIV vaccine, and two, how what we do in terms of research has an impact on the National AIDS Strategy for the United States.

With regard to HIV vaccines, what we have right now is, I think, a considerable amount of progress. There are a couple of things

that happened since we testified before this committee last year. We have implemented the amplification of the original Thailand trial.

You recall the famous RV144 trial, which showed a 31 percent vaccine efficacy in Thailand. We have now used that same protocol to amplify the vaccine strategy used in RV144 with multiple boosts and an adjuvant to start a Phase II b III, vaccine study in South Africa with a version of the virus that is now circulating in South Africa. That is one component of HIV vaccine development.

The other component is the use of broadly neutralizing antibodies in a passive transfer study called AMP, Antibody Mediated Prevention, which just a few months ago was started in southern Africa. If that trial proves the concept that the broadly neutralizing antibodies work, we would use the same structural, biological, and cryo-EM techniques that Dr. Collins just described to determine what the right conformation of a vaccine immunogen would be, and I think we would see some really important advances in HIV vaccine research in the next year.

Finally, how does the NIH have an impact on the National AIDS Strategy? As you well know, you were involved in that strategy, the number one component of the National AIDS Strategy is to prevent and decrease the incidence of HIV infection in the United States, and there are a number of things that we have done to amplify that.

One is pre-exposure prophylaxis, or PrEP, which is highly successful in preventing HIV infection when used. And the other one is the implementation of treatment as prevention. We know now from studies from San Francisco, New York, and other places that if you treat HIV-infected individuals and bring their viral load to below detectable level, the chances of them transmitting the infection to someone else is virtually zero. We never like to say "zero" in biology, but it certainly is close to that. If we implement these strategies based on NIH studies, we are going to make the first component of the National AIDS Strategy a success.

Mr. COLE. Okay. With that, we will move next, again on order of arrival, to my good friend from Michigan, Mr. Moolenaar.

EMERGING AND REMERGING INFECTION DISEASES

Mr. MOOLENAAR. Thank you, Mr. Chairman and members of the panel.

And I also just want to thank you for the chance to tour the NIH and your hospitality. I thought that was very informative, and I appreciate that.

I am going to address these questions, I guess, to Dr. Collins, and then if there are others who you feel are the best to answer the question, feel free to send them over. But over the last several months, many experts and news reports have raised concerns about our Nation's level of preparedness to deal with a possible new pandemic or emerging infectious diseases.

And I am asking what additional steps that you believe need to be taken for the United States to strengthen our level of preparedness and allow us to develop effective countermeasures and treatments posed by emerging infectious diseases.

And I also just wondered if you might comment on the role outside research partners play in battling these threats and any insights you have on what additional things Congress could be doing.

Dr. COLLINS. Well, very appropriate question. I am going to ask Dr. Fauci, as our lead in that area, to answer.

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

Now, obviously, when one addresses emerging and reemerging infectious diseases it is not a one-agency issue. It has to be a co-operation and a collaboration. So one of the mechanisms that we have within the Department of Health and Human Services is called PHEMCE, the Public Health Emergency Medical Countermeasures Enterprise, and that involves the NIH, BARDA, the Biomedical Advanced Research and Development Authority, the FDA, the CDC, and other components, including interagency partners, like the Department of Defense.

The role that NIH has is to provide the research to be able to respond one by, one, understanding the disease, exactly what we did with Ebola and what we are doing with Zika; and two, to provide resources and reagents and capabilities of people in the field to be able to address the disease. Again, we successfully did that with Ebola, and with Zika. There are other examples, but those are the two most recent ones. We also have done it with Chikungunya and other diseases.

And then, finally, we work to develop the research capability to respond with countermeasures, of which there are three main types: diagnostics, therapeutics, and vaccines. And right now what we see are some successes, and I hope we can continue to make progress. For example, the Ebola vaccine, which may be deployed against the outbreak in the Democratic Republic of the Congo because of what we learned from NIH-supported trials for Ebola in West Africa, in the three most affected countries.

Another example is that we are in the process of a phase II vaccine trial of a DNA-based Zika vaccine that was developed at the NIH's Vaccine Research Center. There are about four or five leading candidates for a Zika vaccine. One of them the DNA-based candidate, is advanced enough that if we have outbreak conditions as we get into the summer in Puerto Rico, we will be able to have hopefully what we call a vaccine efficacy signal, namely, knowing if we actually have a vaccine that works.

So we are the research component, but by no means the only component of how this Nation responds to an outbreak.

UPDATE ON BRAIN INITIATIVE

Mr. MOOLENAAR. Okay. Thank you. Thank you for the update.

And just to switch gears a little bit, my understanding is that pathophysiology—am I saying that word right, pathophysiology—of central nervous system disorders is not as well understood as in other diseases, such as infectious diseases or cancer. The 21st Century Cures Act authorized funding for the BRAIN Initiative. I just wondered if you could update us on your plans.

The hope is, I know, to fill major gaps in our current knowledge of how the brain enables the human body to process, store, and retrieve information at the speed of thought. I am just wondering

your plans on how that funding will be used, and is it your intention to devote the full amount of funding for this research?

Dr. COLLINS. I will ask Dr. Gordon, who co-leads this effort with Dr. Koroshetz at NIH, to answer your question about the brain, which is something we are all very excited about.

Dr. GORDON. So as you noted, central nervous system disorders are particularly challenging for physicians and researchers alike because we know so little about how the brain works. And the BRAIN Initiative is really meant to jump-start our efforts to really get down to the nitty-gritty of how neurocircuits produce behavior and how dysfunction within those neurocircuits produce disorders in the central nervous system.

We are very grateful to the work of this committee and other Members of Congress to continue support for the BRAIN Initiative both through the Cures Act that was passed and signed in December and also through the appropriations in fiscal year 2017, which gave us an extra \$100,000,000 for the BRAIN effort.

All of those funds will be devoted to the BRAIN Initiative. And the BRAIN Initiative's targets over the past several years and for the next couple of years are really to develop novel tools that we can use to explore the relationship between brain activity and function and dysfunction.

And over the next couple of years, you will see us pivoting in a few directions. One, dissemination of those tools throughout the neuroscience community so everyone can take advantage of them. Two, education and training of new researchers. Three, data sharing, so that we make sure that all the data that everyone generates through the BRAIN Initiative is available to all researchers to maximally take advantage of. And then, four, trying to figure out how to use these tools to make an impact on illness.

Mr. MOOLENAAR. Okay. Thank you.

And now we will go to my good friend from Wisconsin, Mr. Pocan.

INDIRECT COSTS, 21ST CENTURY CURES ACT, AND MARCH-IN RIGHTS

Mr. POCAN. Thank you, Mr. Chairman.

And thank you, Dr. Collins and everyone, for being here.

First, I just want to say I associate myself with the remarks from our ranking member on the subcommittee and on the committee about concern over the cuts to NIH that could be coming under the Trump budget. You know, the University of Wisconsin-Madison Morgridge Center gets a lot of assistance. It is a world class research facility doing a lot of amazing work.

I was a journalism major, so I took physics for poets. I don't pretend to be someone who fully is in the science realm. But when I go visit companies and see some of the research and learning about 2D and 3D cell technology, it is really amazing stuff that is going on.

So I have three questions I am going to try to put out, three different areas, so the best we can try to answer them.

The first is on—when Dr. Price was here—on indirect costs. I have a real concern, because it was greatly implied that the cut proposed is basically the indirect costs that are often spent by fa-

cilities, that is just the cuts, you won't hurt research with the cuts proposed by the Trump budget.

But reality, it is the indirect costs, and other nonprofits have lower levels. We know that Ford Foundation recently went from 10 to 20 percent, they actually went the other direction, recognizing people have bigger costs. And as I understand it, a lot of times the costs when they get these other grants, the university is filling in the dollars.

Could you just talk a little bit about the indirect cost issue?

Second, the 21st Century Cures Act, big issue that Tammy Baldwin and I have worked on is this loss of young researchers, or potential loss. The fact that grant has gone up to, what, 41 now on average, up about 5 or 6 years from just a couple decades earlier.

Can you just talk a little bit about specifically what you are doing in that area? And are you working with stakeholders to get their input as you move along the process? I think that is a really big concern to those folks.

And the last one, if we have time, I would love to talk a little bit about march-in rights on prescription drugs. You know, we have a lot of NIH research going into this. So sometimes on the front end and then sometimes on the back end, the drugs are being paid for with Medicare and Medicaid. Government is really heavily involved. I don't think we have ever used march-in rights. There have been some issues around that.

If you could just talk about that briefly. But the first two are the ones I really have the most interest in. I can submit that for questions.

Dr. COLLINS. Well, thank you. Let me see if I can get through at least two and maybe three.

Indirect costs are a topic of great interest right now in terms of what are they, after all. Basically, over time, the commitments that the government has made with its grantee institutions is that we are trying to cover the fully loaded cost of research, which means that institutions are motivated to take part of it, as is true certainly in Wisconsin, where great research goes on every day.

Frankly, we have not quite lived up to that. Indirect costs generally don't fully cover, and institutions are, in fact, themselves having to put their own money into supporting the effort.

Indirect costs are not negotiated by NIH. They are negotiated by a component of HHS, the Division of Cost Assessment. And they decide, based upon an OMB guideline, exactly what is appropriate for universities to ask for in terms of covering the actual cost of research, and that includes things like keeping the lights on, maintaining the facilities, running institutional review boards to look at human subjects applications, and so on. And those are negotiated every 4 years based upon the guidance from OMB.

The idea that those could be paid at a lower rate by other sources has certainly been raised by things like foundations. But those foundations are a very small proportion of the overall support of any institution, so perhaps they can afford to absorb that, but they would feel much less happy about having a chance to have to absorb more of that from their major funder, which is, after all, in biomedical research, the NIH.

So it is a very important issue, and certainly presidents of universities are very focused on this, as you can imagine, and we are answering lots of questions from those folks as we go through this conversation.

In terms of early stage investigators, several things. One is, for several years we have insisted that somebody who comes to NIH with their first grant application competes against other people like themselves, who are not the experienced grant writers but the first-timers, and that gives them a boost so they are not being penalized for a limited track record, they are just getting started, and they are not being penalized for being really well-trained grant writers. That has provided quite a benefit for those first-timers.

On top of that, we have designed a number of programs that you can't apply to unless you are a first-time investigator. And we particularly ask those to be very innovative and creative in trying to inspire the creativity.

And then there is this issue that we talked about a moment ago, which is with the Grant Support Index, where we are aiming to see whether we could better utilize the funds that we are given by redistributing some of the dollars from investigators who are very well funded but who are on that flatter part of the productivity curve, and provide those to early stage investigators who are still trying to get started. All of this, of course, depends upon having that stable trajectory we talked about earlier.

Mr. POCAN. Are you seeking input with those folks as you are doing this?

Dr. COLLINS. Yes. So we have multiple workshops and opportunities. The AAU is convening another gathering to talk about this in June. We are listening closely. My advisory committee, the director, has had a major focus on the workforce and what we can do about it for several years now.

And I guess your last question about march-in rights, I will answer for the record.

[The information follows:]

March-In Rights

Drug pricing and patient access are broad and challenging issues in the United States. While the National Institutes of Health (NIH) is sensitive to the impact of drug pricing and a health care product's availability to patients, drug pricing is a complex issue that involves many market factors such as competing products and public and private reimbursement for products that are considered long after NIH's research support ends. In 2004 when similar pricing and availability issues were raised and discussed at a public meeting, the NIH agreed with the public testimony and the policy objectives of the Bayh-Dole Act that the extraordinary remedy of march-in is not an appropriate means of addressing costs of drugs that are broadly available to physicians and patients.

The NIH supports fundamental research that may lead to the development of health care products. Occasionally, the NIH funds a technology that ultimately is incorporated into a pharmaceutical commercial product or process for making a commercial product. It is important to the NIH that companies commercialize new health care products and processes incorporating NIH-funded technology thereby making the technology available to the public. The translation to the market of innovative inventions made during an NIH-funded research program often requires analyses of multiple factors that are not known at the time of NIH research support. These market factors include: considerable financial support to bring an early stage invention to the consumer, safety and efficacy studies, market assessments, and often access to or development of additional non-government funded technologies.

A central purpose of the Bayh-Dole Act requires the development and commercialization of products from inventions made in the course of early-stage federally-funded research. The objectives stated by the Bayh-Dole Act and confirmed by Senator Birch Bayh in his written testimony for the "NIH Public Meeting on Norvir/Ritonavir March-in Request May 25, 2004"ⁱⁱ are, amongst other things, to promote the utilization of inventions arising from federally supported research through use of the patent system by the inventors and their employers, to encourage collaboration between commercial concerns and nonprofit organizations, and to support small business firms in their commercial development of research funded by the federal government.ⁱⁱ

At the time of the enactment of the Bayh-Dole Act in 1980, it was estimated that more than 28,000 patents made by federal agencies' contractors remained dormant because there was no uniform government policy regarding a federal funding recipient's right to elect title to inventions they made or ability to license the invention to a corporation for product development. To resolve the serious issue of non-use and non-development of valuable technologies that were made with federal funds that could be used to benefit the public, the Bayh-Dole Act was enacted and is the primary statutory authority promoting the transfer of technology developed with federal funding to for-profit organizations, including small businesses. These organizations then assume the risk and potential cost of taking basic research funded by the federal government and developing it into products available to the public. The report of the Senate Judiciary Committee explained that the Bayh-Dole Act "is designed to promote the utilization and commercialization of inventions made with government support."ⁱⁱⁱ

To ensure that federal funding recipients license their technologies to corporate entities using reasonable terms that will support the development of inventions into products and bring them to the market, and to ensure that federally funded inventions do not languish unreasonably or are actively suppressed by a company, a march-in provision was included in the Bayh-Dole Act.^{iv} According to Senators Bayh and Robert Dole, the purpose of the march-in provision was to enable a government agency to act, such that if the “health and safety of our citizens is threatened by practices of a government contractor, then Bayh-Dole permits march-in rights, not to set prices, but to ensure competition and to meet the needs of our citizens.”^v Senators Bayh and Dole also stated in their response to the issue of NIH setting prices on drugs made in part with federal research funding: “Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.”^{vi}

In 1989, due to the concerns of rising drug prices, the NIH inserted a provision in its intramural collaborations with industry (not subject to Bayh-Dole march-in but similar to the agreement that an extramural contractor would use) that resulting inventions must demonstrate “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”^{vii} Subsequently, industry collaborations with the NIH intramural research program became far less frequent, and “[b]oth NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.”^{viii} As a consequence of this negative impact in NIH and industry’s collaborations and the development of new drugs and products, NIH removed this provision from its agreements.

NIH’s mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability makes it a leading agency that supports innovative research that benefits the public through the commercial development of new life-saving and life-enhancing products and services. Within the authorities of the Bayh-Dole Act, the NIH is willing to act if a company produces a drug or service using an invention made with NIH funding and does not take “effective steps to achieve practical application of the subject invention” or fails to satisfy “health and safety needs” by not ensuring broad availability to the public, patients, and physicians.^{ix}

ⁱ May 25, 2004, NIH held a public meeting to obtain information on price setting of drugs and services made with federal funds that is permitted under Bayh-Dole.

ⁱⁱ 35 U.S.C. § 202 and 37 C.F.R. 401, et al

ⁱⁱⁱ S. Rep. No. 96-480 at 3 (1979)

^{iv} 35 U.S.C. 203.1

^v “Statement of Senator Birch Bayh to the National Institutes of Health,” May 25, 2004, page 2.

^{vi} Senators Birch Bayh and Robert Dole’s March 27, 2002 in the *The Washington Post* in response to an article published March 27, 2002 by Professors Peter Arno and Michael Davise “Paying Twice for the Same Drugs.”

^{vi} National Institute of Health, “NIH response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests are Protected,” U.S. Government Printing Office, 2001, pg. 9.

^{viii} *Ibid.*, pg. 8.

^{ix} National Institutes of Health Office of the Director, “Determination in the case of Fabrazyme® Manufactured by Genzyme Corporation,” December 1, 2010. <https://www.ott.nih.gov/policies-reports>

Mr. COLE. We will next go to my good friend from Arkansas, Mr. Womack.

INSTITUTIONAL DEVELOPMENT AWARDS (IDEA)

Mr. WOMACK. Thank you, Mr. Chairman.

Dr. Collins, and to your team, thank you. Not lost on me is the fact that this panel before us is as dedicated to what you do as you are accomplished in your fields, and I am grateful, eternally grateful. I always enjoy being with you when we come to visit.

And, Dr. Collins, you know that coming from a small State like Arkansas, I have probably got a question about the Institutional Development Awards.

Dr. COLLINS. I am not surprised.

Mr. WOMACK. So here goes.

That program is a safeguard to ensure that NIH funding ends up in places where we don't have a real high success rate in applications. So what are you doing to ensure that the IDeA States are remaining competitive when they are applying for funding?

Dr. COLLINS. Well, we are very much a fan of that program. We know there is talent all over the country, and that includes in all 50 States, even though not all 50 States happen to have research institutions that are in the top 10 in the country.

But talent exists all over. And so the IDeA program provides an opportunity for the States in that group, 24 of them, to have a capability of being supported through special programs like the Centers of Biomedical Research Excellence, so-called COBRE programs, and the Network of Biomedical Research Excellence, the NBRE programs.

And when we look at the productivity of those, and we look closely, we are very pleased with what we see. And many times that has provided an opportunity for an investigator to get funding and then come back in a fully competitive application to NIH and receive funding for that as well. We have got a lot of success stories we can tell in that regard. We are pleased to see that in the fiscal year 2017 budget that you all approved there is an additional increment for the IDeA program.

Another thing we are excited about is the creation of an IDeA States Pediatric Clinical Research Network, which is part of the ECHO program, the new program that is looking at childhood illnesses, and particularly environmental influences. And having the opportunity to put this in place has been really quite exciting, because this greatly enlarges our opportunity. When there is a chance to look at asthma or a childhood cancer, we have got a broader array of network participants than we would have had before. So we are very much in this space.

Mr. WOMACK. You mentioned the networks.

Dr. COLLINS. Yes.

Mr. WOMACK. So how have the networks assisted in that broader biomedical research arena?

Dr. COLLINS. So the networks are State specific. And NBRE is an opportunity to give an award which brings together the research institutions in a particular State and convinces them of the value of working as a collaborative venture as opposed to isolated institutions. And if you talk to many of them—I have not been to Arkan-

sas, but I went to Louisiana and heard the stories there—this has been real glue, and glue with money attached to it, to encourage that kind of network building and sharing of disciplinary expertise and projects.

DRUG ABUSE

Mr. WOMACK. You should come to Arkansas. I will get the invitation to you.

My next question, I have got a couple of minutes remaining, I want to pivot over to Dr. Volkow.

Our Nation is incredibly impacted by drugs. There is not a person in this room that doesn't know somebody or related to somebody, myself included, in terms, you know, that is impacted. And this is a national problem, and even those that think they may not be impacted are impacted because of the indirect consequences of our inability to get in front of this problem, 52,000 overdoses just last year, 20,000 of them from opioid addiction. This is a top priority for our committee. It is, I think, a shared top priority for the Congress.

So, Dr. Volkow, as Director of the National Institute on Drug Abuse, what strides have you made and are making to enact positive outcomes to alleviate our country from such an awful epidemic? What can we do?

Dr. VOLKOW. Yeah. And thanks for the question.

And indeed this is a priority for HHS. It is a priority for the institute. And the first thing that we are doing is, of course, working collaboratively with our sister agencies. And then within our mission, we have a multipronged approach to address, number one, how do we prevent the prescription opioid epidemic that we are observing from occurring, from people becoming addicted to it, how do we prevent the overdoses, and for those that are actually already addicted, how do we treat it.

So in this respect, for example, the current treatments available for addiction of opioid use disorders have been developed out of research funded by the NIH. But we need much more.

So we have actually identified three areas for development of new therapies. One of them is we need additional medications for the treatment of opioid use disorders, and we are partnering with industry in that process. Number two, we need additional interventions to prevent and revert overdoses from opioids. And, number three, we want to actually contain this epidemic and prevent it from happening in the future, we need alternative, effective, and safe treatment for the management of chronic pain.

Mr. WOMACK. I appreciate that.

Mr. Chairman, before I yield back, this is a classic pay me now or pay me later proposition. I yield back.

Mr. COLE. I couldn't agree more. I thank the gentleman.

I now go to my good friend, the gentlelady from Massachusetts.

BIOMEDICAL RESEARCH

Ms. CLARK. Thank you, Mr. Chairman and Ranking Member DeLauro and Ranking Member Lowey.

I thank you, Dr. Collins, and your entire team for the work you do and for being here. I am so supportive of your efforts, as I know

everyone on this committee is, and it is one of the few bipartisan bright spots that we can agree on this. And I think the 2017 budget that we passed was such a positive step, and I have been so concerned about the proposed cuts and the devastation that would have.

But I have two questions for you, Dr. Collins. One is, as you said, we are now doing inflation plus 5 percent. That is positive. But this is one of our best examples of using public resources to partner with private enterprise. And other countries are making investments at rates that far exceed what we are. I hear from private companies in my district that their talent is being recruited and their research is being outpaced in China, Singapore, Brazil, Israel.

If you can give us some context to what you are seeing in competition. We know the human toll if we don't do research. What is the economic toll for the future of the United States and our innovation economy if we do not support the NIH at higher levels?

And second is you mentioned the importance of consistency in funding. I think a great example of that is in my own district in the Framingham Heart Study that next year will mark 70 years, of third generation of Framingham citizens who are participating in this study. And I wonder if you can talk about particularly the value of that research and, sort of more generally, the value of that long-term research that comes with consistency of funding.

Dr. COLLINS. Great questions.

So with regard to what is the situation with America and the rest of the world in terms of competition, first let me say, the economic case for support of biomedical research has been analyzed by many experts, and it is very compelling. NIH currently supports 379,000 jobs in the United States directly, and those are high-quality, high-paying jobs.

But if you consider the whole ecosystem that builds upon NIH discoveries, that is about 7 million jobs, including the biotech and the pharmaceutical industry. And the return on investment is estimated that every dollar that you all allocate to NIH over the course of 8 years returns \$8.38 in terms of return on investment and economic growth as a consequence of that. That is a pretty good turnaround.

And there are a few stunning examples. I won't be able to resist mentioning the Human Genome Project that was one of them where the money that was put into that now estimates 178 to 1 return on investment in terms of the economic benefits that have come forward to the United States because we led that effort. And we still lead genomic research and all the technologies that come out of that.

Other countries, though, as I said earlier, have read this playbook, and they are very much seeking to do the same sort of thing. And China in particular, on the course they are, will be spending, not just as a percent of GDP, but in total dollars more than the United States, depending upon which curve you look at, around 2021, not that far off. And they are building universities and they are building laboratories and putting a great deal of funds into that. And many very talented scientists that we were confident we could recruit and retain in the United States now go back to China for wonderful offers.

So we have to think carefully about that. If this has been such a strong engine for our country in terms of economics, in terms of health, we don't want to see that engine struggle, and that is very much what your committee has been, gratefully, focused on.

Your question about consistency is also critical, because many of the projects we are talking about, many of them are not 70 years like Framingham, most of them on the average are at least 4 or 5 years, and to be able to plan for that.

FRAMINGHAM HEART STUDY

Ms. CLARK. We are very exceptional.

Dr. COLLINS. Maybe I will ask Dr. Gibbons to say a word quickly about Framingham in the last 35 seconds just to say what an amazing example that is.

Dr. GIBBONS. Yes. The Framingham Heart Study has been an iconic program, as you pointed out, reaching its 70th birthday. Yet it remains very vibrant. It clearly underpins all of our advances in reducing cardiovascular disease by identifying risk factors.

And it has been reinvented in the last decade. It is now the cornerstone of our Transomics for Precision Medicine (TOP Med) program, where we are now layering on the new technologies of genomics in that cohort. It is going to be telling us a lot about the problems, for example, of Alzheimer's disease and vascular dementia. We need to understand the other factors that are critical mediators of those processes and at least identify the new drug targets for tomorrow's breakthroughs. It is still going to continue to pay great dividends.

Ms. CLARK. Thank you.

Dr. COLLINS. And forgive me. Even though this seems like a big investment, when you consider the consequences, that drop in heart attack and stroke that we talked about, 70 percent decrease, if you figure out what was NIH's role in that, it was major, and it cost each American about the cost of two lattes per year.

Ms. CLARK. Wow. On that note, thank you, Mr. Chairman. I yield back.

Mr. COLE. Thank you.

I next go to my good friend, the gentleman from Maryland, Mr. Harris.

MEDICAL MARIJUANA—THERAPEUTIC USES

Mr. HARRIS. Thank you very much.

Good to see all of you again.

Dr. Volkow, I am just going to ask you a very brief question about a topic that has come up in Maryland, and it has to do with marijuana, medical marijuana and the uses of it. We had a bill in the Maryland legislature that would have added treatment of opioid addiction to one of the indications for medical marijuana. Is there any basis for that in scientific research?

Dr. VOLKOW. Thanks very much for the question. And, unfortunately, there is no evidence that marijuana can be used for the treatment of opioid use disorder. But the question does highlight the need, that actually there is an urgent need for more research to understand better the effects of marijuana, because people

across the country are taking it believing that it is beneficial for their ailments, and yet the evidence is not there.

Mr. HARRIS. And I know that we actually have a bipartisan bill we are going to file very soon that will attempt to make it easier to do medical research, not reschedule it, not make it more widely available except to bona fide researchers. Is that something that is a good idea for the country?

Dr. VOLKOW. I think that would be a very good idea. That would help accelerate our knowledge about what is it that cannabinoids can do and what is it that they don't do and how can they be harmful or beneficial.

Mr. HARRIS. Okay. And could you just, off the top of your head, just name all the diseases where there is solid scientific evidence that it is the best drug to use, medical marijuana is the best drug to use to treat something?

Dr. VOLKOW. I do not know that there is any one study that has shown that marijuana is the best drug for a particular disease. I would say from the perspective of what is the strongest evidence for potential therapeutic benefits for marijuana, we know that one of them is an analgesia, another one is as an anti-nausea, and there is some low evidence that it may be useful for glaucoma.

Mr. HARRIS. And maybe spastic diseases, I think, too—

Dr. VOLKOW. Correct.

INDIRECT COST TO UNIVERSITIES

Mr. HARRIS. But it is a very limited amount. That is what I thought.

Could I have—I think I have a couple of slides lined up here, since we are showing slides today. Who do I to ask to get—

Dr. COLLINS. You ask me, and there it is.

Mr. HARRIS. Oh, there it is. Thank you very much. Thank you. And I guess this is the only one I want, except the only thing I want to point out is I have another slide, but I don't need to show it. You know, indirect costs over at the NIH are over \$6,500,000 a year. And, again, I know, because I have seen the budgets of grant requests, I mean, indirect costs are not paying the researchers, they are not paying for whatever you need directly to conduct your experiment. They are overhead costs. I mean, we would call it overhead, I guess, the common person. But what is the average indirect cost that the NIH pays to universities?

Dr. COLLINS. Thirty percent of the total cost is the average.

Mr. HARRIS. No, but the addition, because indirect costs are the grant plus a certain amount. What is that certain amount?

Dr. COLLINS. About 50 percent.

Mr. HARRIS. Fifty percent. Okay. So the American taxpayer is paying 50 percent.

Now, if a university writes a grant to the American Lung Association, they pay zero percent overhead costs; and if they write a grant to the American Heart Association, it might be up to 10 percent; Alzheimer's, 10; March of Dimes, 10; Juvenile Diabetes, 10; Bill and Melinda Gates, \$4,000,000,000 in grants, 10 percent to universities; and Robert Wood Foundation, they are generous, they are at 12 percent.

It sounds like there is a different standard for the American taxpayer, that the American taxpayer pays a whole lot more for indirect costs. Now, some of these are to universities. And remember, some universities declared themselves sanctuaries. So that, you know, the Federal Government is not good enough to describe immigration law, but, boy, they are good enough to take \$6,000,000—\$6,000,000,000, I am sorry, wrong letter in front, \$6,000,000,000 a year to help fund our overhead.

Why do you think it is not the American taxpayer paying far more than private—these nonprofits? And we assume—we are a nonprofit, we are just the largest nonprofit in the world, I guess. Why is this not—why is this reasonable? Why should we pay more than these other nonprofits, my taxpayers, people in the First Congressional District? And we all want research, but if we freed up this \$6,000,000,000, we have heard the effect of \$6,000,000,000, if we freed up a significant amount of that, we could fund thousands of more grants.

Dr. COLLINS. So this is a topic of great interest right now, and you are contributing to it, I think, by raising this question about why these differences exist. Presidents of universities that do a lot of research would tell you that they can afford to absorb the costs of taking on grants from foundations of this sort because it is a small proportion of their budget. But if they were asked to do that with the majority, which tends to be, if it is biomedical research, the NIH, many of them would not be able to continue the effort, they would need to drop out, particularly public universities that don't have large endowments.

But I do think there is an important issue here. People don't realize how these indirect costs are set. They are set by a guidance that is put forward by the Office of Management and Budget and reconfigured every 4 years in a negotiation that goes on between an office in HHS, the Division of Cost Allocation, and universities. We don't play a role in that. We are simply told what is the indirect cost rate for that institution.

I would say universities will also argue that a lot of the cost that they are asking for help with is because of bureaucracy that we put down upon them. And this might be a really good moment to revisit a lot of the regulations that we have asked them to put forward, things like effort reporting, which take a lot of time, that don't really accomplish very much. I think it would be useful to perhaps open up that conversation, think about our contract with our institutions.

But I do want to say that universities would argue, and I will just echo their statements, that they are already paying well over the cost of research that they would be doing if we were fully loaded in our reimbursements. Talk to your friends at Hopkins. Paul Rothman will tell you the hundreds of millions of dollars that they have to put in of their own money in order to keep their research operation going.

Mr. HARRIS. Sure. Thank you. And I agree, we should look into those regulatory burdens.

I yield back.

Mr. COLE. I thank the gentleman.

We will next go to my good friend from California, Ms. Roybal-Allard.

ENVIRONMENTAL INFLUENCES ON CHILD HEALTH OUTCOMES (ECHO)

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

And welcome, Dr. Collins and panelists, and thank you for everything that you do.

Dr. Collins, as you know, I and other members of this subcommittee have been strong long-time supporters of the National Children's Study. We are anxious to hear a progress report on the environmental influences on child health outcomes, the initiative that was subsequently created to meet the goals of the NCS, because we believe it is vitally important to investigate the impact the environment has on the health and development of children.

That is why I was pleased to see since our last meeting that Dr. Matthew Gilman has joined the team to head up the initiative. I am also pleased that 34 ECHO grants have been awarded to a series of existing cohort studies.

Given the NCS original plan to recruit child-bearing-age women and follow their children through adulthood, I am particularly interested in how many of the cohorts you awarded included mothers during pregnancy or preconception. Can you provide us with a summary analysis of the characteristics of the cohorts that were funded?

Also, what are the next steps for getting this program up and running? For example, are you asking the existing cohorts to expand what they are already doing in order to meet the research goals of the original NCS?

Dr. COLLINS. We are very excited about the ECHO program, and thank you for asking about it. Some 84 cohorts have now been brought together as part of this study to try to learn everything we can about environmental influences on child health. Three-quarters of those 84 cohorts were involving women who were enrolled preconception or during prenatal time.

So we have a lot of data there in the earliest stages of development. We have now, because of those cohorts, have the opportunity to start following more than 50,000 children, so the size is substantial, and Dr. Gilman has turned out to be a very skillful project manager for this effort.

All together, this means we are funding something like 44 States to take part in this, and we are looking at ways that the whole can be a whole lot greater than the sum of the parts by adding additional kinds of measurements as we follow these children and their parents that were not contemplated as part of the original cohort studies.

The group has coalesced quite nicely. The leaders of these efforts are meeting monthly to design ways in which this project could be even more bold than we might have imagined to begin with. And we have an external scientific advisory group that will meet for the first time on May 31, which I will be there to give them a charge and to listen to their thoughts about how we can manage this program in the most responsible way possible.

On top of that, the ECHO program, as I mentioned earlier, also funds this IDeA States Pediatric Research Network, which is an

additional resource that we think is going to be extremely valuable for carrying out pediatric trials in States where previously we didn't have the opportunity to do so.

CHIMP ACT

Ms. ROYBAL-ALLARD. Right. That is good news. Thank you.

Dr. Collins, with the passage of the CHIMP Act in 2000 and with the CHIMP Act amendments in 2013, Congress has shown strong bipartisan support for the retirement of federally owned research chimpanzees to Chimp Haven, which is a national primate sanctuary. I know that the humane treatment of these primates in retirement is a priority for you also and that NIH has made a commitment to moving all remaining chimps to Chimp Haven as soon as possible. However, I am concerned that 4 years have passed since the passage of the CHIMP Act, and a large number are still languishing in laboratories, mostly because of the lack of sanctuary space.

My question is, is it true that we pay 100 percent of the cost to keep chimps in laboratories but only 75 percent of the cost to care for them in sanctuary, which is much less expensive? And is it also true that over the last few years, the CHIMP Act, which requires the Federal Government to pay 90 percent of sanctuary construction costs, that Chimp Haven has had to take on that full responsibility?

Dr. COLLINS. I appreciate your interest and concern about this issue, and I share that. I have spent a lot of my own personal time trying to be sure that we are moving away from a time where chimpanzees were utilized for research to a time where we are retiring them all to sanctuary. That is NIH's commitment based upon a National Academy study and our own internal deliberations.

It is challenging, though, to achieve the retirement. This past year, 44 chimpanzees were moved from their existing locations to Chimp Haven. Chimp Haven, because of the need to incorporate those chimps, who often come with their own social groups, needs time with each shipment to be able to accommodate that. So they have asked us not to send more than one shipment per month, and a shipment is no more than nine animals. That is why it has only been 44 animals in the past year and it will be hard to go above that.

So at the moment, actually the limiting factor is not space in Chimp Haven sanctuary, it is the pace of being able to do the transfers.

We now have a very good system where the veterinarians work together to be sure that everything is being done in the fashion that assures the best likelihood of a good outcome for the transfer. I am personally informed weekly about how this is transpiring.

You are right that the way the CHIMP Act was written, we support 75 percent of the care in Chimp Haven, whereas we were supporting 100 percent in the research laboratories, but that is just basically what the law says. We are 100 percent in favor of moving along with the retirement, but realistically, considering we still have 350-some chimpanzees that have not yet made it to sanctuary, it is going to take us several more years.

Ms. ROYBAL-ALLARD. Okay. And I have some other questions that I would like for you to respond to for the record.

Dr. COLLINS. Be happy to.

Mr. COLE. Okay. We will next go to my good friend from Washington, Ms. Herrera Beutler.

NIMH SUICIDE PREVENTION EFFORTS

Ms. HERRERA BEUTLER. Thank you, Mr. Chairman.

I have a couple questions, and I think I am going to start with—I believe they will go for Dr. Gordon. And I am just going to read them so I get it right.

In 2014, suicide was the leading cause of death in youth ages 10 to 24 and young adults ages 25 to 34, and ultimately suicide claimed the lives of over 12,000 people in these age brackets in 2014 alone. And in the city of Battle Ground, which is where I live in Washington State, these troubling statistics have manifested in increasing trends of mental illness issues, depression, and suicide ideation among students. And, I mean, we have been going through it.

Both the city of Battle Ground and the Battle Ground school district have taken steps, any steps that they can, quite frankly, offering counseling, mentoring. And despite their best efforts, I think Battle Ground still is constrained by the resources and continues in honestly understanding how to confront this public health crisis.

So I am aware of the efforts to prevent teen suicide through your Pathways to Prevention workshop. And in that vein, what new research will the Institute of Mental Health be focusing on related to prevention and preventing teen suicide, and is there anything NIH can recommend, quite frankly, to assist this community and others across the country in their ongoing effort? We can't wait years and years for research in this situation.

Dr. GORDON. No, we can't. Suicide prevention is a priority from a research perspective at NIH and from a care perspective throughout HHS. And you are right, we can't wait years, and this is a short-term research need.

The good news is we are putting a lot of resources into this effort, we are putting a lot of resources into efforts that we hope would pay off in the short term, so we hope to be able to bend the curve. But it is a very challenging curve to bend. As you know, the rates are not just high among youth, they are rising, and they are rising nationwide, and they are rising in almost every age group.

Ms. HERRERA BEUTLER. And they are rising across class and gender.

Dr. GORDON. That is correct.

Ms. HERRERA BEUTLER. I mean, it is really phenomenal.

Dr. GORDON. That is correct.

Particularly with regard to youth suicide, there are several things which we are confident in but really need a little bit more research in terms of helping roll it out.

So, for example, the most important thing that you can do is ask about suicide, right? And people are often afraid to ask about suicide, but, in fact, it has been shown in study after study that asking doesn't raise risk, it lowers risk.

And, in fact, a questionnaire that is essentially—it is a very simple four-item questionnaire that was developed in the Intramural Research Program at NIMH and tested across the country at several different academic institutions both here in D.C., in Massachusetts, in Ohio, has shown to dramatically increase the number of at-risk youth who are identified. And this questionnaire is being used in all sorts of settings, but primarily in healthcare settings.

We have several studies that are aimed at this questionnaire and other questionnaires like it to try to demonstrate definitively that it works, but more importantly, to show how it can be rolled out into communities.

So that is just one of actually more than five studies we have specifically targeted at youth suicide trying to look at identification. And then, of course, once you identify at risk youth, you need to know how to treat them. And so we have active programs in trying to figure out what are the best ways to prevent suicide once the high-risk youth are identified.

Ms. HERRERA BEUTLER. Thank you for that. And I would love to receive that information if that is something you would be willing to pass along.

Dr. GORDON. Sure. We can do that through the record.
[The information follows:]

NIMH Suicide Prevention Efforts

For example, NIMH funded a large-scale study, the Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE), on universal screening for suicidal thoughts among emergency department adult patients. This screening doubled the rate of detection, which translates into the potential for 3 million more at-risk individuals who could be identified and helped.

Building on ED-SAFE, NIMH currently funds the Emergency Department Screen for Teens at Risk for Suicide (ED-STARS) in a network of hospital emergency departments across the country to develop and test a personalized, computer-based suicide risk screening tool for teenagers.

We also fund “Zero Suicide” practice-to-research efforts, creating a stronger basis for dissemination and large-scale implementation of effective risk detection, intervention, and service delivery strategies for suicide prevention.

As well, we support suicide prevention research focused on vulnerable populations such as youth, individuals transitioning from incarceration, and American Indian/Alaska Native people.

Suicide Rates

Over the past 15 years, suicide rates have increased for both males and females. According to the Centers for Disease Control, the 2015 National Survey on Drug Use and Health found that the rate of completed suicide for males remains approximately four times higher than that for females, while females are more likely to attempt suicide.

NIMH funds studies that take into account the differential rates of suicide events in clinical populations. One study includes college females and males at a ratio of 2:1 and is designed to determine if certain interventions work equally well for females and males. As well, one of the NIMH-funded Zero Suicide studies enrolls teen girls and boys at a ratio of 2:1, and will investigate gender-related differences in the effects of treatment.

Race and ethnicity also play a role in suicide rates. Suicide rates are highest among American Indian/Alaska Native men and women, followed by White/non-Hispanic men and women.

Suicide Screening Questionnaire

The four suicide screening questions asked on the questionnaire are: In the past few weeks, have you wished you were dead? In the past few weeks, have you felt that you or your family would be better off if you were dead? In the past week, have you been having thoughts about killing yourself? Have you ever tried to kill yourself? These questions quickly assess a patient’s risk and help to determine if they require a safety evaluation before discharge, or if they are at imminent risk. This questionnaire is in the public domain and can be found on the NIMH website by searching “suicide screening.” (<https://www.nimh.nih.gov/news/science-news/ask-suicide-screening-questions-ask.shtm>)

Detection and Suicide Prevention

The “Zero Suicide” effort is one example of NIMH efforts aimed at figuring out the best way to prevent suicide once risk is detected.

STUDIES ON POSTPARTUM DEPRESSION

Ms. HERRERA BEUTLER. And let me move over, I mean actually stick with you, but issues. Perinatal depression is one of the most common medical complications during pregnancy and the postpartum period, impacting one in seven women. Perinatal depression and other mood disorders, such as bipolar and anxiety disorders, can have a horrific effect on women, infants, and families. In fact, maternal suicide exceeds hemorrhage and hypertensive disorders as a cause of maternal mortality.

I had no idea, although I have a son who is about to turn 1 this week. And that fog of war that happens, especially when you are adding to your family, you already have one, is quite something.

And suicide and overdose are the leading cause of maternal mortality in a growing number among States. And given these trends, I wanted to talk about what your—in terms of prioritizing research in pregnant and postpartum women. And I have a bill on safe medications, and so we are interested in this space.

Dr. GORDON. That is really wonderful to hear that you're interested from a legislative perspective.

I come at it from a very personal perspective, I had a patient I treated for years and years, stable on medications with bipolar disorder. She wanted desperately to have a child and we took every safeguard we could. She was fine through the pregnancy and absolutely had a devastating year-long fight with postpartum depression that led to several suicide attempts and months in the hospital. And that is a patient I care deeply about fortunately, I can say that she recovered. But we were at a loss, because every medicine we had ever tried on her failed, electroconvulsive therapy failed, and it was a very challenging situation.

So we need to know more about what makes postpartum depression different from other forms of depression and what forms of treatment work in there in that setting.

Currently, we support research on psychosocial interventions, and we have several grants that we are supporting in that area for postpartum depression. We also have several treatment studies on antidepressant use in pregnant women to try to find out will that actually help forestall, and is it, as you mentioned, is it safe. There are safety concerns as well.

So this is an area of active investigation for us that we are deeply committed to, and I am happy to provide the details afterwards for the record.

[The information follows:]

NIMH STUDIES ON POSTPARTUM DEPRESSION

NIMH-funded efforts to understand postpartum depression range from basic science to identify biomarkers of risk, to research on social factors, to services and interventions research. NIMH also supports research to advance treatment for women with postpartum depression, including psychosocial interventions and antidepressant use in pregnant women. Ultimately, we hope that this research will help us learn more about how pregnancy interacts with risk for certain mental illnesses—including depression—and effective treatment interventions.

Ms. HERRERA BEUTLER. I would love to have that. Thank you. I appreciate it.

Mr. COLE. I thank the gentlelady.

We will next go, finishing out the first round, to my good friend, the distinguished Subcommittee Chairman for Energy and Water, Mr. Simpson from Idaho.

INDIRECT COST

Mr. SIMPSON. Thank you, Mr. Chairman.

First let me say how glad I am and appreciative of the job that you and the Ranking Member did on this appropriation bill with NIH. It shows the bipartisan effort that we can do, and it is vitally important.

I am not one who is easily impressed, but I am always impressed when I come out to the NIH and talk to you all and your researchers out there about the work that you do, and it is one of the fascinating places to go.

And as I have said repeatedly, I say this in Idaho speeches, that it is the best kept secret in Washington, D.C. They do such great work out there, but a lot of people don't know what NIH is and the impact that it has because of all the extramural grants that you have to give out. So, Johns Hopkins gets all the credit for this and all that kind of stuff, but it is funding that comes from the taxpayer through you to do a lot of that research, and it is one of those things we need to continue to work on.

A follow-up on what Mr. Harris was talking about on the indirect costs. You know, it is great if you can reduce the indirect costs and make it make sense and you can put more money into the research and we could, as he said, fund thousands of more research products. The problem is, is you are not funding thousands of more research products if at the same time you are cutting the budget by \$5,000,000,000 or \$6,000,000,000. If you are saving money there and can put it into research, that is great. So we need to be clear about what we are talking about here.

And the question I was going to ask was actually addressed by Mr. Womack, and the need for some of these smaller States and their research universities and those types of things and some of the incredible work that they do. And I know it is not your job to make sure that all the money is funded fairly throughout the country and so forth, your job is to get the research done at the best place to do it.

But as you are well aware, there are many smaller States that have research capabilities and are developing more and more research capabilities. Boise State University is doing some great biomedical research. When I look at the dollars that are being spent in Idaho versus Montana or the Dakotas or Utah or something like that, you know, your first reaction is, well, that is not quite fair.

I think they just don't know the opportunities that exist. And what I would like to invite you to do is when you stop in Arkansas to see Mr. Womack, get back on the plane and come to God's country in—

Mr. COLE. You mean Oklahoma?

IMPACT OF 16-DAY SHUTDOWN

Mr. SIMPSON. Yeah. You passed right over Oklahoma.

And stop. And I would ask that you—you know, I know if you can't make it out there, what I would like to do is ask you to sit

down with the researchers at Boise State University and the other research institutions in Idaho and talk about the collaboration and the efforts that they can have of the opportunities that they might have to work in some of these areas, but they are really developing some great capabilities in some of these smaller States. And I know you know that.

So the question I am going to ask is one that—I have given this answer many times, but when we were out visiting NIH a year ago, year and a half ago, something like that, two years ago maybe it was, one of the Members that was with us asked you a question. And I have repeated this answer many times, but I think you need to repeat it for the public record, especially since I have seen individuals say that maybe what we need is a good government shutdown in September. First of all, I have never seen a good government shutdown.

What was the impact of the 16-day shutdown, the last shutdown we had, on NIH, and how did it affect you and your colleagues?

Dr. COLLINS. It was probably the darkest hour that I have experienced since I have been the NIH director, and it is now 8 years. For those 16 days, all of our intramural scientists were sent home, because they were not allowed to come to work. They were even told they might be prosecuted if they did. That meant that experiments that were in the middle of being conducted, many of them which take many days, were wasted.

The most heartbreaking part was what this required me to do as far as overseeing our Clinical Center, the largest research hospital in the world, where we basically had to turn patients away who had, many of them, been scheduled for weeks or months to come, oftentimes because we are the court of last resort.

That is what the NIH Clinical Center does. People come there when everything else has run out of possibilities and we have an experimental protocol they are willing to try. And except for a few patients each day who were literally in an extreme circumstance of potential imminent death, we had to turn away everybody else, and for 16 days hopes were dashed.

That was a deeply, deeply troubling circumstance that I hope never would be repeated.

Meanwhile, all of our extramural efforts, we had to cancel thousands of peer review sections that were scheduled to review grants, and all of those had to somehow be quickly rescheduled after the 16-day period started up again. Enormously challenging and stressful for everybody. We were determined not to have it result in a slowdown of grant reviews, but it was painful, to put it mildly.

So my hope would certainly be that whatever we have to do to figure out budget circumstances, that a shutdown would not be on the list of options. For us, it was just purely destructive.

Mr. SIMPSON. I thank you for that answer. It is good for the public to know that, because oftentimes we hear, you know, out in the hinterlands when we go home or something like that, "Well, you know, the shutdown didn't affect me. What the heck?" It has a real impact, and people need to know that. As I have said, I have repeated your answer many times in talks that I have given and stuff.

So, I appreciate and thank you all for the work that you do. It is incredible stuff.

Mr. COLE. I want to thank my friend for a great question.

And just a little piece of advice, Dr. Collins. When you go to Idaho, as I am sure you will, try to pick football season. My guys at the University of Oklahoma will tell you they play pretty good football out there too.

Dr. COLLINS. Sounds like I am going to be traveling a lot this year.

Mr. COLE. We can arrange your fall schedule.

Mr. SIMPSON. Yes, we can.

H7N9 BIRD FLU

Mr. COLE. But just in the interest of time, I want to advise my colleagues we are going to try and cut to 2 minutes so we can get as many additional questions as we can in. And let me begin that round.

Dr. Fauci, I understand that while the H7N9 flu virus circulating in China right now is not easily transmitted, or not yet at least, easily transmitted between humans, it has shown signs it really could be a lot deadlier than other flu strains that we have seen circulated in the United States. So would you please tell us what both you are doing at the NIH and NIAID is doing to better understand the virus and prepare?

I mean, sadly, we have all learned we are only one pandemic away from a real challenge, and these things seem to be popping up, if anything, more frequently than they did and moving much faster than they did in previous eras.

Dr. FAUCI. Thank you for the question, Mr. Chairman.

The H7N9 bird flu, which is an influenza that affects chickens, predominantly in China, what we saw starting in 2013 was the ability of that virus to jump from the chicken to a human. In humans, it causes very serious disease, and has caused 30 or more percent mortality.

Fortunately, it jumped from chicken to human, but did not develop the capability of going efficiently from human to human. But every single season from 2013, 2014, 2015, and 2016, we have had cases of a virus that keeps recurring. In 2017, what we have seen is a virus that has reemerged as a slightly different strain in a way that is not covered by the vaccine that we made back in 2013 and put in our stockpile.

So the major effort underway right now, together with the PHEMCE group that I just described a few minutes ago, is to develop a vaccine that would be specific against this particular strain of the H7N9 virus. And we are working together with the CDC, the FDA, and BARDA, and pharmaceutical companies to be able to get that into the stockpile in case that virus does develop the capability of spreading from human to human.

One last thing to mention for a few seconds. This is the reason why we need a universal influenza vaccine and what we are putting a lot of effort on, so that we don't have to be constantly responding to potential pandemics and seasonal flu. But maybe I could provide additional information that at another question.

Mr. COLE. Absolutely. And it is also the reason why we need to maintain a very robust capability, which was one of the points I wanted to make. This is not something—we can't recreate what you guys do overnight. And so if you don't have it and maintain it, you don't have the ability to respond when something like this pops up.

With that, I want to go to my good friend, the gentlelady from Connecticut, the ranking member.

DEVELOPMENT OF UNIVERSAL INFLUENZA AND MOSQUITO VACCINES

Ms. DELAUB. Let me pick up on that, and I am going to try to get in a couple questions here. But my question was to follow up on the vaccine, which is, where are we on the long term to developing a universal vaccine?

And then you have got the issue of a broad spectrum response to mosquito-borne flaviviruses, if that is what they are called, Zika, Dengue, West Nile, Yellow Fever, in terms of one product, if you will, dealing with that.

And then, Dr. Collins, I want to ask you about the impact of the hiring freeze on the NIH's ability to conduct and support biomedical research.

Dr. Fauci.

Dr. FAUCI. For the universal influenza vaccine, on May 23, literally in a few days, several of our scientists will be meeting with individuals in Palo Alto who are putting together a program of consortia of a meeting that we will be holding here in the Rockville area in the third week in June to get the best scientists in the country together to have a consortium of an effort to develop a universal influenza vaccine. I can't tell you exactly when we will have a universal vaccine, but the scientific advances are substantial, and we are doing it as a consortium, the same way we did many years ago when we put people together to create the Vaccine Research Center. It will be a center without walls. And we are going to be aiming towards that.

I will give a final answer to your question about maybe a universal type of vaccine against mosquitoes. There is a very ingenious approach that though I can't tell you it is going to be ultimately successful, is essentially to develop a vaccine against proteins in the saliva of a mosquito. When the mosquito bites there will be an inflammatory response around the bite area which would prevent whatever microbe, Zika or Chikungunya or any of the other flaviviruses or other viruses or even malaria, to block the microbe before it actually disseminates through the body. That is being started right now at the NIH.

HIRING FREEZE

Ms. DELAUB. Yay.

Dr. Collins, hiring freeze.

Dr. COLLINS. Very quickly on the hiring freeze. Every time there is a change in administrations, those of us that have been around a while recognize that a hiring freeze is likely to be imposed as the new group comes to town and figures out how they want to manage.

We have, of course, a particular circumstance where we, with a very large staff, 17,000 people, and patient care responsibilities,

have a particular need to be able to keep things moving. We were pleased that patient care positions were exempted from that, so we have been able to continue to staff our Clinical Center for the most part, with some exceptions of things that were still being studied.

And we have very recently, working with the Department, with Secretary Price, been given an opportunity to proceed with other critical hires, such as what we need now to staff up the Precision Medicine Initiative, the All of Us Program that is going to enroll a million Americans over the next two or three years and aims to launch in the next few months and needed some very senior staff to manage it, and they have given us a green light for that.

So, we are hopeful that this difficult period, which happens every time there is a change in administrations, is beginning to settle out.

Ms. DELAUBO. Thank you, Mr. Chairman.

Mr. COLE. Thank you very much.

We will go next to my good friend, the Ranking Member of the Full Committee.

LACK OF DETECTION METHODS FOR CERTAIN CANCERS

Mrs. LOWEY. Dr. Lowy, I am particularly concerned, as you know, about a lack of early detection tools for certain cancers, in particular kidney and pancreatic cancer, which can often develop into an advanced stage before a patient may even know he or she is sick. If you can tell me what research is NIH supporting to lead to early detection of these cancers.

And the development of immunotherapy has been a great public health achievement, leading to lifesaving outcomes for some cancer patients. However, immunotherapy is not an option for all cancer patients. Why is this the case? Are there ways to bridge this gap so that more tailored cancer treatments are available to more patients.

In about 1 minute.

Dr. LOWY. Thank you, Congresswoman Lowey.

So, first, in terms of early detection for pancreatic cancer and kidney cancer, we certainly share your concern, and the NCI is supporting research in both of these areas. With pancreatic cancer, we have joint programs with the National Institute of Diabetes and Digestive Kidney Diseases, particularly focused on diabetes as a potential biomarker for early steps in pancreatic cancer.

For kidney cancer, the two principal areas right now are imaging, where sophisticated imaging processes are able to detect cancer at an earlier stage than with older forms of technique, and, in addition, there is some sense that urine tests for kidney cancer and also for bladder cancer could be hallmarks. These are areas of active investigation.

In terms of your second question, we certainly share your interest in and concern about immunotherapy, which has in many ways revolutionized the treatment of cancer, and not just one form of cancer, but many forms of cancer. Thanks to the generous support of your Committee and the Congress, the Cancer Moonshot is supporting a major initiative to try to understand why is it that some patients and some cancers make a strong response to immunotherapy, whereas others don't.

Thank you very much.

Mrs. LOWEY. Thank you.

Thank you, Mr. Chairman.

Mr. COLE. Absolutely.

The gentleman from Maryland, my friend Mr. Harris.

BIODEFENSE SPEND PLAN

Mr. HARRIS. Thank you very much.

And just to follow up with the gentleman from Idaho about shutdowns, look, I was disappointed the Senate Minority Leader basically was threatening to shutdown the Government over, you know, not building a southern border defense. I can't understand that.

I hope this administration will be different than the last administration, though, in determining that the NIH is essential to protecting human life and property, because the President does have the ability to designate the NIH is important to human life and property.

Just to the Director, I hope that we take a careful look at the human-animal Chimera research and make sure that all adequate ethical protections are in place, because it is kind of an interesting type of research on the horizon, and that we audit fetal tissue researchers. The Special Investigative Panel on Infant Lives noted and found that there are investigators who are probably acquiring tissue that is not in compliance with statutes regarding acquisition, and I would hope that the NIH is willing to audit that at some point.

Anyway, Dr. Fauci, my question to you is specifically about biodefense measures. And my understanding is that some of—about 15 percent of the funding administered by the NIAID actually is spent on threats that are termed to be material threats.

Is there a biodefense spending plan from NIAID looking into the future? I mean, because I view your institute as kind of critical to this. Is there a long-range plan—

Dr. FAUCI. Yes.

Mr. HARRIS [continuing]. About what is needed?

Dr. FAUCI. Thank you for that question, Dr. Harris.

There is a long-range plan. And what we have been doing is transitioning over to the strategy of developing what we call universal platforms to be able to respond to many organism, as opposed to picking out this organism, that organism, and the other, because if you guess wrong, you put a lot of investment and you risk not having anything to be able to show for it.

So the vast majority of what we are doing right now, for example, in the arena of vaccines, is to develop the 21st century version of the vaccine rather than having to grow an organism attenuated or kill it and then developed it into a vaccine. And we are doing the same thing with universal platforms for diagnostics, that you could just plug it in to a single platform and know right away what organism you are dealing with. That gets away from the guessing game, that sometimes is not a good investment.

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

Mr. COLE. We will next go to the gentlelady from California, Ms. Roybal-Allard, and then Ms. Lee on the second round.

TRANS-DISCIPLINARY APPROACH TO PRECISION MEDICINE/CANCER
MOONSHOT

Ms. ROYBAL-ALLARD. Dr. Collins, the National Institute of Nursing Research supports scientific studies that build the foundation for clinical practice that promote health and prevent illness, manage and eliminate symptoms caused by illness, and enhance end-of-life and palliative care. Unfortunately, funding for the NINR has remained flat at less than half of 1 percent of the total NIH research budget. And I am going to just ask you to submit this, in the interests of time.

Will you please submit highlights of the findings from NINR research studies that have resulted in improved quality of care and/or lowered health care costs? What percentage of studies in other NIH institutes are conducted by nurse scientists? And how is NIH working to promote a trans-disciplinary approach in its initiatives like Precision Medicine and the Cancer Moonshot?

[The information follows:]

Trans-Disciplinary Approach to Precision Medicine/Cancer Moonshot

The Precision Medicine Initiative, touches every aspect of biomedical research, requiring trans-disciplinary approaches to ensure the Initiative's success. For example, nurse scientists within the NINR intramural and extramural research communities are actively engaged in research to move the concept of precision medicine into every day clinical practice and patient care, particularly in the area of symptom science.

Another aspect of the Precision Medicine Initiative, the *All of Us* Research Program will gather data over time from 1 million or more people living in the United States, with the ultimate goal of accelerating research and improving health. Unlike research studies that are focused on a specific disease or population, *All of Us* will serve as a national research resource for all research communities to inform thousands of studies, covering a wide variety of health conditions. NINR participates in a trans-NIH group that is helping to define the scientific priorities for *All of Us* over the near and long-term.

In keeping with the trans-disciplinary nature of the Precision Medicine Initiative, NINR-supported scientists across the U.S. are exploring how differences in individuals' genes, environments, and behaviors affect how they experience the adverse symptoms of illness and how these symptoms can best be managed. For example, nurse scientists are using genomics to examine the microbiome of preterm infants to determine the link between the microbiome and infants' health, growth, and development over time.

NINR intramural researchers examined a protein in the brain known as tau as a potential biomarker for predicting recovery times for athletes with a sports-related concussion, a group at risk for long-term symptoms and deficits if they return to play too soon and then have a subsequent concussion. Findings showed that a higher level of tau following a sports-related concussion was related to a prolonged period before the athlete could return to play, suggesting that tau levels may provide an important objective measure to inform decisions about how long athletes should wait to return to play.

In addition, NINR supports research to improve wellness and quality of life in people with cancer. For example, a recent NINR-supported study on lymphedema, which is a painful condition often experienced by women following breast cancer surgery, found that specific genes known to be related to inflammation were associated with lymphedema symptoms including impaired limb mobility, fluid accumulation, and discomfort. Such findings help us understand how our genes may influence our symptoms and behaviors, and may lead to more targeted and effective treatments.

One recent project in NINR's intramural program examined genomic profiles of men with fatigue, comparing those who were receiving radiation therapy for prostate cancer to those not receiving radiation therapy. Findings showed that men receiving radiation treatment had an increase in fatigue over the course of radiation treatment. The investigators identified several fatigue-related genes and potential biological pathways that may serve as targets for the development of new treatments for treatment-related fatigue.

Cancer Moonshot

Cancer research has a long history of trans-disciplinary collaborations, and NCI has incorporated the lessons learned from these collaborations into elements of the NCI Precision Oncology Initiative and Cancer MoonshotSM. The very nature of precision medicine in oncology – characterizing a patient’s cancer by molecular abnormalities with treatment based on molecular changes instead of the organ in which the cancer occurs – is founded on the intersection of basic cancer biology with genomics and clinical oncology. A central component of the NCI Precision Oncology Initiative involves new and expanded clinical trials where drug therapies are selected and targeted based on the patient’s specific molecular abnormalities rather than the site of tumor.

NCI is testing this approach through the Molecular Analysis for Therapy Choice (NCI-MATCH) clinical trial. Launched in 2015 for participants with a range of cancers for which there is no standard treatment or for which treatment has failed, the MATCH trial is the result of extensive collaboration with the research community, the FDA, and industry. To date, over 6,000 patients have enrolled in the study from communities across the country, from both academic centers and private practices. MATCH offers 24 treatment arms, with combinations of over 20 different agents. This study relies on a variety of expertise to deliver progress for patients. In addition to the oncologists to treat the patients, MATCH relies on interventional radiologists to do the research biopsies, pathologists to prepare the tumor, molecular biologists to do genetic testing of the sample, and bioinformaticians to create statistical and computational tools to align mutations with specific drugs.

Other examples of ongoing trans-disciplinary work being conducted under the Cancer Moonshot initiatives include projects with the U.S. Department of Energy to apply supercomputing expertise to develop predictive models that will allow us to better ascertain the appropriate treatments for cancer patients. Under the Cancer Moonshot, NCI is also collaborating with the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) to undertake a comprehensive clinical, epidemiological, and biological characterization of patients with chronic pancreatitis to better understand associations with diabetes, pancreatitis, and pancreatic cancer. Additionally, efforts are underway to create a cancer tumor “atlas” that will expand our ability to create models and predict responses to treatment. Together, these projects will require bringing together multiple disciplines that, at a minimum, encompass basic cancer biology, immunology, biomedical engineering, imaging sciences, bioinformatics, and computational biology.

NEW DIAGNOSTIC TREATMENT AND DIAGNOSTIC TOOLS

Ms. ROYBAL-ALLARD. And, Dr. Fauci, as you know, tuberculosis is the leading global infectious disease killer, taking the lives of 1.8 million people around the world annually. And in the U.S., TB cases are found in every State, and States are struggling to pay for the treatment of the disease. Drug-resistant tuberculosis has also been identified by the CDC as a serious antibiotic-resistant threat to the U.S., but research and development on TB is underfunded globally.

Can you update the subcommittee on how NIAID is coordinating research to develop new diagnostic treatment and prevention tools to address this global and domestic public health threat?

Dr. FAUCI. Thank you for that question.

Very briefly, the NIAID, as part of NIH is one of the major components of a new tuberculosis working group that developed a national plan that involves a variety of not only other agencies, but also pharmaceutical companies. We had the mandate to develop a report in December 2015, and we have just this past March submitted that report, which is posted on the USAID website, to be seen by everyone and anyone, and it is a plan that is an accelerated way to partner with industry.

One of the specific examples of that is the new trial of drugs against multiple-drug-resistant tuberculosis, including delamanid and bedaquiline, along together with the existing drug linezolid and they all look pretty good against multiple-drug-resistant tuberculosis.

Ms. ROYBAL-ALLARD. Okay. Great. Thank you.

SICKLE CELL AND COPD

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

Ms. LEE. Thank you very much.

Many of you know that I have had a very keen interest in sickle cell research, sickle cell trait, COPD, and multiple sclerosis. My mother passed away from complications from COPD. And I have learned a lot about these diseases as a result of personal experience, but also as a result of your understanding and response on them.

So with regard to COPD, I have learned, of course, 15 million people have COPD, a lot—many of these don't even know they have COPD. I want to thank you for developing and putting forward a COPD action plan and want to know kind of what are the key items from that and what resources do you need to implement that.

Second, with regard to MS, where are we in terms of finding a cure for multiple sclerosis and how the BRAIN Initiative will engage patients living with MS.

And, finally, on sickle cell research, oh, boy, I tell you, on the trait, we haven't done a lot of research. I want to know if you are doing anything with regard to sickle cell, the sickle cell trait, and where we are in terms of sickle cell disease. I know, Dr. Collins, you mentioned to me that we are close on disease, but I would like to know more.

Thank you.

COPD NATIONAL PLAN

Dr. COLLINS. Maybe to take it in order. Dr. Gibbons on COPD.

Dr. GIBBONS. Yes. Thank you for that. We received guidance from Congress to put forward this COPD National Action Plan, and we have collaborated with our sister agencies, CDC, CMS, and key stakeholders. Certainly a key part of that engagement involved patients and families, families like yours, that have been touched by this devastating and debilitating disorder.

What we have learned from that engagement process has been critical to formulating an action plan. In general, it has five goals. A key thing was raising awareness. As you mentioned, many individuals are affected, but unaware. So it is raising awareness. Certainly, there was a great call to advance our treatments, so much of what we do needs to be updated, and we must advance new treatments, as well as preventive interventions.

So we do have more work to do, and that is part of our research agenda that has come forward with the action plan. And we look forward to that being released soon perhaps within the next week or two.

Mr. COLE. Okay. We will next go for our last set of questions to my good friend from Massachusetts, Ms. Clark.

Ms. LEE. Can I just ask that the response to the other two questions be in writing, if we don't have time?

Mr. COLE. Yeah. We are getting close, so if that is okay with you, then that is what I would prefer.

Dr. COLLINS. Will do.

[The information follows:]

Sickle Cell Trait and Sickle Cell Disease

Regarding sickle cell trait, we do not understand its health consequences as well as we understand those of sickle cell disease, but we are working toward improved understanding. Small observational studies have found a possible association between sickle cell trait and several health risks, including chronic kidney disease and a risk of sudden death during strenuous physical activity. However, because these studies were small and have produced conflicting results, we are supporting larger, more robust studies to explore health risks faced by people with sickle cell trait.

One recent study supported by NHLBI and the Uniformed Services University of the Health Sciences examined a cohort of about 50,000 black U.S. Army soldiers to determine whether those with sickle cell trait had a higher risk of exertion-related death. The study found that sickle cell trait was not associated with a higher risk of exertion-related death or death from any cause. However, soldiers with sickle cell trait had a 54% higher risk of severe muscle breakdown, or rhabdomyolysis, after exertion. This finding may warrant further research, as rhabdomyolysis itself is a significant illness that can lead to kidney damage if not treated effectively.

As to where we are on sickle cell disease, we are catalyzing a cure, with several gene- and cell-based therapies showing promise. NHLBI is currently funding several groups that are taking these approaches to curing the disease.

But even as we pursue these promising leads, we are supporting studies designed to improve existing care. One problem with the current state of care is that the fruits of past research investments, such as treatments like hydroxyurea, are being underutilized.

To overcome this problem, NHLBI is supporting implementation research. This research will test interventions designed to ensure that individuals with sickle cell disease receive proper care and adhere to care regimens. For example, the Sickle Cell Disease Implementation Consortium is assessing barriers to care in urban, suburban, and rural areas and will then develop interventions to overcome those barriers. The program includes eight regional centers, including one at the Children's Hospital and Research Center in Oakland, California. NHLBI is also testing an app to improve patient adherence to use of oral hydroxyurea. Through implementation research projects such as these, we are working to improve the quality of life and longevity of all individuals with sickle cell disease.

Mr. COLE. Thank you.

Ms. LEE. Okay. Thank you.

Mr. COLE. Ms. Clark.

OPIOID OVERDOSE

Ms. CLARK. Thank you, Mr. Chairman.

A couple of questions for Dr. Volkow.

Seven hundred and fifty people last year in Massachusetts under the age of 35 died from opioid overdoses. We need to study the long-term effects on young people, their brains, social development, and how to best treat younger Americans who are in the grips of this deadly crisis.

So my first question is, can you tell us what NIDA is doing to better understand the needs of young people struggling with substance use disorder, and do you have the support and latitude to act in this area?

And a related question is, I have been very interested in medically assisted treatment, specifically looking at that for young people and increasing the alternatives that might be available. Last week, Secretary Price referred to MAT, medically assisted treatment, as, quote, just substituting one opioid for another. I believe this kind of attitude is why it is so difficult for people struggling to survive with opioid use to gain effective treatment.

Do you agree that we need more access to MAT for people struggling with addiction, including adolescents and young adults? And can you tell us a little bit about why treating Fentanyl addiction poses such a particular challenge? I know you are doing some work and have an upcoming meeting on that.

Dr. VOLKOW. Yes. Thanks very much for the questions. And indeed, within the tragedy of what we are living with the opioid crisis, is of utmost priority, of course, are the young people, because, first of all, they are much more vulnerable to become addicted, and then if they do become addicted, they have a whole life of consequences.

So one of our priorities in partnership with several of the institutes at the NIH is the equivalent of the Framingham study, but for adolescents. So we are recruiting 10,000 children, that as they transition from childhood into adulthood we are going to be periodically characterizing them and obtaining brain imaging to understand what are the normal developmental trajectories of the human brain, so that we may be able to understand better how drugs change it and how they interact with the environment and how that affects also mental illnesses.

As it relates to the treatment of opioid use disorders among teenagers, we have actually—we have shown, we have provided research to show that actually there is benefit of the use of Buprenorphine treatment for the adolescent population, that your outcomes are much better.

As you are mentioning, right now on top of everything that we have seen with the opioid crisis we are faced with new synthetic opioids which are much more potent than anything that we have ever heard. As a result of that, we are challenged with the fact that the medications that we use to use in order to reverse the opioid overdoses are no longer working.

So one of the priorities that we have is to actually why there is such an urgency to develop treatments that can reverse these extremely lethal opioid drugs, and obviously, along all of these, working with the other agencies in order to be able to prevent access to these type of drugs, such as Fentanyl, or even more potent ones like Carfentanil.

Ms. CLARK. Thank you.

Mr. COLE. Thank you. And that concludes our hearing, but I would be remiss—I certainly will—just not to thank all of our witnesses.

Dr. Collins, thank you and your colleagues. It is always a compelling display, quite frankly, of the talent, the compassion, the commitment that we have working on our behalf as American people at the National Institutes of Health. So we very much appreciate you giving your time and your expertise to this committee.

I now recognize my friend, the ranking member, for any closing comments she cares to make.

Ms. DELAURO. Thank you very much, Mr. Chairman. And if I can, I would love to get written responses. I wanted to ask Dr. Lowy about where we are on the Moonshot. We have done 300 million, we are going to do another 300, where that takes us.

Ms. DELAURO. I associate myself with my colleague who talked about the funding for the Institute of Nursing and what the rationale is for where they come on the pecking order.

I will submit for the record a question on the sex-gender balance in biomedical research and where we stand on that. There were a couple of questions in that area. And also what in terms of the funding for individual investigators, what kind of allowances will be made or will there be special exceptions to what you are looking at in that direction.

[The information follows:]

Sex/Gender Balance in Biomedical Research

NIH has long appreciated the importance of participation of men and women in clinical research. The appropriate sex/gender balance of participants provides a basis for application of results and identification of factors that affect disease course and treatment outcome. Females account for over half of the participants in NIH-supported clinical research and over half of the participants in NIH-defined phase III clinical trials. NIH-supported clinical research is subject to NIH's Policy on the Inclusion of Women in Clinical Research. As part of the implementation of this policy, peer reviewers examine the appropriateness of inclusion of women and men in the context of the scientific question proposed in the application. Females must be included in NIH-funded clinical research unless there is a scientific or ethical rationale for excluding them. If the NIH finds an application's plan for inclusion of women in the proposed study to be unacceptable, the study will not be funded until concerns are resolved. NIH reports the aggregate sex/gender distribution of participants in clinical research in its Report on the Inclusion of Women and Minorities in Clinical Research available on the NIH website at https://report.nih.gov/recovery/inclusion_research.aspx. For phase III clinical trials, NIH Program Officers review progress towards analyses of sex/gender differences in annual progress reports.

Successful clinical research depends in part on the preclinical research that precedes it. Sex and gender play a role in how health and disease processes differ across individuals, and consideration of these factors in research studies informs the development and testing of preventive and therapeutic interventions in both sexes. In June 2015, NIH introduced the NIH Policy on Consideration of Sex as a Biological Variable in NIH-funded Research (NOT-OD-15-102). The policy focuses on NIH's expectation that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. NIH application instructions and review criteria have been updated to reflect this policy, effective for applications submitted for due dates on or after January 25, 2016. Informative materials have been developed and disseminated to help investigators to understand and comply with this policy.

Consideration of sex may be critical to the interpretation, validation, and generalizability of research findings. NIH expects appropriate analysis and transparent reporting of data by sex and/or gender. While sex is recognized implicitly as an important factor in both pre-clinical and clinical research, more work is needed to standardize the way sex and gender are reported in scientific publications and to elucidate the way these characteristics function independently and together to influence health and health care.

In addition to ensuring the appropriate sex/gender distribution in NIH-supported research, NIH recognizes the importance of research focused on the needs of women. From FY 2013 to FY 2016 funding for women's health research increased from \$3.7 billion to \$4.5 billion. More information about NIH funding for women's health research is available at https://report.nih.gov/categorical_spending.aspx.

Ms. DELAURO. But it is always enormously gratifying to listen to what you all are engaged in. What you are engaged in is what your life's mission is and what you have done to be able to save lives. I count myself very blessed to have the opportunity to be elected to this body and to have been here now for 26 years. And what you do has never ceased to amaze all of us, as we have said here today.

And what is critical in understanding for all of us on both sides of the aisle is why we come here and what the potential, because that is what this institution has, is great potential. And that great potential, if we push the edge of the envelope in the way that you push the edge of the envelope in your discoveries, and to provide—we have the power here to provide the resources to allow you to push the edge of that envelope and to save lives.

That is pretty extraordinary with the mission of the United States Congress, and you take it seriously, we take it seriously. You don't have to comment on the budget, but we certainly have to comment on what it is and where we believe it needs to go.

Thank you very, very much, all of you, for what you do.

Thank you, Mr. Chairman.

Mr. COLE. I am certainly not going to try and top that. And I can assure everyone in the listening audience, my friend does push the envelope on behalf of things in which she believes very, very extensively.

So with that, again, our gratitude to all of you coming and testifying today. It is a very valuable committee. I think more profoundly it is very important to the American people to have an opportunity to hear both the possibilities and the challenges that you face and why this is a very worthy endeavor for them to invest their taxpayer dollars in, because, as you have each demonstrated in different ways today, the return to them and their families and, frankly, people all over the world is astronomical.

So, again, we thank you for your work, and we appreciate your time today.

The hearing is adjourned.

Funding Levels

Cole 1: Dr. Collins, I would expect that a reduction in funding at the level included in the request would have a significant impact on the number of new research grants NIH could award. Would you please describe some ways in which NIH could mitigate this impact and keep the research grant success rate as high as possible given budget constraints?

Response:

NIH calculates its success rates each fiscal year (FY) by dividing the number of competing applications funded by the total number of competing applications reviewed from the extramural research community. For reference, the success rate in FY 2016 for research project grant applications was 19.1 percent compared to 18.3 percent in FY 2015.¹ Additional historical information regarding success rates can be found on NIH's RePORT website.²

Success rates continue to remain far below the 30 percent levels seen 15-20 years ago, during the NIH budget doubling. The biomedical research community has expressed concerns that many meritorious applications are going unfunded, discouraging early-career scientists from continuing to pursue research careers and calling into question the health of the research enterprise. Many factors contribute to a lower success rate including, but not limited to, increasing numbers of investigators competing for research funding that is not growing at a similar rate, overall number of awarded larger (R01-equivalent) compared to smaller (e.g. R21) grants, as well as rising inflationary costs of doing research.

NIH continues to consider approaches to keep the research grant success rate as high as possible. Options to address this issue could range from reducing or limiting the size of an award; limiting the number of awards and/or dollar amount of funds to an investigator; reducing salary contributions on an award; as well as identifying new strategies to reduce the overall cost of research. These costs may be associated with, for example, reducing administrative burden (such as allowing more application materials being submitted Just In Time) and establishing single Institutional Review Boards for multi-site clinical trials (NIH policy effective in January 2018³).

Though discussions related to success rates will continue, program officials will also encourage investigators to seek other funding options for highly scored applications that were not recommended for funding at NIH, such as private support through platforms like the Online Partnership to Accelerate Research.⁴ In addition, NIH will continue to communicate and coordinate with other federal funders to ensure supported research is not duplicative or redundant. Overall, NIH remains dedicated to ensuring that the agency continues to support the most meritorious research, while remaining proper stewards of taxpayer funds.

¹ <https://nexus.od.nih.gov/all/2017/02/03/fy2016-by-the-numbers/>

² https://report.nih.gov/success_rates/

³ <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

⁴ <https://onpar.leidosweb.com/>

Basic Research Percentage

Cole 2: Dr. Collins, NIH is the primary funder of basic biomedical research in the country. This research is the foundation upon which all treatments and cures are based. You've estimated that about 52 percent of NIH funding in fiscal years 2016 and 2017 supports basic research. Are you proposing to maintain this percentage in your fiscal year 2018 request? How will you ensure that basic research remains a priority within constrained resources?

Response:

Basic research provides fundamental knowledge of the mechanisms of biology and behavior, often built in small increments across various fields that accumulate into the knowledge needed to make substantial breakthroughs. By providing information about how living systems work, basic research sets the stage for new preventive methods, treatments, and cures, ultimately laying the groundwork for tackling newly emerging diseases or complex chronic diseases. As such, basic science research is a main focus of NIH investment and plays a crucial part in the first objective outlined in the agency's NIH-Wide Strategic Plan (Fiscal Years 2016-2020).⁵

Many NIH research initiatives naturally strike a balance that continues the agency's commitment to basic research while also advancing our translational, clinical, and infrastructure investments. The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a prime example of this. Despite the many advances in neuroscience in recent years, the underlying causes of most neurological and psychiatric conditions remain largely unknown due to the vast complexity of the human brain. In an effort to develop effective ways of treating these devastating conditions, BRAIN Initiative researchers are working to develop a more complete arsenal of tools and information for understanding how the brain functions both in health and disease. This includes research to identify and provide experimental access to the different brain cell types to determine their roles in health and disease, generate circuit diagrams of the whole brain, and produce a dynamic picture of the functioning brain by developing and applying improved methods for large-scale monitoring of neural activity. By investing in this type of basic research, the resulting tools will stimulate generations of new studies aimed at curing complex and debilitating diseases like Parkinson's and Alzheimer's, providing clues for tackling depression and addiction, and understanding how the human brain impacts all areas of our health and well-being.

Supporting basic research through major initiatives as well as investigator-initiated projects will remain a vital part of NIH's portfolio. NIH's priority setting process for allocating research dollars accounts for many factors, including peer review of meritorious research, scientific opportunity, public health needs, and portfolio balance, including maintaining an appropriate balance of basic, translational, and clinical research. NIH's commitment to improve our understanding of human biology and expand our knowledge of the fundamental underpinnings of health and disease represents a critical component of fulfilling the NIH mission and will persist into the future.

⁵ <https://www.nih.gov/about-nih/nih-wide-strategic-plan>

IDeA Program

Cole 3: Dr. Collins, In tight budget times, it is more important than ever to support programs like the Institutional Development Award (IDeA) program, which broadens the geographic distribution of NIH funding for biomedical research and enhances the competitiveness of investigators at institutions located in states like Oklahoma.

Response:

The National Institutes of Health (NIH) agrees that initiatives like the Institutional Development Award (IDeA) program administered by the National Institute of General Medical Sciences (NIGMS) are important in ensuring that jurisdictions and institutions across the United States are afforded the opportunity to become active and significant contributors to this country's biomedical research efforts. Currently, institutions in 23 States⁶ and Puerto Rico are eligible for and receive funding from the IDeA Program.

For FY 2017, the IDeA program continues support for investigators in eligible states through the following initiatives:

- (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 through a statewide program that links a research-intensive institution with primarily undergraduate institutions. INBRE supports institutional research and infrastructure development; research by faculty, postdoctoral scientists, and students at participating institutions; and outreach to build science and technology knowledge in the states' workforces. Only one award is made per IDeA-eligible state. In FY 2016, the NIGMS supported 24 INBRE awards. For FY 2017, the NIGMS continues to support the INBRE program.
- (2) *Centers of Biomedical Research Excellence (COBRE – Phases I, II, and III)*. The goal of the COBRE initiative is to strengthen institutional biomedical research capabilities in IDeA states through three competitive 5-year phases of infrastructure and faculty development of thematic and multidisciplinary research centers. In FY 2016, the NIGMS supported 112 COBRE awards, for a total of 122 active COBRE awards. In FY 2017, the NIGMS continues its support for non-competing awards and new COBRE awards for outstanding applications.
- (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. IDeA-CTR awards support mentoring and career development activities in clinical and translational research. In FY 2016, the NIGMS supported 7 IDeA-CTR awards, for a total of 9 active IDeA-CTR awards. In FY 2017, the NIGMS continues supporting non-competing and competing (new and renewal) awards.

⁶ 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.

(4) Research co-funding. IDeA co-funding is provided to eligible applications that have already been judged meritorious by NIH peer-review committees and national advisory councils but are outside the range of applications under consideration for funding by the other NIH Institutes/Centers (I/Cs). In FY 2016, IDeA co-funded 58 research project grant awards (including three to Oklahoma) at 17 NIH I/Cs. In FY 2017, the NIGMS continues co-funding meritorious applications from other I/Cs.

The IDeA Program in Oklahoma

In FY 2016, the IDeA Program supported the following awards in Oklahoma (Table 1) totaling \$24.6 million: 1 INBRE, 9 COBREs, 1 IDeA-CTR, 3 co-funding awards, and 2 core consolidation supplements. Oklahoma investigators continue to submit proposals and will be in open competition with investigators from other IDeA states for support for new awards.

Table 1. IDeA Program-funded Awards in Oklahoma, FY 2016

Grant #	Title	FY 2016
INBRE		
P20GM103447	Oklahoma IDeA Network of Biomedical Research Excellence	\$ 3,662,374
COBRE		
P30GM103510	Science in a Culture of Mentoring	No cost extension
P30GM110766	Molecular Mechanisms and Genetics of Autoimmunity	\$ 1,229,328
P30GM114731	Interdisciplinary Research in Vascular Biology	\$ 1,293,750
P20GM104934	Mentoring Diabetes Research in Oklahoma	\$ 2,137,761
P20GM103639	Mentoring Translational Cancer Research in Oklahoma	\$ 2,030,950
P20GM103640	Oklahoma COBRE in Structural Biology	\$ 1,508,224
P20GM103636	Expanding Excellence in Developmental Biology in Oklahoma	\$ 2,520,000
P20GM109097	Children's Health Equity Solutions Center	\$ 2,367,310
P20GM103648	Oklahoma Center for Respiratory and Infectious Diseases	\$ 2,181,997
IDeA-CTR		
U54GM104938	Oklahoma Shared Clinical and Translational Resources	\$ 4,000,000
Co-Funding		
R01GM118599	Deciphering ShcA-mediated ROS Production as a Novel Intervention Strategy in Diabetes Therapy	\$ 282,505
R01HD083418	Podoplanin-mediated platelet activation and vascular integrity in the developing brain	\$ 276,690

R01GM089886	Microbial Ecologies of Indigenous Communities	\$ 320,000
Supplements		
3P20GM103447	Oklahoma IDeA Network of Biomedical Research Excellence	\$ 493,475
3P30GM103510	Science in a Culture of Mentoring	\$ 328,037
TOTAL		\$ 24,632,401

The OK IDeA-CTR award supporting the Oklahoma Shared Clinical and Translational Resources (OSCTR) is serving as a catalyst for clinical research aimed at improving health for the underserved and underrepresented populations living in the state. Some recent research projects that OSCTR investigators have been pursuing include the following:

- Examination of the relationship between pre-pregnancy obesity and diabetes with adverse birth outcomes among American Indians and Alaska Natives (AI/AN). Investigators found that AI/AN maternal body mass index does not predict preterm delivery and diabetes status does not predict low birth weight. In other indices, however, the profile for AI/AN mothers are similar to those for other groups: diabetes increases the odds for preterm delivery, overweight reduces the odds for low birthweight, and overweight and diabetes increases odds for macrosomia (a newborn with significantly larger than average birth weight) [Anderson *et al* (2016) *Obesity, Diabetes, and Birth Outcomes Among American Indians and Alaska Natives. Maternal and Child Health Journal* 20: 2548-2556].
- Identification of mediators impacting disease flare in African-American systemic lupus erythematosus (SLE) patients. African-Americans SLE patients have an increased prevalence of complications from disease flares and end-organ damage that leads to increased morbidity and early mortality. Investigators observed significant alterations in 34 soluble mediators at baseline and a few mediators weeks before clinical disease flare. This led to the development of a 'soluble mediator score' that approximates the immune status of SLE patients and provides robust, predictive gauge of impending disease flare [Munroe *et al* (2017). Pathways of Impending Disease Flare in African-American Systemic Lupus Erythematosus Patients. *Journal of Autoimmunity* 78: 70-78].

Some exciting research projects that investigators supported by the OK INBRE are currently pursuing include:

- Development of a mobile-cloud computing based (MCC) system incorporating emerging mobile and cloud computing technologies to better assess spinal cord-injured wheelchair users' activity levels. Investigators hope to discover ways to improve the quality of life for people with physical mobility restrictions. As the number of wheelchair users increases every year, there is an urgent and growing need to help wheelchair users maintain a healthy level of activities [Fu *et al* (2016). A Novel Mobile-Cloud System for Capturing and Analyzing Wheelchair Maneuvering Data: A Pilot Study. *Assistive Technology*, 28:105-114].
- Development of an alternative plant-seed-based platform for large scale and low-cost production of functional blood-clot dissolving proteins for the treatment of heart attack, cardiovascular disease, and acute stroke patients [Yao *et al* (2015). Plants as Factories for

Human Pharmaceuticals: Applications and Challenges. *International Journal of Molecular Sciences* 16:28549-28565].

A Core Consolidation supplement awarded to the OK INBRE, in partnership with the Arkansas INBRE, enabled the creation of the *IDeA National Resource for Proteomics* which synergizes and coordinates resources in both states ensuring that researchers in IDeA states can easily and cost-effectively access resources necessary to investigate proteins. The supplement award funds core facilities with state-of-the-art capabilities to study proteins, particularly those that may have therapeutic potential or can advance our understanding of biology and health. This resource is advancing the work of over 50 NIH research grants and 70 researchers. If this model is successful in improving access to technologies and creating economies of scale, NIGMS hopes to use it nation-wide.

IDeA Program - Increased Funding in Omnibus

Cole 4: I was proud that Congress was able to provide a \$13 million increase for this program in the fiscal year 2017 omnibus spending bill. Can you please tell us more about how these additional fiscal year 2017 funds will support research across the country?

Response:

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 facilitating the development of competitive and sustainable biomedical research programs in a broader range of institutions and states. The \$13 million increase for the IDeA program allowed NIGMS to fund additional meritorious grant applications.

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

- One new and two renewal applications for the IDeA-CTR awards:
 - [ME] *Northern New England Clinical and Translational Research Network* (New award, Maine Medical Center). The mission of the Northern New England Clinical and Translational Research (NNE-CTR) Network is to develop and sustain a clinical and translational research infrastructure that supports improvement in rural and community health for inhabitants in the IDeA states of Maine, New Hampshire, and Vermont.
 - [WV] *West Virginia Clinical and Translational Science Institute: Improving Health through Partnerships and Transformative Research* (Renewal award, West Virginia University). The West Virginia Clinical and Translational Science Institute (WVCTSI) was created in 2012 through the initial Clinical and Translational Research (CTR) award competition and has subsequently formed a well-connected, statewide research network, creating the infrastructure to address the substantial health disparities that exist in West Virginia. The network includes investigators from all academic medical centers within the state as well as the University of Kentucky, the Veterans Administration, and the National Institute for Occupational Safety and Health.
 - [LA] *Louisiana Clinical and Translational Science Center (LA CaTS)* (Renewal award, LSU Pennington Biomedical Research Center). Pennington Biomedical Research Center (PBRC) is the lead LA CaTS institution and will continue to partner with Louisiana State University Health Sciences Center-New Orleans (LSUHSC-NO) and Tulane University Health Sciences Center (TUHSC) in this effort. The renewal expands the reach of the Center by adding strengths, diversity, and resources for clinical and translational research at Southeast Louisiana Veterans Healthcare System (SLVHCS), a newly opened University Medical Center in New Orleans, Ochsner Health and the LSUHSC-NO School of Dentistry. Major areas of research focus will be obesity, diabetes, cardiovascular disease, cancer, aging and cognitive dysfunction.
- Six new COBRE (Phase I) awards:
 - [NM] *Autophagy, Inflammation, and Metabolism (AIM) in Disease* (University of New Mexico Health Sciences Center). The proposed COBRE for Autophagy, Inflammation,

and Metabolism (AIM) in Disease will serve biomedical excellence for mentored research on autophagy – the process through which cells get rid of damaged or unnecessary components - and its interactions with inflammatory and metabolic processes. Both New Mexico and the nation lack a program to develop faculty and coherent research programs in this novel, evolving area with many potential medical implications. With regional and national goals, AIM will close that gap.

- [ME] *Mesenchymal and Neural Regulation of Metabolic Networks* (Maine Medical Center). The overall program goal is to define specific molecular and signaling pathways that integrate the brain, bone, and adipose (fat) tissue in regulation of metabolic networks. These studies will lead to translational and clinical research that will ultimately advance better treatment and prevention programs for obesity and osteoporosis, and more effective use of antipsychotic medications.
- [HI] *Diabetes COBRE* (University of Hawaii at Manoa). Diabetes disproportionately affects racial and ethnic minorities including Native Hawaiians, Pacific Islanders, and Asians. This Center will span departmental and campus borders to promote the metabolic health of the people of Hawaii and the Pacific region.
- [WY] *Wyoming Sensory Biology COBRE* (University of Wyoming). The mission of the Wyoming Sensory Biology COBRE (SBC) is to foster and conduct high quality scientific research that advances the understanding of our sensory systems and related disorders.
- [OK] *The Center for Neuroscience-based Mental Health Assessment and Prediction (NeuroMAP)*(Laureate Institute for Brain Research). The Center for Neuroscience-based Mental Health Assessment and Prediction (NeuroMAP) aims to provide a scientific, operational, and educational infrastructure for innovative neuroscience-based research to use individual differences on several biological levels together with sophisticated statistical approaches to generate clinically meaningful predictions of risk and outcomes for mood, anxiety, and eating disorders.
- [NH] *Center of Integrated Biomedical and Bioengineering Research (CIBBR)*(University of New Hampshire). The center will focus on the complex interactions of genes, environment, behavior, and human diseases.
- Two renewal COBRE (Phase II) awards:
 - [DE] *Delaware Center for Neuroscience Research* (Delaware State University). The Delaware Center for Neuroscience Research, established in 2012 with a phase I COBRE award, is a collaboration between Delaware State University (DSU) and the University of Delaware (UD) that uniquely brings together faculty and research resources from two very different institutions: a minority-serving, undergraduate university with an emerging strength in neuroscience research (DSU), and the state's flagship research university (UD). The overarching scientific goal of the Neuroscience Center is to bring together and support neuroscientists working at multiple scales, from human subjects to rodent and invertebrate models to improve understanding of the dynamic function of the brain.
 - [NV] Center for Integrative Neuroscience (University of Nevada Reno). Neurological impairments and disease are a major focus of healthcare, and understanding and treating these impairments is central to the mission of many NIH institutes. The COBRE will support research to help characterize the healthy brain and neural disorders, and advance knowledge ranging from the neural basis of behavior to neural damage and repair.

Native American Health Issues

Cole 5: This question is for anyone who would like to answer, but I would particularly like to hear from Dr. Gordon. As you know, I have a particular interest in Native American issues. Please give us an update on what the NIH is doing specifically to address Native American health, particularly with regard to research to address the disproportionately high rate of suicide among Native Americans.

Response:

The National Institutes of Health (NIH) has taken major steps forward in addressing Native American health through the creation of the Tribal Health Research Office (THRO) located in the Division of Program Coordination, Planning, and Strategic Initiatives in the Office of the NIH Director. Functions of the THRO include coordinating tribal health research-related activities across NIH; serving as a liaison to and NIH representative on tribal health-related committees and working groups; coordinating and supporting the NIH Tribal Advisory Committee; collaborating with NIH Institutes and Centers (ICs) on the development of reports on tribal health topics; managing information dissemination related to tribal health research coordination; convening trans-NIH committees, workshops, meetings and other activities related to tribal health research and scientific priorities; coordinating with NIH ICs to leverage resources or develop initiatives to support tribal health research; and convening annual Tribal Consultation sessions. Dr. David R. Wilson, a registered member of the Navajo Nation, was appointed the first Director of THRO in January 2017 and is working to enhance the coordination and support for activities that address American Indian and Alaska Native (AI/AN) health. Current activities in THRO include the development of a 5-year strategic plan for the office and an NIH wide portfolio analysis of NIH supported research in AI/AN communities. On June 6, 2017, NIH held a tribal consultation at the National Indian Health Board's Annual Public Health Summit. The consultation was facilitated by NIH staff and NIH Tribal Advisory Committee members to hear comments and feedback for the strategic plan. Nearly 100 individuals participated in this event either in person or by phone. The NIH Tribal Health Research Coordinating Committee (THRCC), a trans-NIH committee, has also been created to support the work of THRO. The committee has been actively engaged in the strategic planning process and is currently working to identify and apply best practices to increase the numbers of AI/AN student interns at NIH. More information can be found on the THRO website.⁷

NIH is committed to supporting research related to suicide prevention among American Indians and Alaska Natives. As a federal partner in the National Action Alliance for Suicide Prevention, NIH's National Institute of Mental Health (NIMH) works with other federal agencies (e.g., Indian Health Service, Substance Abuse and Mental Health Services Administration (SAMHSA), and the Centers for Disease Control and Prevention (CDC)) to seek sustainable suicide prevention strategies for AI/AN communities. NIMH Director Dr. Joshua Gordon has identified suicide prevention as one of his priority areas, and NIMH supports research in culturally appropriate suicide prevention. For example, one NIMH-funded study adapts an intervention called **Caring Texts** in four AI/AN communities. In addition to usual care, this intervention leverages the cultural importance of social connection in AI/AN communities by

⁷ <https://dpcpsi.nih.gov/thro>

utilizing text messaging to send expressions of care, concern, and interest to high-risk youth. NIMH also supports an intervention research study for Alaska Native youth called **Qungasvik (Toolbox)** which was developed in consultation with community and tribal leadership to ensure cultural relevance. The Qungasvik intervention uses Yup'ik cultural practices and values to reduce alcohol use disorder and suicide in AN youth and helps communities identify effective prevention strategies. The **Promoting Community Conversations about Research to End Suicide (PC-CARES)** study aims to reduce barriers for mental health help-seeking, and to promote early interactions between providers and community members to better meet the needs of Native youth. This project takes a public health approach, aiming to shift from crisis intervention to selective outreach and community-integrated care of youth at risk for suicide. Native village counselors and non-Native clinicians are trained to facilitate community outreach sessions that bring together cultural and local knowledge and clinical expertise. NIH also supports research on factors that lead to suicide in American Indians such as intergenerational trauma and post-traumatic stress disorder. In FY 2017, NIH will make awards to develop collaborative research hubs to reduce the burden of suicide and promote resilience among AI/AN youth. These projects aim to increase the reach and research base for effective and culturally relevant preventive interventions by focusing on strong community and tribal partnerships that build on communities' strengths, challenges, cultural practices, and approaches. More information on this program is available online.⁸

In addition to supporting research on suicide prevention, NIH has supported inter-agency and cross-governmental activities in suicide prevention. In April 2017, NIH convened more than 20 federal partners to develop a federal action plan to address youth suicide based on recommendations from a March 2016 NIH workshop on Advancing Research to Prevent Youth Suicide.⁹ The Indian Health Service was a key partner in this meeting, suggesting ways to connect various federal datasets, methods for creating an index of exposures relevant to American Indians and Alaska Natives, and ensuring proper representation of the youth suicide prevention needs of AI/AN communities. NIH has also served as the technical lead on the 2015-2017 United States Chairmanship of the Arctic Council, in partnership with SAMHSA, CDC, and U.S. Department of State. This chairmanship gave rise to the Reducing the Incidence of Suicide in Indigenous Groups – Strengths United through Networks (RISING SUN)¹⁰ initiative, which has made strides toward facilitating efforts to reduce suicide among Alaska Native and other Arctic communities; used community-driven stakeholder engagement, consensus-building, and priority-setting processes; and built a narrative around outcomes and measures that can be used to evaluate the effectiveness of suicide prevention programs that are being implemented among Arctic indigenous communities. A forthcoming web-based toolkit will provide resources including stakeholder-based outcomes and their measures to assist communities, governments, researchers, and service providers in reducing the burden of suicide among indigenous peoples, including Alaska Native communities.

⁸ <https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-350.html>

⁹ <https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/suicide-prevention>

¹⁰ <https://www.nimh.nih.gov/about/organization/gmh/risingsun/index.shtml>

Chimp Haven

Fleischmann 1: According to an article in Wired in August of 2016, 9 of 13 animals sent to the Chimp Haven sanctuary in 2014-2015 died within months of arrival. The transfer and resocialization process is highly stressful on chimps; why subjugate them to all the stress when they are well taken care of in their current homes?

Response:

The Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act, P.L. 106-551), requires the Secretary of HHS to establish and operate a sanctuary system for chimpanzees that are no longer needed for research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government. The CHIMP Act also requires that these chimpanzees be retired to the sanctuary system (operated by Chimp Haven, Inc.). Efforts are being made to relocate the animals as quickly and safely as possible while allowing for optimal transition of each individual chimpanzee with careful consideration of their welfare, including their health and social grouping. The NIH-supported chimpanzee facilities have decades of experience relocating chimpanzees and ensuring adherence to animal welfare policies as defined by the Animal Welfare Act administered by the Animal Care, Animal and Plant Health Inspection Service; the Health Research Extension Act of 1985; and the Public Health Service Policy on Humane Care and Use of Laboratory Animals implemented by the NIH Office of Laboratory Animal Welfare. Additionally, a veterinarian accompanies every transport to assure the chimpanzees' welfare. All institutions housing NIH-owned or -supported chimpanzees are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, further demonstrating NIH's commitment to responsible animal care and use.

The animals housed at the Federal Sanctuary are an aging population and many have chronic health conditions. Even though 9 of a cohort of 13 chimpanzees transported to the Sanctuary unfortunately died, in an analysis of mortality, no association of death could be linked to location after accounting for age and sex.¹ Additionally, NIH analyzed the outcomes of 764 chimpanzees that were located at various sites and found that among 273 chimpanzees who were transferred to the Federal Sanctuary, there was no increased risk in mortality in the first 30 days after arrival.¹¹ NIH continues to work towards relocating retired chimpanzees safely with upmost care for their health and social welfare.

¹¹ <http://www.biorxiv.org/content/early/2016/08/10/068858>

Chimp Haven

Fleischmann 2: How many NIH-owned animals have died at the sanctuary since the Director's announcement to retire the animals to Chimp Haven and can the NIH explain why it appears, according to an April 2016 GAO report, that the sanctuary has a higher mortality rate than the medical research centers?

Response:

A total of 24 chimpanzees have died at the Federal Sanctuary from November 1, 2015 to June 30, 2017. The animals housed at the Federal Sanctuary are an aging population and many have chronic health conditions. Based on the age and health of the chimpanzees housed at the Federal Sanctuary, the number of deaths during this period is within the expected range for an aging population with co-morbidities.

Chimp Haven

Fleischmann 3: Has the NIH adequately considered whether it would cost the taxpayer less money and be more beneficial to the welfare of the animals to retire them in their current location?

Response:

Retirement of Federally-owned/supported animals no longer needed for research is mandated under the CHIMP Act, which created the Federal Sanctuary System overseen by NIH. The CHIMP Act Amendments of 2013 (P.L. 113-55), authorizes the NIH to continue funding the care, maintenance, and transportation of the agency's chimpanzees including those housed in the Federal Sanctuary.

In April 2016, the US Government Accountability Office (GAO) performed an independent evaluation regarding chimpanzees under NIH's ownership or control. Based on the findings of the GAO Report, NIH developed and posted on the NIH website a retirement plan to transfer chimpanzees to the Federal Sanctuary that considers both costs and chimpanzee welfare.¹² This plan is being implemented. Based on details in the GAO report and cost information posted on the NIH website, it is most cost-effective to the tax payers to have all animals at the Sanctuary. The costs for transport to the Federal Sanctuary are minimal.

In terms of animal welfare, all facilities that house, care for, or are engaged in the transport of NIH-owned chimpanzees are subject to the Animal Welfare Act administered by the Animal Care, Animal and Plant Health Inspection Service, the Health Research Extension Act of 1985, and the Public Health Service Policy implemented by the NIH Office of Laboratory Animal Welfare (OLAW). All NIH-supported chimpanzee facilities employ trained animal behaviorists to address psychological well-being, and veterinarians, particularly those with a specialization in primate medicine, to address health concerns. All of the institutions housing NIH-owned chimpanzees are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, demonstrating their commitment to responsible animal care and use.

¹² <https://orip.nih.gov/comparative-medicine/programs/nih-plan-retire-all-nih-owned-and-supported-chimpanzees>

Chimp Haven

Fleischmann 4: Has the decision to retire all NIH chimpanzees from research had any detrimental effects on the ability of researchers to improve the lives of wild chimps, for example by hampering Ebola vaccine research?

Response:

NIH's mission is to seek fundamental knowledge about living systems and the application of that knowledge to enhance [human] health, lengthen life, and reduce illness and disability. NIH also has a goal of finding and using alternatives to animal models, including chimpanzees, in studying diseases. The December 2011 Institute of Medicine (IOM) report¹³ on the necessity to use chimpanzees in biomedical and behavioral research stated that, among other things, chimpanzees in research are "largely unnecessary," and NIH accepted that conclusion. Additionally, over the last few years the demand for chimpanzees in NIH-supported biomedical research has significantly decreased, which further contributed to the November 2015 NIH decision that NIH will no longer support biomedical research on chimpanzees and all NIH-owned chimpanzees are eligible for retirement.

Although the IOM Report concluded that the majority of research in chimpanzees was largely unnecessary, there were specific exceptions noted, such as development of a prophylactic hepatitis C virus vaccine. With respect to the development of an Ebola virus vaccine, studies in chimpanzees have proven valuable. Specifically, an Ebola vaccine trial conducted in chimpanzees in 2011 led to the development of a potential vaccine for humans and wild gorillas, whose populations had been reduced by the Ebola virus. In a study published in 2016,¹⁴ an experimental Ebola vaccine tested in humans has shown to provide 100 percent protection against this lethal disease. Although the vaccine has not yet been approved by any regulatory authority, it is considered so effective that an emergency stockpile has been created for use should an outbreak occur again.

¹³ <http://www.nationalacademies.org/hmd/Reports/2011/Chimpanzees-in-Biomedical-and-Behavioral-Research-Assessing-the-Necessity/Report-Brief.aspx>

¹⁴ [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32621-6/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32621-6/abstract)

Administrative Burden Reduction and Indirect Costs

Harris 1: Director Collins, does NIH intend to form the Administrative Burden Reduction Workgroup in addition to participating in the NAS study? And based on the NAS study, what sort of reforms do you envision that may reduce the regulatory burdens for researchers? Could you provide an update as to how NIH's Division of Financial Advisory Services (NIH-DFAS) has implemented reforms to address the concerns raised in the GAO report, "Agencies Involved in the Indirect Cost Rate-Setting Process Need to Improve Controls?"

Response:

For decades, NIH has focused on reducing administrative burden in various ways. This includes leading efforts within the Federal Demonstration Partnership (FDP). NIH also leads efforts to reduce administrative burden through the Research Business Models (RBM), an Interagency Working Group nested within the OSTP's National Science and Technology Council. The NIH Director co-chairs the parent RBM committee within NSTC and served as a member of the NSTC. The RBM, as a subcommittee of the SBE, facilitates efforts across Federal research agencies to improve coordination and collaboration among research agencies to streamline requirements for the extramural community.

In addition, following the FY 2015 omnibus report language requiring NIH to initiate an Administrative Burden Workgroup, NIH engaged an ad hoc committee of the National Academies of Science's National Research Council to further examine ways to reduce administrative burden. This collaboration studied Federal regulation and reporting requirements with specific attention to those directed at research universities. The resulting report, "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century" focused on regulatory issues identified as of most pressing concern to the research community and analyzed topics that adversely affect the nation's ability to optimize its investment in academic research.

The report recommended harmonizing existing policies and processes across Federal agencies (e.g. uniform format for grant proposals and research progress reporting) as well as reducing the regulatory burden associated with policies for human subjects' research, animal care and use, monitoring of sub-recipients, reporting of financial expenditures, and disclosure of financial conflicts of interest. In addition, the recently enacted 21st Century Cures Act (P.L. 114-255) requires that the Director of the White House Office of Management and Budget (OMB) establish a Research Policy Board (RPB), which would serve as a public-private forum for discussions relating to regulations of federally-funded research established to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

NIH continues to lead efforts with FDP and other professional societies on ways to address the recommendations to reduce the administrative burden associated with Federal research funding outlined in the NAS report and 21st Century Cures Act. For some of these recommendations, such as but not limited to Subrecipient Monitoring as well as Financial Conflict of Interest, NIH intends to initiate action by implementing changes to grant policies. However, addressing other

recommendations will require rulemaking efforts or changes in legislation. NIH is revising its internal control processes to address the recommendations from the GAO report. NIH-DFAS has developed a draft internal guidance that addresses the supervisory review of the indirect cost negotiation process. NIH-DFAS plans to finalize these procedures by August 31, 2017.

Additionally, NIH-DFAS has finalized three out of the five formal policies for the indirect cost negotiation process. The three finalized policies were effective July 1, 2017. The three finalized policies address the key characteristics, such as policy number, purpose of the policy, effective date, and approving official. The remaining two policies will be finalized by August 31, 2017. A final recommendation from GAO is that the Director of NIH-DFAS should establish a mechanism for tracking key milestones in the indirect cost rate-setting process, such as when indirect cost rate proposals are due. NIH-DFAS is continuing to work with a contractor to develop a web based system that will establish a system to track when indirect cost proposals are due from organizations. The original initiative to enable the electronic submission of indirect cost proposals was modified to incorporate this new requirement. The planned timing for implementation of the eFlow system is Fall 2017.

Grant Support Index

Harris 2: Thank you for your efforts to increase young investigators and bring down the average age for grant recipients. As part of this effort, you recently announced the GSI proposal. I was wondering if, and how, you have tested this GSI proposal to determine its impact toward the average age and young investigators?

Response:

NIH and its stakeholder community have for many years been concerned about the long-term stability of the biomedical research enterprise. Too many researchers vying for limited resources have led to a hypercompetitive environment, with many highly meritorious applications going unfunded. In some cases, the hypercompetitive environment has also resulted in the loss of NIH investments in research training, as emerging investigators are unable to establish stable careers. This has too often resulted in misaligned incentives and unintended consequences for talented researchers at all career stages who are trying to succeed and stay in science.

NIH has implemented a variety of programs over the past decade to help stabilize the biomedical research workforce, especially for new and early-stage investigators. While the percentage of NIH awards that support early-career investigators has stabilized over this time, these gains have been offset by a decline in the percentage of NIH awards that support mid-career investigators. To continue addressing these workforce issues, NIH proposed the Grant Support Index (GSI) policy in May 2017, which aimed to limit the total NIH grant support provided to an individual principal investigator. The focus at the time was to redistribute or balance NIH investments by redirecting some of the resources currently going to our most highly funded investigators to supporting those at earlier career stages.

Following the GSI announcement, NIH received many comments from the biomedical research and advocacy communities, as well as from outside members of various Institute and Center advisory councils. Their valid concerns centered around potential unintended consequences of implementing the GSI policy as proposed, including effects on team science and training grants. As a result, NIH refined the proposal to take a more focused approach to bolster support to early-stage (ESI) and early-established investigators (EEI). While ESIs are those within ten years of their terminal degree, EEIs are those within ten years of the first major NIH competing award as an ESI. In recognition of the call for such action in the 21st Century Cures Act, this effort is named the Next Generation Researchers Initiative (Next Gen). Through this effort, NIH anticipates funding approximately an additional 200 grants to ESIs and approximately another added 200 grants to EEIs beginning in FY 2017.

NIH will track the impact of Institute and Center funding decisions for ESIs and EEIs on an ongoing basis with fundable scores to ensure this new strategy is effectively implemented. Additionally, NIH, working with outside experts, will also encourage multiple approaches to develop and test metrics that can be used to assess the impact of NIH grant support on scientific progress. A working group of the Advisory Committee to the Director, the Next Gen working group, has been formed, consisting of investigators at all levels including graduate students and full professors, to refine and implement the initiative. NIH will use public meetings, conferences,

and the Next Gen public website to communicate progress to the community.¹⁵ Moving forward, NIH will continue focusing attention on programs to strengthen the biomedical workforce, including those that will impact the average age of new investigators for their first award.

¹⁵ <https://grants.nih.gov/ngri.htm>

Reorganization

Harris 3: Are you looking at consolidating institutes for administrative and program management processes? If so, could you provide examples?

Response:

As a public science agency, NIH uses transparent, data-driven approaches in its decision-making to exercise optimum stewardship of taxpayer funds. NIH is continuously evaluating its research portfolio, as well as its administrative and program management processes, in order to maximize the efficiency with which it carries out its mission.

NIH is currently developing and validating methodologies and tools that can be used to evaluate scientific investments and identify overlap and duplication, as well as areas of opportunity, in research. For example, NIH created the Relative Citation Ratio (RCR) to measure the influence of a scientific article, regardless of the journal in which it is published and the scientific field. Another resource developed by NIH is *iSearch*,¹⁶ a portfolio analysis tool that enables immediate insight into current and emerging research areas. These types of tools provide NIH with the evidence base it needs to make funding decisions that promote an efficient and impactful biomedical research portfolio.

NIH also regularly examines its administrative processes for opportunities to streamline and increase efficiencies, both within the agency and for the research community more broadly. Currently, NIH is considering several efforts, including:

- Streamlining the grant application and reporting requirements, including simplifying the biographical information that scientists are required to submit with grant applications; and
- Simplifying conflict-of-interest reporting regulations and financial reporting.

In addition to the examples outlined above, NIH is actively consolidating facilities, such as its off-site leases, to maximize productivity and operational efficiency while reducing recurring lease costs. NIH is also examining additional efficiencies that could be gained from its operation of a Central Utility Plant (CUP) at its Bethesda campus, a facility that is used to generate electricity, chilled water, and steam. By leveraging novel and sophisticated self-learning models and continuously looking for ways to optimize the performance of the CUP, NIH can reduce operational costs significantly. Finally, NIH has taken advantage of advances in information and communication technologies to streamline operations in these areas. Such improvements include integrating and consolidating the communications platform for NIH employees; leveraging an electronic performance management system; consolidating mobile device management and computer purchasing; and using global recruitment announcements (one announcement for multiple positions) to save time and eliminate duplication of effort.

NIH continues to look for ways to increase efficiency in its programs and processes. NIH leadership remain in active and ongoing discussions about this issue.

¹⁶ <https://itools.od.nih.gov/dashboard/#login>

Embryonic stem cell

Harris 4: Do you have an estimate for the number of diseases that have been successfully treated in patients with embryonic stem cells?

Response:

NIH is aware of three non-NIH funded, FDA-regulated, clinical trials using investigational cell therapies developed from human embryonic stem cells (hESCs) originally approved for use by NIH-funded researchers. The trials are focused on spinal cord injury, macular degeneration, and type 1 diabetes:

- Spinal Cord Injury. Asterias Biotherapeutics, in Fremont, California, is testing a cellular therapeutic (in which cellular materials are injected into the patient), developed from hESCs, which protects spinal nerve cells and stimulates nerve growth, in a Phase 1/2 clinical trial with patients who have spinal cord injuries. ClinicalTrials.gov (NCT02302157): Dose escalation study of AST-OPC1 in Spinal Cord Injury
- Type 1 Diabetes. ViaCyte, in San Diego, California, is testing an encapsulation device (in which the device protects its contents from the immune system) containing human pancreatic progenitor cells, developed from hESCs, in a Phase 1/2 clinical trial with patients who have type 1 diabetes. ClinicalTrials.gov (NCT02239354): A Safety, Tolerability, and Efficacy Study of VC-01™ Combination Product in Subjects With Type I Diabetes Mellitus
- Macular Degeneration. Regenerative Patch Technologies, in Palo Alto, California, is testing a cellular therapeutic product, developed from hESCs, in a Phase 1/2 trial with patients who have macular degeneration. ClinicalTrials.gov (NCT02590692): Study of Subretinal Implantation of Human Embryonic Stem Cell-Derived RPE Cells in Advanced Dry AMD

And, do you have any indication where such embryonic stem cell-based treatments have saved patient lives?

Response:

These are early stage clinical trials to test new therapies and devices which have not yet been approved for the safe and effective treatment of diseases.

Embryonic Stem Cell Research and Fetal Tissue

Harris 5: Are you aware of any audits to confirm whether NIH grantees are in compliance with statutory requirements regarding fetal tissue research? Previous NIH reports to Congress have indicated that NIH has not supported transplantation research, could you explain why? Do you intend to take any action based on the Select Investigative Panel on Infant Lives and the Senate Judiciary Committee's reports on the fetal tissue procurement industry? Are you considering a moratorium on NIH funding of any fetal tissue research until any legal and ethical problems can be studied in greater detail?

Response:

NIH is aware of recent inquiries by the Department of Health and Human Services Office of the Inspector General (OIG) and the U.S. House of Representatives Select Panel on Infant Lives. The OIG conducted a review in 2015-2016 of NIH policies and procedures for approval and oversight of research involving human fetal tissue (both for the NIH intramural program and NIH extramural grants and contracts). The OIG did not identify any problems at NIH, per a May 18, 2016, letter provided to NIH from the OIG to Senator Perdue. This supports previous findings from the Government Accountability Office in 2000 in which Federal human fetal tissue procurement policies and guidance were found to be consistent with Federal law (<http://www.gao.gov/new.items/d0165r.pdf>). NIH also provided information and a number of documents in response to requests from the U.S. House of Representatives Select Panel on Infant Lives, including documents related to assurances by grantees involved with fetal tissue research on compliance with Federal law and NIH policy. NIH is not aware of any audits concluding that NIH grantees are out of compliance with statutory requirements regarding fetal tissue research.

The last year that the NIH supported a clinical trial on the transplantation of fetal tissue for therapeutic purposes was in fiscal year 2003. In later fiscal years, the NIH supported follow-up research related to these trials and the development of a surgical instrument. In designing research proposals, investigators consider what types of cells are most appropriate for their research goals. In making decisions about what research proposals to fund, NIH considers which proposals are the most meritorious, based on evaluation by peer review panels and Advisory Councils, consistent with the public health priorities of NIH. Thus, there is no predetermined stance on whether NIH will fund transplantation research using human fetal tissue in a given fiscal year—instead, NIH funding decisions are based on NIH's assessment of what are the most meritorious research proposals, consistent with NIH's public health priorities.

NIH issued a reminder to all NIH-supported researchers of the requirements under Federal law and NIH policy regarding use of human fetal tissue in research on August 14, 2015 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-143.html>). Subsequently, after a careful consideration of the current policy, NIH issued an additional policy regarding informed consent on February 11, 2016, for all uses of human fetal tissue in research (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-033.html>). The consent policy articulates the NIH's expectations that researchers obtain informed consent for all uses of human fetal tissue in research supported or conducted by NIH.

The NIH continually seeks to ensure public funding is used for scientifically sound research that meets the highest ethical standards and is conducted in accordance with Federal laws, regulations, and policies, including those related to research involving human fetal tissue.

Biodefense

Harris 6: Director Fauci, you cited the existence of a long range spend plan for NIAID biodefense spending during your testimony, would you please share a copy of this plan? In addition to the spending plan, please also provide a list of projects and amounts funded by NIAID that have transitioned to BARDA for advanced development over the last five years. Further, please provide a list of current NIAID projects and amounts that are expected to help fill remaining material threat determination (MTD) preparedness gaps.

Response:

The National Institute of Allergy and Infectious Diseases (NIAID) is an active participant in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates Federal efforts to develop medical countermeasures (MCMs, which include both treatments and diagnostics) to enhance preparedness for chemical, biological, radiological and nuclear threats, and emerging infectious diseases. The PHEMCE multi-year budget plan links MCM research, development, and procurement investments across the Department of Health and Human Services PHEMCE participants, including the National Institutes of Health (NIH), the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). The PHEMCE multi-year budget report was transmitted to Congress in April 2016 and covers biodefense planning for fiscal year (FY) 2015-2019. A copy of the report is provided.

As a member of PHEMCE, NIAID biodefense research focuses on: (1) threats for which the Department of Homeland Security (DHS) has issued a Material Threat Determination (MTD); (2) basic and translational research, product development, and animal models that could be used for multiple threat agents; and (3) basic and immunological research on more than 50 emerging and re-emerging pathogens not enumerated in the multi-year PHEMCE budget that pose potential threats.

NIAID routinely transitions high-priority MCM candidates to ASPR's Biomedical Advanced Research and Development Authority (BARDA) for advanced development. Transferred MCM candidates cover a broad range of biological, chemical, and radiological public health threats, with the final goal of obtaining FDA approval and possible inclusion in the Strategic National Stockpile (SNS). A list of NIAID-funded MCM candidates that have transitioned to BARDA for advanced development over the last five years, including relevant funding from NIAID, is provided below. This list also includes medical countermeasures for nuclear, radiological, and chemical threats, where NIAID is the lead Institute but funding is from NIH's annual appropriation. NIH funding amounts listed here reflect support for pre-clinical and early clinical development of the specific product listed. Please note that this funding amount excludes additional investments in basic research critical to the understanding of underlying biological mechanisms and the discovery of targets for the development of eventual MCMs. Note: NIAID typically supports multiple product candidates to address threat agents with MTDs to increase the likelihood of successful MCM development. Funding also has been excluded for those product candidates that have not transitioned to BARDA.

For the purposes of this document, transitions to BARDA during the requested timeframe (FY 2012-FY 2016) include MCMs with development that was further funded by BARDA, or those that were procured for the SNS. It should also be noted that numerous MCMs that received NIAID support transitioned to BARDA prior to the timeframe of the current request. Many of these early-transitioning MCMs continue to be advanced within the BARDA portfolio.

NIH Support for Products Transitioned to BARDA for Advanced Development (FYs 12 - 16)								
MTD Portfolio	Project/Product description	FY 12	FY 13	FY 14	FY 15	FY 16	Destination Agency	NIH Funding for Development (Millions)
Anthrax Vaccine	Emergent AV7909			X			BARDA	\$60.9
Anthrax Therapeutic	ANTHIM® (ETI-2054 monoclonal antibody)	X					BARDA	\$47.8
Anthrax Vaccine	Post-Exposure Prophylaxis (PEP) - BioThrax	X					BARDA	\$72.0
Chemical Threat Countermeasure	Activase® (alteplase) - tissue plasminogen activator (tPA) - Treatment for pulmonary effects of sulfur mustard				X		BARDA	\$22.1
Chemical Threat Countermeasure	R-107 (Radikal Therapeutic) - Treatment of chlorine inhalation					X	BARDA	\$2.6
Chemical Threat Countermeasure	Midazolam - Advanced anticonvulsant		X				BARDA	\$26.0
Nuclear/Radiation Threat Countermeasure	Neulasta® - Treatment of radiation exposure		X				BARDA	\$9.0
Nuclear/Radiation Threat Countermeasure	Neupogen® - Treatment of radiation exposure		X				BARDA	\$18.3

Nuclear/Radiation Threat Countermeasure	OrbeShield® (beclomethasone dipropionate) - Treatment for gastrointestinal acute radiation syndrome (GI-ARS)		X				BARDA	\$1.0
Nuclear/Radiation Threat Countermeasure	Yel 002 (BCN Bioscience) - Treatment for hematopoietic acute radiation syndrome (H-ARS)		X				BARDA	\$0.6
Nuclear/Radiation Threat Countermeasure	Biodosimetry Test (MRI Global)					X	BARDA	\$2.0
Nuclear/Radiation Threat Countermeasure	Biodosimetry Test (REDI-Dx® - DxTerity Diagnostics, Inc.)					X	BARDA	\$1.3
Nuclear/Radiation Threat Countermeasure	Hydroxypyridonate (HOPO) - Radionuclide decorporation agent	X					BARDA	\$9.2

NIH Support for Products Transitioned to BARDA for Advanced Development (FYs 12 - 16)

MTD Portfolio	Project/Product description	FY 12	FY 13	FY 14	FY 15	FY 16	Destination Agency	NIH Funding for Development (Millions)
Filovirus Vaccine	Johnson & Johnson/Bavarian Nordic prime-boost Ebola vaccine (Johnson & Johnson AdVac® vaccine and Bavarian Nordic MVA-BN® vaccine)				X		BARDA	**\$92.7

Filovirus Vaccine	rVSV-ZEBOV-GP vaccine (Merck) and ChAd3 EBO-Z vaccine (NIAID/GSK) (PREVAIL I clinical trial)				X		BARDA	\$73.0
Filovirus Vaccine	ChAd3 EBO-Z vaccine (NIAID/GSK) (vaccine development)				X		BARDA	\$108.4
Filovirus Therapeutic	ZMapp™ - Monoclonal antibody cocktail for Ebola virus (product development and PREVAIL II clinical trial)				X		BARDA	\$58.5
Filovirus Therapeutic	BioCryst- BCX4430 (GALIDESIVIR) - Treatment for Ebola and Marburg viruses				X		BARDA	\$17.9

*Not included in these figures are costs that have supported the development of the second-generation smallpox vaccine, MVA, which transitioned to BARDA prior to FY 2012. These developmental efforts were pivotal for the development of a MVA platform that was utilized as a component of multiple Ebola virus vaccines, including the Bavarian Nordic MVA-BN® vaccine.

In addition to products transitioned to BARDA, NIAID has supported the development of MCMs that have proceeded to advanced development within other government agencies as well as to the FDA for approval via other routes, including partnerships with industry and investigational new drug submissions to the FDA. Regardless of the route of advanced development, NIAID remains committed to research on high-priority MCMs to combat emerging or re-emerging disease threats and chemical and radiological agents.

A list of current NIAID-managed projects and funding amounts relevant to MTD preparedness has been included. This list includes nuclear/radiological (nuc./rad.) and chemical (chem.) threats, where NIAID is the lead Institute but funding is from NIH's annual appropriation. NIAID research addressing agents with MTDs is designed to enhance our understanding of these threats as well as address research gaps and identify targets for the development of MCMs. It is important to note that, in addition to MTDs, NIAID research addresses a broad spectrum of threats, including pathogens that may pose a threat to the public health as well as a multitude of chemicals identified in the latest version of the Chemical Threat Risk Assessment (CTRA) developed by the DHS Chemical Security Analysis Center. This DHS-led assessment currently contains over 160 different chemicals identified as civilian threats.

The importance of cross-cutting NIAID biodefense research has been recently highlighted by NIAID's response to the Zika virus, which emerged in 2016 as a cause of serious congenital abnormalities, and to H7N9 influenza, which has re-emerged in 2017 as a modified strain that is not covered by the currently stockpiled vaccine. NIAID remains committed to research addressing a wide spectrum of biodefense and emerging infectious disease threats.

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Anthrax	A cyclic di-GMP signaling system of spores of <i>Bacillus anthracis</i>	UNIVERSITY OF MISSOURI-COLUMBIA	Stewart, George	5 R21 AI112725 -02	\$211,571
Anthrax	Administrative Core	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Coggeshall, Kenneth	5 U19 AI062629 -13 Core A	\$159,822
Anthrax	Analyzing a novel mechanism of action of bacterial cAMP producing toxins	UNIVERSITY OF CALIFORNIA SAN DIEGO	Bier, Ethan	5 R01 AI110713 -03	\$303,944
Anthrax	Animal Model Core	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Lupu, Florea	5 U19 AI062629 -13 Core C	\$534,514
Anthrax	Anti-Peptidoglycan Antibodies and Complement in Anthrax Pathogenesis	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Coggeshall, Kenneth	5 U19 AI062629 -13 Project 3	\$434,293
Anthrax	Assembly of the envelope of <i>Bacillus anthracis</i> vegetative forms	UNIVERSITY OF CHICAGO	Lunderberg, Justin	5 F30 AI110036 -03	\$48,494
Anthrax	B Cell Population Dynamics in	DUKE UNIVERSITY	Kelsoe, Garnett	5 U19 AI117892 -02	\$310,650

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Affinity Maturational			Project-002	
Anthrax	Bacillus anthracis egress from infected macrophages	UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN	Blanke, Steven	1 R21 AI122202 -01	\$224,048
Anthrax	Bacillus anthracis Targets Involved in Chemokine-Mediated Antimicrobial Activity	UNIVERSITY OF VIRGINIA	Hughes, Molly	4 R01 AI099097 -04	\$446,401
Anthrax	Bacillus-containing vacuole-mediated interactions of Bacillus anthracis with macrophages	UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN	Blanke, Steven	5 R21 AI105664 -02	\$268,858
Anthrax	Conjugate Anthrax Vaccine with Dual Virulence Factor Specificity	BIOLOGICS RESOURCES, LLC	Giri, Lallan	4 R01 AI105172 -04	\$1,217,595
Anthrax	Development of an Adjuvant with Vaccines for Anthrax, and West Nile Virus (WNV)	LEIDOS BIOMEDICAL RESEARCH, INC.	Koontz, Casey	N01 AI130002 9C-0-1.	\$1,310,911

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Anthrax	Development of anthrax vaccine formulation	EMERGENT PRODUCT DEVELOPMENT GAITHERSBUR	Lemiale, Laurence	N01 AI140003 8C-0-1	\$4,726,061
Anthrax	Development of anthrax vaccine formulations	PHARMATHENE, INC.	Troyer, John	N01 AI140004 0C-0-1	\$4,314,913
Anthrax	Development of Enabling Vector/Antigen Expression Technology for an Orally-Delive	PROTEIN POTENTIAL, LLC	Sim, B.	4 R01 AI098884 -05	\$619,333
Anthrax	Development of Technologies to Facilitate the use and Response of Vaccines	PAXVAX, INC.	Gurwith, Marc	N01 AI100003 6C-0-1	\$670,521
Anthrax	Enhanced Shelf-life Nanovaccine Formulation for Immunity to Biodefense Pathogens	IOWA STATE UNIVERSITY	Narasimha n, Balaji	5 R01 AI111466 -03	\$195,986
Anthrax	Flow Cytometry Core	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Thompson, Linda	5 U19 AI062629 -13 Core D	\$83,518
Anthrax	Functional similarity of PRD-containing virulence	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	Raynor, Malik	5 F31 AI110101 -03	\$33,798

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	regulators in B. anthracis				
Anthrax	Human Antibody Core	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Smith, Kenneth	5 U19 AI062629 -13 Core E	\$167,035
Anthrax	Humoral Mechanisms of Protection from Bacillus anthracis Sepsis	OKLAHOMA MEDICAL RESEARCH FOUNDATION	Farris, A	5 U19 AI062629 -13 Project 4	\$668,142
Anthrax	Influenza and Emerging Infectious Diseases	LABORATORY OF IMMUNOREGULATION	Davey, Richard	ZIA AI000984 -10	\$136,754
Anthrax	Mechanisms by which B. anthracis Spores Escape the Lung	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	Metcalf, Jordan	5 U19 AI062629 -13 Project 2	\$517,543
Anthrax	Microparticles for Directing Immune Cell Trafficking	GEORGE MASON UNIVERSITY	Popov, Serguei	5 R21 AI117425 -02	\$172,639
Anthrax	Molecular analyses of toxin nanopore structural dynamics	UNIVERSITY OF MARYLAND BALTIMORE	Krantz, Bryan	1 R21 AI124020 -01	\$276,317
Anthrax	Molecular Genetics and Pathogenesis of Anthrax	LABORATORY OF PARASITIC DISEASES	Leppla, Stephen	ZIA AI001030 -09	\$487,136

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Anthrax	Novel vita-vaccine formula combines safety of dead and efficacy of live vaccines	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	Blander, Julie magarian	1 R01 AI127658 -01	\$157,360
Anthrax	Pathobiology of heme inducible transporters in Gram positive pathogens	VANDERBILT UNIVERSITY	Skaar, Eric	5 R01 AI073843 -07	\$11,853
Anthrax	Pathobiology of heme inducible transporters in Gram positive pathogens	VANDERBILT UNIVERSITY MEDICAL CENTER	Skaar, Eric	6 R01 AI073843 -08	\$210,771
Anthrax	Pathogenesis, Treatment and Prevention of Emerging Infectious Diseases	LABORATORY OF IMMUNOREGULATION	Lane, Clifford	ZIA AI000936 -13	\$91,137
Anthrax	Pathophysiologic Actions of Anthrax Virulence Determinants	LABORATORY OF PARASITIC DISEASES	Leppia, Stephen	ZIA AI001032 -09	\$292,282
Anthrax	Physical Principles of Bacterial Toxin Translocation across Membranes	UNIVERSITY OF MARYLAND BALTIMORE	Krantz, Bryan	5 R01 AI077703 -09	\$433,687

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Anthrax	Pilot Project Program	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	Ballard, Jimmy	5 U19 AI062629 -13 Core B	\$167,035
Anthrax	Single Dose, Multivalent, Anthrax Plague Vaccines using Bacteriophage T4 Nanopart	CATHOLIC UNIVERSITY OF AMERICA	Rao, Venigalla	5 R01 AI111538 -03	\$359,540
Anthrax	Structural genomics centers for infectious diseases	NORTHWESTERN UNIVERSITY AT CHICAGO	Anderson, Wayne	N01 AI120002 6C-0-2	\$1,006,974
Anthrax	Structure and Function of Virulence Factors of Bacillus anthracis	LABORATORY OF PARASITIC DISEASES	Leppla, Stephen	ZIA AI001031 -09	\$383,620
Anthrax	Structures and Interactions of Antibodies Produced by Affinity Maturation	CHILDREN'S HOSPITAL CORPORATION	Harrison, Stephen	5 U19 AI117892 -02 Project-003	\$172,772
Anthrax	Surface Proteins of Bacillus anthracis	UNIVERSITY OF CHICAGO	Schneewind, Olaf	4 R01 AI069227 -10	\$434,675
Anthrax	Targeted-delivery of small interference RNA against	TEXAS TECH UNIVERSITY	Zeng, Mingtao	3 R21 AI118228 -02S1	\$32,091

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	anthrax (1 R21 AI118228-01A1)	HEALTH SCIS CENTER			
Anthrax	Targeting Heme Transporters for Improved Vaccines against Anthrax	BAYLOR COLLEGE OF MEDICINE	Marecko, Anthony	5 R21 AI109465 -02	\$223,907
Anthrax	Technologies to Advance Next Generation Anthrax Vaccines	CENTER FOR EXPERIMENTAL SOFTWARE ENGR MD	Yusibov, Vidadi	N01 AI120003 4C-0-1	\$861,647
Anthrax	Technologies to Advance Next Generation Anthrax Vaccines	PFENEX, INC.	Squires, Chuck	N01 AI120003 3C-0-1	\$1,159,376
Anthrax	Toxin-Mediated Suppression of Human PBMC Responses During Bacteremia	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	Ballard, Jimmy	5 U19 AI062629 -13 Project 1	\$543,869
Anthrax	Vaccines and Therapeutics for Anthrax	LABORATORY OF PARASITIC DISEASES	Leppla, Stephen	ZIA AI000929 -14	\$767,240
Anthrax	Virulence gene expression by <i>Bacillus anthracis</i>	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	Koehler, Theresa	2 R01 AI033537 -21	\$391,590

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Botulinum	A Multidisciplinary Approach for the Treatment of Botulinum Intoxication	SCRIPPS RESEARCH INSTITUTE	Janda, Kim	1 R01 AI119564 -01A1	\$709,984
Botulinum	Characterization of Botulinum Neurotoxin A Subtypes	UNIVERSITY OF WISCONSIN-MADISON	Johnson, Eric	4 R01 AI095274 -05	\$439,657
Botulinum	Development of Real-Time Cellular Screening Systems for BoNT Intoxication	SCRIPPS RESEARCH INSTITUTE	Dickerson, Tobin	5 R01 AI109208 -03	\$518,324
Botulinum	Generation of therapeutic antibodies to serotype F botulism	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	Marks, James	4 R01 AI104579 -04	\$572,434
Botulinum	Mechanisms of Bacterial Toxin Action	MEDICAL COLLEGE OF WISCONSIN	Barbieri, Joseph	5 R01 AI030162 -25	\$217,267
Botulinum	Microbiology and infectious diseases biological research repository (MID BRR)	AMERICAN TYPE CULTURE COLLECTION	Stedman, Timothy	N01 AI160001 3C-0-6	\$635,450

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Botulinum	Molecular mechanisms of botulinum neurotoxin neutralization	UNIVERSITY OF CALIFORNIA-IRVINE	Jin, Rongsheng	1 R01 AI125704 -01	\$719,042
Botulinum	Neuronal-specific cargo-delivery platforms as post-exposure botulism therapies	UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN	Wilson, Brenda	5 R33 AI101504 -05	\$432,454
Botulinum	Novel therapeutic approaches to treatment of botulinum neurotoxin poisoning	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	Ichtchenko, Konstantin	4 R01 AI093504 -05	\$1,399,585
Botulinum	Production of monoclonal antibody-based therapeutics for botulism	NANTHERAPEUTICS, INC.	House, Robert	N01 AI160000 9C-0-1	\$2,316,620
Botulinum	Structural and functional studies of botulinum neurotoxin	UNIVERSITY OF CALIFORNIA-IRVINE	Jin, Rongsheng	4 R01 AI091823 -06	\$392,861
Botulinum	Structural mechanism for recognition of host receptor by	UNIVERSITY OF CALIFORNIA-IRVINE	Jin, Rongsheng	1 R21 AI123920 -01	\$261,907

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	botulinum neurotoxin A				
Botulinum	Targeting Cellular Processes to Counter the Effects of BoNT Intoxication	GENEVA FOUNDATION	Bavari, Sina	5 R33 AI101387 -05	\$416,735
Botulinum	TASK 16: Production of Botulinum Complex	SCIENCE APPLICATIONS INTERNATIONAL CORP	Koontz, Casey	N01 AI110002 3I-27200016-1	\$42,225
Botulinum	Trispecific monoclonal antibody for botulinum neurotoxin intoxication therapy	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	Marks, James	5 R33 AI101539 -05	\$504,876
Botulinum	Using Allosteric Inhibition as a Means to Ablate Botulinum Neurotoxin Protease	SCRIPPS RESEARCH INSTITUTE	Janda, Kim	1 R21 AI117878 -01A1	\$326,325
Botulinum	Vaccines Against Botulism	MEDICAL COLLEGE OF WISCONSIN	Barbieri, Joseph	5 R01 AI118389 -02	\$678,093
Botulinum	VTEU: PHASE I Clinical Trial for Clostridium	DUKE UNIVERSITY	Walter, Emmanuel	N01 AI130001 7I-71	\$1,777,171

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Botulinum Therapeutics			27200013-1	
Chem.	Accelerated AChE Reactivator Design by Mechanistic Neutron Scattering Studies	UNIVERSITY OF CALIFORNIA SAN DIEGO	Radic, Zoran	5 U01 NS083451 -03	\$656,765
Chem.	Administrative Core	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Laskin, Jeffrey	2 U54 AR05507 3-11 Admin- Core-001	\$153,794
Chem.	Administrative Core	UNIVERSITY OF CALIFORNIA AT DAVIS	Lein, Pamela	4 U54 NS079202 -05 Core D	\$194,732
Chem.	Administrative Core	UNIVERSITY OF COLORADO DENVER	White, Carl	1 U54 ES027698 -01 Admin- Core-001	\$418,112
Chem.	Administrative core for center management and operations	BRIGHAM AND WOMEN'S HOSPITAL	Macrae, Calum	4 U54 NS079201 -05 Core A	\$382,073
Chem.	Amelioration of soman-induced neuropathology with NAAG-	HENRY M. JACKSON FDN FOR THE ADV MIL/MED	Mccabe, Joseph	5 R21 NS089488 -02	\$348,807

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	related compounds				
Chem.	Amelioration of Vesicant-Induced Skin Injury by High Dose 25-Hydroxyvitamin D	CASE WESTERN RESERVE UNIVERSITY	Lu, Kurt	4 U01 AR06414 4-05	\$955,018
Chem.	Analytical chemistry	UNIVERSITY OF CALIFORNIA AT DAVIS	Wulff, Heike	4 U54 NS079202 -05 core A	\$402,708
Chem.	Anti-fibrotic therapies for chronic lung disease due to sulfur mustard	UNIVERSITY OF COLORADO DENVER	Veress, Livia	1 U54 ES027698 -01 Project-002	\$883,913
Chem.	Atropine for chlorine inhalation toxicity	UNIVERSITY OF COLORADO DENVER	Veress, Livia	5 R21 ES026830 -02	\$334,131
Chem.	Blocking Arsenicals-induced Cutaneous Injury	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Athar, Mohammad	5 U01 NS095678 -02	\$733,530
Chem.	Brain-penetrating acetylcholinesterase reactivators for several organophosphates	MISSISSIPPI STATE UNIVERSITY	Chambers, Janice	3 U01 NS083430 -03S1	\$144,881

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Chem.	Brain-penetrating acetylcholinesterase reactivators for several organophosphates	MISSISSIPPI STATE UNIVERSITY	Chambers, Janice	5 U01 NS083430 -03	\$721,494
Chem.	Bromine Inhalation Induced Lung Injury: Novel Mechanisms and Treatment Strategies	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Matalon, Sadis	5 U01 ES026458 -02	\$714,998
Chem.	CIALIS® reverses halogen induced injury to pregnant animals and their offspring	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Matalon, Sadis	1 U01 ES027697 -01	\$748,796
Chem.	Cobinamide for acute methylmercaptan inhalation	UNIVERSITY OF COLORADO DENVER	Boss, Gerry	1 U54 ES027698 -01 Project-003	\$366,264
Chem.	Countermeasure Therapeutics for Acute Lung Injury	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Leikauf, George	1 R21 ES027390 -01	\$231,375
Chem.	Countermeasures Against Chemical Threats ^ Preclinical	SRI INTERNATIONAL	Green, Carol	N01 NS062369 -0-1	\$917,058

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Development Facility				
Chem.	Countermeasures for chlorine-induced airway fibrosis	UNIVERSITY OF LOUISVILLE	Hoyle, Gary	4 U01 ES022564 -05	\$370,718
Chem.	Developing Drugs to Mitigate Parathion Intoxication	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Laskin, Jeffrey	4 U01 NS079249 -04	\$794,992
Chem.	Development of the Vitamin B12 Analog cobinamide as a Hydrogen Sulfide Antidote	UNIVERSITY OF CALIFORNIA SAN DIEGO	Boss, Gerry	5 U01 NS087964 -02	\$732,948
Chem.	Development of therapeutics for chlorine-induced airway and lung injury	DUKE UNIVERSITY	Gunn, Michael	4 U01 ES017219 -08	\$743,914
Chem.	Educational Core	UNIVERSITY OF COLORADO DENVER	White, Carl	1 U54 ES027698 -01 Core-001	\$142,416
Chem.	Effective Therapies for Ocular Injuries by Vesicating Agents	UNIVERSITY OF COLORADO DENVER	Agarwal, Rajesh	4 U01 EY023143 -05	\$735,546

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Chem.	Effects of acute administration of the Phenothiazinium Chromophore Methylene blue during life threatening cyanide intoxication	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	Haouzi, Philippe	1 R21 NS098991 -01	\$247,195
Chem.	Efficacy of GluR5 Antagonists Against Soman-Induced Seizures and Neuropathology	HENRY M. JACKSON FDN FOR THE ADV MIL/MED	Braga, Maria	3 U01 NS058162 -09S1	\$153,979
Chem.	Extracellular RNA as therapeutic target after toxic chemical inhalation	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Ahmad, Aftab	5 U01 ES025069 -03	\$497,767
Chem.	Fibrinolytic therapies for methyl isocyanate	UNIVERSITY OF COLORADO DENVER	White, Carl	1 U54 ES027698 -01 Project-001	\$933,418
Chem.	Functional Genomics of Chemical-Induced Acute Lung Injury	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Leikauf, George	3 U01 ES015675 -10S1	\$153,997

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Chem.	Glutathione Monoesters to Counteract Ocular Chemical Injury	YALE UNIVERSITY	Vasiliou, Vasilis	5 R21 EY026776 -02	\$386,411
Chem.	High throughput in vivo discovery of cyanide antidotes	BRIGHAM AND WOMEN'S HOSPITAL	Macrae, Calum	4 U54 NS079201 -05 project 1	\$227,221
Chem.	Identification of treatments for chemical threat agent seizures	UNIVERSITY OF CALIFORNIA AT DAVIS	Rogawski, Michael	4 U54 NS079202 -05 project 1	\$620,170
Chem.	Improved standard of care reactivators and facilitative transport into the centra	U.S. ARMY MEDICAL RESEARCH INST CHEM DEF	Mcdonough, John	4 U01 NS083448 -02	\$541,096
Chem.	Intralipid: A novel frontline countermeasure for brodifacoum poisoning	UNIVERSITY OF ILLINOIS AT CHICAGO	Feinstein, Douglas	4 U01 NS083457 -04	\$671,901
Chem.	Metabolomic phenotyping ("Metabolomics")	BRIGHAM AND WOMEN'S HOSPITAL	Gerszten, Robert	4 U54 NS079201 -05 core C	\$645,687
Chem.	Methylene blue as an antidote against hydrogen	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	Haouzi, Philippe	1 U01 NS097162 -01	\$803,839

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	sulfide intoxication				
Chem.	Mitigation of neurological damage following seizures	UNIVERSITY OF CALIFORNIA AT DAVIS	Lein, Pamela	4 U54 NS079202 -05 project 2	\$905,229
Chem.	Molecular Imaging of Chemical Threats and Countermeasures	UNIVERSITY OF MONTANA	Thompson, Charles	5 U01 NS092495 -02	\$717,099
Chem.	Neuroprotective effects of AEOL 10150 against organophosphate toxicity	UNIVERSITY OF COLORADO DENVER	Patel, Manisha	4 U01 NS083422 -04	\$793,984
Chem.	Neurosteroid Treatment for OP Intoxication	TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	Reddy, Doodipala	4 U01 NS083460 -04	\$654,238
Chem.	New Chelating (decorporating) Agents for Azide	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Pearce, Linda	1 R21 NS098989 -01	\$192,812
Chem.	Nitrite dependent protection against Cl2 gas toxicity_role of chlorinated lipids	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Patel, Rakesh	4 U01 ES023759 -04	\$815,300
Chem.	Novel mechanisms for seizure	UNIVERSITY OF CALIFORNIA AT DAVIS	Pessah, Isaac	4 U54 NS079202	\$438,943

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	mitigation and neuroprotection			-05 project 3	
Chem.	Optimizing novel cyanide countermeasures	BRIGHAM AND WOMEN'S HOSPITAL	Peterson, Randall	3 U54 NS079201 -05S1 project 2	\$150,000
Chem.	Optimizing novel cyanide countermeasures	BRIGHAM AND WOMEN'S HOSPITAL	Peterson, Randall	4 U54 NS079201 -05 project 2	\$376,561
Chem.	Overlay independent X-ray data analysis for enhanced oxime OP-ChE reactivation	UNIVERSITY OF CALIFORNIA SAN DIEGO	Radic, Zoran	1 R21 NS098998 -01	\$155,000
Chem.	Pharmacotherapy to counterACT parathion-induced NMJ dysfunction	UNIV OF MASSACHUSETTS MED SCH WORCESTER	Gaspari, Romolo	4 U01 NS083452 -04	\$670,513
Chem.	Photonics Monitoring and Modeling Core	UNIVERSITY OF COLORADO DENVER	Brenner, Matthew	1 U54 ES027698 -01 Core-002	\$691,303
Chem.	Probe and pharmaceutical optimization core	UNIVERSITY OF CALIFORNIA AT DAVIS	Wulff, Heike	4 U54 NS079202 -05 core B	\$418,620
Chem.	Reactivation of Aged Acetylcholinesterase: Design and	OHIO STATE UNIVERSITY	Hadad, Christophe	5 U01 NS087983 -03	\$376,048

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Development of Novel Therap				
Chem.	Research Education Core	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Laskin, Debra	2 U54 AR05507 3-11 Core-001	\$167,049
Chem.	Research Project I - Vesicant-Induced Skin Injury	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Gerecke, Donald	2 U54 AR05507 3-11 Project-002	\$846,767
Chem.	Research Project II - Vesicant-Induced Corneal Injury	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Gordon, Marion	2 U54 AR05507 3-11 Project-001	\$388,378
Chem.	Research Project III - Vesicant-Induced Lung Injury	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Laskin, Debra	2 U54 AR05507 3-11 Project-003	\$1,125,015
Chem.	Research Support Assessment - Chemical Countermeasures R&D Contracts (IAA)	U.S. NATIONAL INSTITUTES OF HEALTH	N/A	Y02 AI099911 -0-0	\$13,031,609
Chem.	Research Support Assessment - Chemical	U.S. NATIONAL INSTITUTES OF HEALTH	N/A	5 RMS AI099911 -05	\$676,076

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Countermeasures RMS Salaries				
Chem.	Scientific Core - Pharmaceutics and Midicinal Chemistry	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Sinko, Patrick	2 U54 AR05507 3-11 Core-003	\$745,877
Chem.	Scientific Core - Pharmacology and Drug Development	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Heck, Diane	2 U54 AR05507 3-11 Core-002	\$453,120
Chem.	Statistics and data management core	UNIVERSITY OF CALIFORNIA AT DAVIS	Nguyen, Danh	4 U54 NS079202 -05 core C	\$236,661
Chem.	Targeting Injury Pathways to Counteract Pulmonary Agent and Vesicant Toxicity	DUKE UNIVERSITY	Jordt, Sven-eric	5 U01 ES015674 -10	\$583,965
Chem.	Targeting the Glutamatergic System to Counteract Soman Toxicity in Immature Rats	HENRY M. JACKSON FDN FOR THE ADV MIL/MED	Braga, Maria	5 R21 NS094131 -02	\$371,941
Chem.	Therapy for ocular mustard gas exposure using engineered FGF derivatives	E AND B TECHNOLOGIES, LLC	Eveleth, David	5 R21 EY026777 -02	\$303,690

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Chem.	Training and Education Core	BRIGHAM AND WOMEN'S HOSPITAL	Peterson, Randall	4 U54 NS079201 -05 Core B	\$284,148
Chem.	Training and Education Core	UNIVERSITY OF CALIFORNIA AT DAVIS	Inceoglu, Ahmet	4 U54 NS079202 -05 core E	\$65,738
Chem.	Treatment of persistent chlorine-induced small airway disease	UNIVERSITY OF LOUISVILLE	Hoyle, Gary	1 R21 ES027391 -01	\$201,270
Chem.	UMDNJ/Rutgers University CounterACT Research Center of Excellence	RBHS-ROBERT WOOD JOHNSON MEDICAL SCHOOL	Laskin, Jeffrey	3 U54 AR05507 3-10S1	\$1,421,485
Chem.	Validating promising drug candidates in mammalian models of CN poisoning	BRIGHAM AND WOMEN'S HOSPITAL	Boss, Gerry	4 U54 NS079201 -05 project 3	\$482,546
Filoviruses	A New System to Modulate Phosphatidylserine to Investigate Filovirus Budding	INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS	Stahelin, Robert	1 R21 AI121841 -01	\$248,628
Filoviruses	Administrative Core	UNIVERSITY OF NORTH	Baric, Ralph	4 U19 AI107810	\$50,885

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
		CAROLINA SYSTEM		-04 Core A	
Filoviruses	Administrative Core	UNIVERSITY OF WISCONSIN-MADISON	Kawaoka, Yoshihiro	4 U19 AI106772 -04 Core D	\$94,994
Filoviruses	Advanced Development of an Ebola Vaccine	CRUCELL HOLLAND, BV	Callendret, Benoit	N01 AI080005 6C-0-1	\$2,335,728
Filoviruses	Antiviral responses in iPSC-derived human primary cells to Ebola virus infection	BOSTON UNIVERSITY MEDICAL CAMPUS	Muehlberg er, Elke	1 R21 AI126457 -01	\$305,135
Filoviruses	Biodefense/Emerging Infection Vaccine Studies	VACCINE RESEARCH CENTER	Ledgerwo d, Julie	ZIA AI005047 -14	\$768,258
Filoviruses	Cis and Trans-acting Factors that Modulate Ebola Virus RNA Synthesis	WASHINGTON UNIVERSITY	Basler, Christophe r	1 P01 AI120943 -01A1 Project-001	\$398,529
Filoviruses	Clinical Sequelae and Urogenital Viral Dynamics in Survivors of Ebola Virus Disease	UNIV OF NORTH CAROLINA CHAPEL HILL	Fischer, William	1 K23 AI121516 -01	\$208,166
Filoviruses	Computational Modeling Core	BATTELLE PACIFIC	Waters, Katrina	4 U19 AI106772	\$375,857

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
		NORTHWEST LABORATORIES		-04 Core B	
Filoviruses	Data Management and Resource Dissemination Core	UNIVERSITY OF NORTH CAROLINA SYSTEM	Dittmer, Dirk	4 U19 AI107810 -04 Core C	\$42,370
Filoviruses	Data Management and Resources Dissemination	UNIVERSITY OF WISCONSIN-MADISON	Livny, Miron	4 U19 AI106772 -04 Core C	\$28,320
Filoviruses	Defining the Role of Host Factors in Ebola Virus RNA Synthesis	WASHINGTON UNIVERSITY	Lacount, Douglas	1 P01 AI120943 -01A1 Project-003	\$960,991
Filoviruses	Determining the functions of novel genes for influenza A and Ebola viruses	UNIVERSITY OF WISCONSIN CENTERS	Kawaoka, Yoshihiro	4 U19 AI107810 -04 Project 2	\$189,902
Filoviruses	Discovery and Characterization of B-Cell Epitopes for Hepatitis C Virus and Ebola Virus	INTEGRAL MOLECULAR	Doranz, Benjamin	N01 AI140005 8C-0-1	\$404,605
Filoviruses	Ebola Vaccine Development	VACCINE RESEARCH CENTER	Sullivan, Nancy	ZIA AI005079 -12	\$1,939,775

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Filoviruses	Ebola virus and other emerging & re-emerging infectious diseases	LEIDOS BIOMEDICAL RESEARCH, INC.	Baseler, Elizabeth	N01 CA15000 03I- 26100033-1	\$34,023, 508
Filoviruses	Expression, Biochemistry and Immune Reagent Core	UNIVERSITY OF NORTH CAROLINA SYSTEM	Heise, Mark	4 U19 AI107810 -04 Core B	\$75,951
Filoviruses	Function and assembly of the Ebola virus nucleocapsid	SCRIPPS RESEARCH INSTITUTE	Saphire, Erica	1 R01 AI118016 -01A1	\$569,252
Filoviruses	Fusion protein TM-TM interactions: Modulation of pre-fusion protein stability	UNIVERSITY OF KENTUCKY	Webb, Stacy	5 F31 AI120653 -02	\$7,895
Filoviruses	Hemorrhagic Fever Viruses	KEYSTONE SYMPOSIA	Woodland, David	1 R13 AI126804 -01	\$2,113
Filoviruses	Identification and Validation of Novel Human T cell Epitopes in Lassa Fever	SCRIPPS RESEARCH INSTITUTE	Oldstone, Michael b.a.	N01 AI140004 8C-0-1	\$810,526
Filoviruses	Influenza and Emerging Infectious Diseases	LABORATORY OF IMMUNOREGULATION	Davey, Richard	ZIA AI000984 -10	\$273,510

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Filoviruses	Integrated Research Facility at Fort Detrick	Division of Clinical Research	Jahrling, Peter	ZID AI009006 -08	\$2,140,594
Filoviruses	International Research in Congo	RML, Laboratory of Virology	Munster, Vincent	ZIA AI001190 -03	\$72,477
Filoviruses	Lipid-protein interactions in viral assembly and virus like particle formation	INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS	Stahelin, Robert	2 R01 AI081077 -05A1	\$421,764
Filoviruses	Mali International Center for Excellence in Research	RML, Laboratory of Virology	Feldmann, Heinrich	ZIA AI001189 -03	\$25,737
Filoviruses	Mechanism of receptor-mediated entry and infection by filoviruses	ALBERT EINSTEIN COLLEGE OF MEDICINE, INC	Chandran, Kartik	5 R01 AI101436 -06	\$876,197
Filoviruses	Mechanisms of Antiviral Action of Human Interferon-alpha	Division of Intramural Research	Zoon, Kathryn	ZIA AI001039 -09	\$34,570
Filoviruses	Microbiology and infectious diseases biological research	AMERICAN TYPE CULTURE COLLECTION	Stedman, Timothy	N01 AI160001 3C-0-9	\$1,906,350

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	repository (MID-BRR)				
Filoviruses	Microbiology and infectious diseases biological resource repository (MID-BRR)	AMERICAN TYPE CULTURE COLLECTION	Stedman, Timothy	N01 AI100002 7C-0-5	\$29,273
Filoviruses	Molecular Basis of Host-Filovirus Interactions in Pathogenesis	RML, Laboratory of Virology	Ebihara, Hideki	ZIA AI001136 -06	\$773,352
Filoviruses	Molecular Mechanisms of Viral Membrane Fusion	UNIVERSITY OF VIRGINIA	Tamm, Lukas	4 R01 AI030557 -25	\$293,786
Filoviruses	NIAID Vaccine Immune T Cell and Antibody Laboratory Core	VACCINE RESEARCH CENTER	Koup, Richard	ZIC AI005123 -04	\$701,340
Filoviruses	Pathogenesis and countermeasures of poxviruses, hemorrhagic fever viruses, MERS	Division of Intramural Research	Jahrling, Peter	ZIA AI001025 -10	\$783,188
Filoviruses	Pathogenesis, Treatment and Prevention of Emerging	LABORATORY OF IMMUNOREGULATION	Lane, Clifford	ZIA AI000936 -13	\$1,458,191

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Infectious Diseases				
Filoviruses	Production of Alternate Adenovector Filovirus Vaccines	VACCINE RESEARCH CENTER	Schwartz, Richard	ZIB AI005092 -10	\$2,447,948
Filoviruses	Project 1: Evaluation of Second Generation Lassa Fever Immunoassays as Point-of-Care Diagnostics and Surveillance Tools for Lassa Fever.	TULANE UNIVERSITY OF LOUISIANA	Shaffer, Jeffrey	5 U19 AI115589 -02 Project-001	\$182,243
Filoviruses	Project 2. Expansion of Clinical Research Capacity at Kenema Government Hospital	TULANE UNIVERSITY OF LOUISIANA	Schieffelin, John	5 U19 AI115589 -02 Project-002	\$158,834
Filoviruses	Protein Production and Protein Interaction Core	WASHINGTON UNIVERSITY	Leung, Daisy	1 P01 AI120943 -01A1 Core-001	\$338,277
Filoviruses	Proteomics, Metabolomics and Lipidomics	BATTELLE PACIFIC	Smith, Richard	4 U19 AI106772	\$200,464

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
		NORTHWEST LABORATORIES		-04 Core A	
Filoviruses	Role for polyamines in Ebola Virus Replication	BOSTON UNIVERSITY MEDICAL CAMPUS	Connor, John	1 R21 AI121933 -01	\$278,295
Filoviruses	Structural and Functional Studies of Ebola Virus RNA Synthesis	WASHINGTON UNIVERSITY	Amarasinghe, Gaya	1 P01 AI120943 -01A1 Admin- Core-001	\$206,750
Filoviruses	Structural genomics centers for infectious diseases	SEATTLE BIOMEDICAL RESEARCH INSTITUTE	Myler, Peter	N01 AI120002 5C-0-3	\$953,312
Filoviruses	Structural Mechanisms of Ebola Virus RNA Synthesis	WASHINGTON UNIVERSITY	Amarasinghe, Gaya	1 P01 AI120943 -01A1 Project- 002	\$896,516
Filoviruses	Systems Biology Analysis of Influenza A Virus and Ebola Virus	UNIVERSITY OF WISCONSIN-MADISON	Kawaoka, Yoshihiro	4 U19 AI106772 -04 Project 1	\$1,222,289
Filoviruses	Task X14: Evaluation of Ebola Vaccines	BATTELLE CENTERS/PUBLIC HEALTH RES & EVALUATN	Bruce, Mary	N01 AI120000 3I- 27200014-1	\$177,944

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Filoviruses	Task X18: Evaluation of Filovirus Vaccines	BATTELLE CENTERS/PUB HLTH RES & EVALUATN	Hornback, Randi	N01 AI120000 3I- 27200018-1	\$5,106,239
Filoviruses	Task X8: Efficacy Testing of Filovirus Vaccines in Non-Human Primates	BATTELLE CENTERS/PUB HLTH RES & EVALUATN	Sabourin, Carol	N01 AI120000 3I- 27200008-2	\$456,997
Filoviruses	Task X9: Development of Standardized Filovirus Immune Assays and Reagents	BATTELLE CENTERS/PUB HLTH RES & EVALUATN	Bruce, Mary	N01 AI120000 3I- 27200009-1	\$314,642
Filoviruses	The viral bioinformatics resource center	NORTHROP GRUMMAN INFORMATION TECHNOLOGY,	Walden, Aimee	N01 AI140002 8C-0-6	\$402,128
Filoviruses	Uganda International Center for Excellence in Research	RML, Laboratory of Virology	Feldmann, Heinrich	ZIA AI001188 -03	\$8,066
Filoviruses	Understanding Ebola virus replication and spread in skin	UNIVERSITY OF IOWA	Maury, Wendy	1 R21 AI123616 -01	\$257,669
Filoviruses	Viral Genomics: evolution,	BROAD INSTITUTE, INC.	Sabeti, Pardis	5 U19 AI110818	\$363,641

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	spread, and host interactions			-03 Project 1	
Filoviruses	Viral Hemorrhagic Fevers: Disease Modeling and Transmission	RML, Laboratory of Virology	Feldmann, Heinrich	ZIA AI001089 -08	\$1,184,285
Filoviruses	Virology BSL4 Core	WASHINGTON UNIVERSITY	Davey, Robert	1 P01 AI120943 -01A1 Core-002	\$449,513
Filoviruses	Virus Ecology Unit	RML, Laboratory of Virology	Munster, Vincent	ZIA AI001179 -04	\$421,871
Filoviruses	Virus-Host Interactions: Induction and Evasion of Host Innate Immunity	RML, Laboratory of Virology	Best, Sonja	ZIA AI001125 -07	\$628,045
Nuc./Rad.	2-O, 3-O desulfated heparin as a Countermeasure for Radiation-Induced Thrombocytopenia	CHILDREN'S HOSP OF PHILADELPHIA	Lambert, Michele	N01 AI140003 3C-0-1	\$1,861,316
Nuc./Rad.	A Novel Nanoparticle Platelet Analogue for Radiation-Induced	DUKE UNIVERSITY	Chen, Jun	N01 AI140003 4C-0-1	\$289,982

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Thrombocytopenia				
Nuc./Rad.	Acute and Long Term Immune Responses to Radiation and Mitigation	UNIVERSITY OF CALIFORNIA LOS ANGELES	Cheng, Genhong	5 U19 AI067769 -12 Project-001	\$427,384
Nuc./Rad.	Administrative Core	COLUMBIA UNIVERSITY HEALTH SCIENCES	Brenner, David	5 U19 AI067773 -12 Admin-Core-001	\$435,166
Nuc./Rad.	Administrative Core	UNIVERSITY OF CALIFORNIA LOS ANGELES	Mcbride, William	5 U19 AI067769 -12 Admin-Core-001	\$261,107
Nuc./Rad.	Administrative Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Greenberg, Joel	5 U19 AI068021 -12 Admin-Core-001	\$572,435
Nuc./Rad.	Administrative Core A	DUKE UNIVERSITY	Chao, Nelson	5 U19 AI067798 -12 Admin-Core-001	\$765,773
Nuc./Rad.	Age-Related Differences in Response to Radiation and	INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS	Orschell, Christie	1 UH2 AI128894 -01	\$26,082

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Medical Countermeasures				
Nuc./Rad.	Biostatistics Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Wang, Hong	5 U19 AI068021 -12 Core-006	\$187,308
Nuc./Rad.	Bone Marrow Stromal Cells as Mitigators of Radiation Injury	Unknown	Unknown	Y02 RC013027 -0-1	\$77,000
Nuc./Rad.	CCL1 gene therapy to inhibit bacterial translocation in acute radiation syndromes	UNIVERSITY OF TEXAS MEDICAL BR GALVESTON	Suzuki, Fujio	4 U01 AI107355 -04	\$509,429
Nuc./Rad.	Computational Systems Pharmacology Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Bahar, Ivet	5 U19 AI068021 -12 Core-007	\$257,450
Nuc./Rad.	Coordinating Center Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Greenberg, Joel	5 U19 AI068021 -12 Core-001	\$397,927
Nuc./Rad.	Development of lisinopril for post-exposure mitigation of late effects from a rad	MEDICAL COLLEGE OF WISCONSIN	Medhora, Meetha	4 U01 AI107305 -04	\$641,332

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Nuc./Rad.	Development of medical countermeasures to mitigate and/or treat radiation-induced lung injury after a radiological/nuclear incident	LIGNAMED, LLC	Harris, Jim	N01 AI150000 5C-0-1	\$2,101,929
Nuc./Rad.	Development of medical countermeasures to mitigate and/or treat radiation-induced lung injury after a radiological/nuclear incident	BCN BIOSCIENCES, LLC	Norris, Andrew	N01 AI150000 4C-0-1	\$2,309,176
Nuc./Rad.	Development of Medical Countermeasures to Mitigate or Treat GI-ARS	SOLIGENIX, INC.	Rivenburg, Thomas	N01 AI130003 0C-0-1	\$575,242
Nuc./Rad.	Differentiating Radio-sensitivities Among Intestinal Stem Cell Pools	COLUMBIA UNIVERSITY HEALTH SCIENCES	Wang, Timothy	3 U01 DK10315 5-03S1	\$130,000
Nuc./Rad.	Differentiating Radio-sensitivities	COLUMBIA UNIVERSITY	Wang, Timothy	5 U01 DK10315 5-03	\$366,638

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Among Intestinal Stem Cell Pools	HEALTH SCIENCES			
Nuc./Rad.	Discovering tissue-specific biomarkers of radiation injury in SILAC-labeled mice	FRED HUTCHINSON CANCER RESEARCH CENTER	Paulovich, Amanda	4 R01 AI101832 -05	\$440,000
Nuc./Rad.	Epidermal growth factor mitigates radiation-induced hematopoietic failure	UNIVERSITY OF CALIFORNIA LOS ANGELES	Chute, John	5 U01 AI107333 -04	\$505,120
Nuc./Rad.	High throughput biodosimetry using a fully automated dicentric assay on commercial high-content screening platforms	COLUMBIA UNIVERSITY HEALTH SCIENCES	Garty, Guy	N01 AI160004 0C-0-1	\$1,583,934
Nuc./Rad.	Identification of Biomarkers for Late Radiation Lung Damage	UNIVERSITY OF ROCHESTER	Finkelstein, Jacob	4 R01 AI101732 -05	\$386,250
Nuc./Rad.	IGF::OT::IGF Support services for radiation cancer risk. 09/19/2016-09/18/2017.	SOCIAL AND SCIENTIFIC SYSTEMS, INC.	Archer, Janet	N02 CP140001 01-2610007-1	\$30,000

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	TASK ORDER 7 - REB core support services. HHSN26120140 0010I, CAN# SEVERAL				
Nuc./Rad.	Imaging Radiation Pathology Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Watkins, Simon	5 U19 AI068021 -12 Core-009	\$338,852
Nuc./Rad.	IND-Enabling Preclinical Development of a New Radiomitigator	UNIVERSITY OF TENNESSEE HEALTH SCI CTR	Tigyi, Gabor	4 U01 AI107331 -04	\$662,618
Nuc./Rad.	Informatics and Biostatistics Core	TRANSLATIONAL GENOMICS RESEARCH INST	Bittner, Michael	5 U19 AI067773 -12 Core-004	\$183,456
Nuc./Rad.	Innovative Biomarkers to Predict Radiation Lung Injury	MEDICAL COLLEGE OF WISCONSIN	Medhora, Meetha	4 R01 AI101898 -05	\$379,928
Nuc./Rad.	Innovative Medicinal Chemistry Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Wipf, Peter	5 U19 AI068021 -12 Core-004	\$432,119
Nuc./Rad.	Irradiation Core	COLUMBIA UNIVERSITY HEALTH SCIENCES	Garty, Guy	5 U19 AI067773 -12 Core-002	\$314,133

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Nuc./Rad.	Lipidomics and Bioanalytical Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Tyurina, Yulia	5 U19 AI068021-12 Core-008	\$238,020
Nuc./Rad.	Long-acting growth factors for treating the acute and long term effects of lethal	BOLDER BIOTECHNOLOGY, INC.	Cox, George	4 U01 AI107340-04	\$674,036
Nuc./Rad.	Metabolomic biomarkers and instrumentation for assessment of radiation injury	GEORGETOWN UNIVERSITY	Fornace, Albert, Jr	4 R01 AI101798-05	\$382,724
Nuc./Rad.	Mitigation of Radiation-Induced Pulmonary Injury with Nrf2 activator	UNIVERSITY OF MARYLAND BALTIMORE	Vujaskovic, Zeljko	4 U01 AI107361-04	\$521,199
Nuc./Rad.	Molecular-Targeted Radiation Therapy	Unknown	Unknown	Y02 RC013028-0-1	\$112,999
Nuc./Rad.	Mouse Core	COLUMBIA UNIVERSITY HEALTH SCIENCES	Smilenov, Lubomir	5 U19 AI067773-12 Core-001	\$210,787
Nuc./Rad.	Opportunities Fund	COLUMBIA UNIVERSITY	Amundson, Sally	5 U19 AI067773	\$3,423,018

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Management Core	HEALTH SCIENCES		-12 Core-006	
Nuc./Rad.	Oral Radiation Nuclear Decoration Agents	SRI INTERNATIONAL	Shankar, Gita	N01 AI100002 9C-0-1	\$40,614
Nuc./Rad.	Organ-specific NRF2-mediated protein signatures of radiation exposure & tissue da	UNIVERSITY OF CALIFORNIA LOS ANGELES	Whitelegg e, Julian	4 R01 AI101888 -05	\$385,000
Nuc./Rad.	PGE2 mitigation of acute and late radiation injury	UNIVERSITY OF ROCHESTER	Palis, James	4 U01 AI107276 -04	\$609,773
Nuc./Rad.	Primate Core - Core D	WAKE FOREST UNIVERSITY HEALTH SCIENCES	Cline, J.	5 U19 AI067798 -12 Core-007	\$2,435,589
Nuc./Rad.	Product Development Core	UNIVERSITY OF CALIFORNIA LOS ANGELES	Whitelegg e, Julian	5 U19 AI067769 -12 Core-004	\$491,612
Nuc./Rad.	Product Testing Animal Core	UNIVERSITY OF CALIFORNIA LOS ANGELES	Iwamoto, Keisuke	5 U19 AI067769 -12 Core-005	\$670,622
Nuc./Rad.	Protection against Radiation-	Unknown	Unknown	Y02 RC013029 -0-1	\$106,000

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Induced Carcinogenesis				
Nuc./Rad.	Protein Tyrosine Phosphatase-Sigma, A Novel Target for Mitigation of Acute Radiation Injury	UNIVERSITY OF CALIFORNIA LOS ANGELES	Chute, John	5 U19 AI067769 -12 Project-003	\$444,369
Nuc./Rad.	Radiation Biodosimeter	Unknown	Unknown	Y02 RC012034 -0-1	\$50,000
Nuc./Rad.	Radiation Biodosimetry using Gene Expression Signatures	COLUMBIA UNIVERSITY HEALTH SCIENCES	Amundson, Sally	5 U19 AI067773 -12 Project-002	\$502,654
Nuc./Rad.	Radiation Mitigation and Normal Tissue Stem Cells	UNIVERSITY OF CALIFORNIA LOS ANGELES	Pajonk, Frank	5 U19 AI067769 -12 Project-004	\$446,395
Nuc./Rad.	Radiation Mitigators Targeting Regulated Necrosis Pathways of Necroptosis and Ferroptosis	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Bayir, Hulya	5 U19 AI068021 -12 Project-003	\$383,320

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Nuc./Rad.	Radiation Physics Core	UNIVERSITY OF CALIFORNIA LOS ANGELES	Sheng, Ke	5 U19 AI067769 -12 Core-003	\$314,207
Nuc./Rad.	Radiation Survivor Core	WAKE FOREST UNIVERSITY HEALTH SCIENCES	Cline, J.	5 U19 AI067798 -12 Core-004	\$104,387
Nuc./Rad.	Radiation/nuclear medical countermeasure (MCM) product development support	SRI INTERNATIONAL	Chang, Polly	N01 AI150001 3I-27200005-1	\$7,029,841
Nuc./Rad.	Radiation/nuclear medical countermeasure (MCM) product development support services. formulation of 3,4,3-LI(1,2-HOPO)	SRI INTERNATIONAL	Chang, Polly	N01 AI150001 3I-27200003-1	\$584,303
Nuc./Rad.	Radiation/nuclear medical countermeasure (MCM) product development support services. Formulation of recombinant human	SRI INTERNATIONAL	Chang, Polly	N01 AI150001 3I-27200004-1	\$397,869

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	pleiotrophin (RHPTN)				
Nuc./Rad.	Radiation/nuclear medical countermeasure (MCM) product development support services. Task order A-1 administrative and technical support	SRI INTERNATIONAL	Chang, Polly	N01 AI150001 3I- 27200001- 1	\$1,832,316
Nuc./Rad.	Radiobiological Standardization Core	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Epperly, Michael	5 U19 AI068021 -12 Core- 005	\$198,946
Nuc./Rad.	Rapid Automated High-Throughput Radiation Biodosimetry	COLUMBIA UNIVERSITY HEALTH SCIENCES	Brenner, David	5 U19 AI067773 -12 Project- 001	\$557,694
Nuc./Rad.	Rapid Non-invasive Radiation Biodosimetry through Metabolomics	GEORGETOWN UNIVERSITY	Fornace, Albert, Jr	5 U19 AI067773 -12 Project- 003	\$713,457
Nuc./Rad.	Recombinant Fc Chimeras of R-spondin 1 and Slit2 for Medical Countermeasure	UNIVERSITY OF MICHIGAN	Geng, Jian-guo	1 UH2 AI128900 -01	\$43,361

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	of Chronic Radiation Syndrome				
Nuc./Rad.	Research Project 2: Nucleic acid scavengers-a novel radiation countermeasure	DUKE UNIVERSITY	Sullenger, Bruce	5 U19 AI067798 -12 Project-002	\$284,695
Nuc./Rad.	Research Project 3: Innate immune pathways that mitigate delayed radiation-induced damage	UNIV OF NORTH CAROLINA CHAPEL HILL	Ting, Jenny	5 U19 AI067798 -12 Project-003	\$422,454
Nuc./Rad.	Research Project 5: Glycogen synthase kinase-3 (GSK-3) inhibitors as mitigators of the acute radiation syndrome	DUKE UNIVERSITY	Kirsch, David	5 U19 AI067798 -12 Project-005	\$281,710
Nuc./Rad.	Research Support Assessment - NUC/RAD RMS	U.S. NATIONAL INSTITUTES OF HEALTH	N/A	5 RMS AI099912 -05	\$26,660
Nuc./Rad.	Research Support Assessment - NUC/RAD Support for various	U.S. NATIONAL INSTITUTES OF HEALTH	N/A	N01 AI099914 -0-0	\$105,325

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	intramural research				
Nuc./Rad.	Restoring Immune Function Following Radiation Injuries by TLR9 Agonist Treatment	BRIGHAM AND WOMEN'S HOSPITAL	Lederer, James	4 U01 AI107360 -04	\$584,538
Nuc./Rad.	Sample Engineering Core	UNIVERSITY OF ARIZONA	Zenhausern, Frederic	5 U19 AI067773 -12 Core-003	\$533,273
Nuc./Rad.	Serum microRNA as biomarker for radiation injury to lung and hematopoietic cells	DANA-FARBER CANCER INST	Chowdhury, Dipanjan	4 R01 AI101897 -05	\$422,319
Nuc./Rad.	Service Core B - Biostatistics	DUKE UNIVERSITY	Owzar, Kouros	5 U19 AI067798 -12 Core-005	\$281,377
Nuc./Rad.	Service Core C - Immune Monitoring	DUKE UNIVERSITY	Sempowski, Gregory	5 U19 AI067798 -12 Core-006	\$456,673
Nuc./Rad.	Signature-Directed Combination Mitigator	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Greenberg, Joel	5 U19 AI068021 -12	\$449,786

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Therapy Based on GS-Nitroxides			Project-001	
Nuc./Rad.	Support For Thyroid Cancer & Other Thyroid Diseases in Belarus	Unknown	Rozhko, Alexander	N02 CP130000 2C-0-1	\$50,000
Nuc./Rad.	Targeting Intestinal Stem Cell Dysfunctions in Radiation Mitigation	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Yu, Jian	5 U19 AI068021 -12 Project-004	\$322,062
Nuc./Rad.	Targeting of New Cardiolipin-Derived Lipid Mediators Pathways for Radiomitigation.	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Kagan, Valerian	5 U19 AI068021 -12 Project-002	\$364,154
Plague/Tular emia	Administrative Core	ALBANY MEDICAL COLLEGE	Metzger, Dennis	4 P01 AI056320 -12 Core A	\$100,639
Plague/Tular emia	Administrative Core	UNIVERSITY OF CHICAGO	Crosson, Sean	4 U19 AI107792 -04 Core A	\$43,961
Plague/Tular emia	Bifunctional Control of Yop Translocation by YopK	TUFTS UNIVERSITY BOSTON	Marketon, Melanie	5 R01 AI107055 -05	\$466,178

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Plague/Tular emia	Chromosome-encoded T3S effectors of <i>Yersinia pestis</i>	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	Plano, Gregory	5 R21 AI119450 -02	\$216,844
Plague/Tular emia	CRISPR/Cas systems in bacterial gene regulation and virulence	EMORY UNIVERSITY	Weiss, David	5 R01 AI110701 -03	\$249,050
Plague/Tular emia	Development of Enabling Vector/Antigen Expression Technology for an Orally-Delive	PROTEIN POTENTIAL, LLC	Sim, B.	4 R01 AI098884 -05	\$619,332
Plague/Tular emia	Dissecting Bubonic Plague	UNIV OF NORTH CAROLINA CHAPEL HILL	Miller, Virginia	5 R01 AI119032 -02	\$425,547
Plague/Tular emia	Elucidating the Biogenesis of the <i>Yersinia pestis</i> Containing Vacuole	UNIVERSITY OF LOUISVILLE	Lawrenz, Matthew	1 R21 AI119557 -01A1	\$253,618
Plague/Tular emia	<i>Francisella tularensis</i> Pathogenesis	UNIV OF NORTH CAROLINA CHAPEL HILL	Kawula, Thomas	5 R01 AI082870 -06	\$472,438
Plague/Tular emia	Genes in the <i>Yersinia pestis</i> lifecycle	UNIVERSITY OF CHICAGO	Schneewind, Olaf	4 U19 AI107792 -04 Project 3	\$275,399

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Plague/Tular emia	Heterologous polysaccharide synthesis in attenuated <i>Salmonella</i>	UNIVERSITY OF FLORIDA	Kong, Qingke	7 R01 AI112680 -02	\$128,200
Plague/Tular emia	Immune Protection Against Pulmonary Tularemia	ALBANY MEDICAL COLLEGE	Metzger, Dennis	4 P01 AI056320 -12 Project 1	\$734,445
Plague/Tular emia	Immunity to Pneumonic Tularemia	Laboratory of Bacteriology	Bosio, Catharine	ZIA AI001013 -10	\$784,576
Plague/Tular emia	Immunology Core	ALBANY MEDICAL COLLEGE	Gosselin, Edmund	4 P01 AI056320 -12 Core C	\$250,228
Plague/Tular emia	Mechanism of TolC in the virulence of <i>Francisella tularensis</i>	STATE UNIVERSITY NEW YORK STONY BROOK	Thanassi, David	5 R21 AI115069 -02	\$220,455
Plague/Tular emia	Microbiology Core	ALBANY MEDICAL COLLEGE	Bai, Guangchun	4 P01 AI056320 -12 Core B	\$292,469
Plague/Tular emia	Modulation of Human Cells by Virulent <i>Francisella tularensis</i>	Laboratory of Bacteriology	Bosio, Catharine	ZIA AI001097 -08	\$435,875

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Plague/Tular emia	Modulation of Inflammasome Activation by Yersinia	UNIVERSITY OF PENNSYLVANIA	Brodsky, Igor	4 R01 AI103062 -04	\$452,052
Plague/Tular emia	NMR studies of bacterial needle and tip proteins	UNIVERSITY OF KANSAS LAWRENCE	De guzman, Roberto	5 R01 AI074856 -08	\$103,288
Plague/Tular emia	Persistence in an intracellular pathogen Francisella tularensis	UNIVERSITY OF VIRGINIA	Ramakrishnan, Girija	1 R21 AI119471 -01A1	\$267,841
Plague/Tular emia	Post-transcriptional regulation of Crp in Yersinia pestis	NORTHWESTERN UNIVERSITY AT CHICAGO	Lathem, Wyndham	1 R21 AI111018 -01A1	\$253,299
Plague/Tular emia	Redox Control of F. tularensis Pathogenesis	ALBANY MEDICAL COLLEGE	Gosselin, Edmund	4 P01 AI056320 -12 Project 3	\$483,692
Plague/Tular emia	Regulation of cytosolic pattern recognition receptor signaling in macrophages	NORTHWESTERN UNIVERSITY AT CHICAGO	Stehlik, Christian	4 R01 AI099009 -04	\$218,256
Plague/Tular emia	Regulation of Yersinia pestis flea-borne transmission	WASHINGTON STATE UNIVERSITY	Vadyvaloo, Viveka	1 R01 AI117016 -01A1	\$516,970

FY 2016 NIAID-managed MTD Projects					
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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Plague/Tular emia	Structural genomics centers for infectious diseases	NORTHWESTERN UNIVERSITY AT CHICAGO	Anderson, Wayne	N01 AI120002 6C-0-16	\$1,566,405
Plague/Tular emia	Technology Core	UNIVERSITY OF CHICAGO	Kim, Youngchang	4 U19 AI107792 -04 Core B	\$82,242
Plague/Tular emia	The Structural Determinants of Innate Immune Modulation by Francisella LPS	UNIVERSITY OF IOWA	Barker, Jason	5 R01 AI104728 -03	\$426,624
Plague/Tular emia	TLR2/NLR Signal Regulation of Protective Immunity to <i>F. Tularensis</i>	ALBANY MEDICAL COLLEGE	Harton, Jonathan	4 P01 AI056320 -12 Project 2	\$413,032
Plague/Tular emia	Transmission of <i>Yersinia pestis</i> by Fleas: Molecular Mechanisms	RML, Laboratory of Zoonotic Pathogens	Hinnebusch, B	ZIA AI000796 -20	\$435,241
Smallpox	Biogenesis of the Poxvirus Membrane	MEDICAL UNIVERSITY OF SOUTH CAROLINA	Traktman, Paula	5 R01 AI107123 -03	\$422,386
Smallpox	Control of antiviral-viral B cell responses by	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Lund, Frances	5 U19 AI109962 -03 Project 3	\$242,940

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Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	IFNy T-bet and Eomes				
Smallpox	Control Systems Governing Short vs Longterm Humoral & Cellular Immunity	AUSTRALIAN NATIONAL UNIVERSITY	Goodnow, Christophe	4 U19 AI100627 -05 Project 2	\$475,058
Smallpox	Detrimental T cells cross-reactivity during respiratory infections	UNIV OF MASSACHUSETTS MED SCH WORCESTER	Selin, Liisa	5 U19 AI109858 -03 Project 3	\$53,896
Smallpox	DsRNA Characterization in Monkeypox-infected Cells	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	Jacobs, Bertram	4 R01 AI095394 -05	\$758,769
Smallpox	Functional Biology of T Cells	Laboratory of System Biology	Germain, Ronald	ZIA AI000758 -19	\$83,217
Smallpox	Genomic analysis of the canonical case of virulence evolution: Myxomatosis in Au	PENNSYLVANIA STATE UNIVERSITY-UNIV PARK	Read, Andrew	4 R01 AI093804 -05	\$543,542
Smallpox	Imaging Antiviral Immunity	LABORATORY OF VIRAL DISEASES	Yewdell, Jonathan	ZIA AI001212 -01	\$443,144

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Smallpox	Immunodominant Viral Memory CD4 Epitopes of Biosecurity and Geriatric Medicine Concern	UNIVERSITY OF WASHINGTON	Mhyre, Tim	N01 AI140004 9C-0-1	\$635,179
Smallpox	Impact of envelope proteins on poxviral pathogenesis	MEDICAL UNIVERSITY OF SOUTH CAROLINA	Bartee, Eric	1 R21 AI123803 -01	\$211,193
Smallpox	Importance of Species-Specific Interactions of PKR with Poxvirus Inhibitors for Virus Replication and Host Range	KANSAS STATE UNIVERSITY	Rothenburg, Stefan	5 R01 AI114851 -02	\$412,497
Smallpox	Integrated Research Facility at Fort Detrick	Division of Clinical Research	Jahrling, Peter	ZID AI009006 -08	\$713,532
Smallpox	Interplay between cellular bioenergetics and vaccinia virus infection	MEDICAL UNIVERSITY OF SOUTH CAROLINA	Traktman, Paula	5 R21 AI115056 -02	\$211,193
Smallpox	Manipulation of inflammasomes and NF- κ B signaling in	UNIVERSITY OF FLORIDA	McFadden, Grant	4 R01 AI100987 -04	\$423,798

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	human myeloid cells by Myxom				
Smallpox	Mechanism of the Antiviral Activity of BAF Against Poxvirus and HSV-1 Infection	UNIVERSITY OF NEBRASKA LINCOLN	Wiebe, Matthew	5 R01 AI114653 -02	\$208,105
Smallpox	Mechanisms of NK Cell Migration to the Draining Lymph Node in Viral Infections	THOMAS JEFFERSON UNIVERSITY	Sigal, Luis	7 R01 AI065544 -10	\$571,615
Smallpox	MHC-1 regulation by virus	WASHINGTON UNIVERSITY	Fremont, Daved	4 R01 AI019687 -32	\$214,725
Smallpox	MHCII Cross-presentation as a Driver of CD4+ T Cell Responses to Poxviruses	CHILDREN'S HOSP OF PHILADELPHIA	Eisenlohr, Laurence	5 R01 AI110542 -03	\$638,046
Smallpox	NK and T Cell Control of Cowpox Virus	WASHINGTON UNIVERSITY	Yokoyama, Wayne	5 U19 AI109948 -03 Project 1	\$1,437,570
Smallpox	Novel approaches to propagate molluscum contagiosum	UNIVERSITY OF PENNSYLVANIA	Isaacs, Stuart	5 R21 AI117100 -02	\$278,250

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	virus in cell culture				
Smallpox	Pathogenesis and countermeasures of poxviruses, hemorrhagic fever viruses, MERS	Division of Intramural Research	Jahrling, Peter	ZIA AI001025 -10	\$130,531
Smallpox	Poxvirus Assembly and Egress	LABORATORY OF VIRAL DISEASES	Moss, Bernard	ZIA AI001074 -09	\$541,582
Smallpox	Poxvirus Entry	LABORATORY OF VIRAL DISEASES	Moss, Bernard	ZIA AI000539 -29	\$722,108
Smallpox	Poxvirus Gene Expression and DNA Replication	LABORATORY OF VIRAL DISEASES	Moss, Bernard	ZIA AI000307 -35	\$722,108
Smallpox	Poxvirus Immune Evasion Mechanisms	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	Xiang, Yan	5 R01 AI079217 -07	\$420,034
Smallpox	Poxvirus pathogenesis and immunity	LABORATORY OF VIRAL DISEASES	Moss, Bernard	ZIA AI000979 -11	\$722,108
Smallpox	Poxviruses and Pro-Resolving Lipids	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	Norbury, Christopher	5 R21 AI115230 -02	\$269,053
Smallpox	Protein Interactions Involved in	UNIVERSITY OF ROCHESTER	Ward, Brian	5 R01 AI067391 -08	\$433,404

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
	Orthopoxvirus Envelopment				
Smallpox	Regulation of cytosolic pattern recognition receptor signaling in macrophages	NORTHWESTERN UNIVERSITY AT CHICAGO	Stehlik, Christian	4 R01 AI099009 -04	\$218,256
Smallpox	Regulation of follicular helper CD4 T cell (Tfh) and Th1 differentiation in vivo	LA JOLLA INST FOR ALLERGY & IMMUNOLGY	Crotty, Shane	5 U19 AI109976 -03 Project 1	\$123,166
Smallpox	Studies in Poxvirus Host Range Genes and Tropism	UNIVERSITY OF FLORIDA	Mcfadden, Grant	5 R01 AI080607 -07	\$423,798
Smallpox	TF regulation of CD8 and CD4 T cell memory in both systemic and dermal infection	UNIVERSITY OF CALIFORNIA SAN DIEGO	Goldrath, Ananda	5 U19 AI109976 -03 Project 3	\$373,897
Smallpox	The Toponome of Virus Infected Skin	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	Norbury, Christopher	1 R21 AI121876 -01A1	\$218,539
Smallpox	Translation in Immunity	LABORATORY OF VIRAL DISEASES	Yewdell, Jonathan	ZIA AI001210 -01	\$96,938

FY 2016 NIAID-managed MTD Projects					
July 31, 2017					
Portfolio	Project Title	Institution	Principal Investigator	Project ID	Funding
Smallpox	Vaccinia DNA Replication	MEDICAL UNIVERSITY OF SOUTH CAROLINA	Traktman, Paula	5 R01 AI021758 -32	\$422,386
Smallpox	Viral Stocks and Reagents	UNIVERSITY OF ALABAMA AT BIRMINGHAM	Lund, Frances	5 U19 AI109962 -03 Core B	\$42,464
Smallpox	Virus Induction of Primary and Memory B- and T-Cell Responses	LABORATORY OF VIRAL DISEASES	Bennink, Jack	ZIA AI000814 -20	\$345,413
				TOTAL \$228,675,427	

Clinical and Translational Science Award

Roby 1: I'm very proud that my home state of Alabama has a highly regarded academic medical center like the University of Alabama at Birmingham. Thanks to UAB, underserved populations in Alabama don't have to travel long distances or across state lines to receive quality specialty care. UAB does a lot of work in addressing health disparities. Specifically, the Center for Clinical and Translational Science at UAB serves a population heavily burdened with cardio-metabolic, vascular and cancer-related diseases, and focuses on conditions that disproportionately affect minority and special populations in Alabama. Can you explain your vision for the CTSA program, and how the NIH plans to address health disparities more broadly in Alabama and across the Deep South?

Response:

The National Center for Advancing Translational Science's (NCATS's) Clinical and Translational Science Awards (CTSA) Program supports a national network of medical research institutions that work together to improve the translational research process to get more treatments to more patients more quickly. CTSA Program support enables research teams including scientists, patient advocacy organizations, and community members to tackle system-wide scientific and operational problems in clinical and translational research that no one team can overcome. The Program has five strategic goals, one of which focuses on promoting the integration of special and underserved populations in translational research across the human lifespan.

NCATS and NIH recognize health disparities as an important factor to be considered when developing translational innovations, and several CTSA Program institutions are supporting studies aimed at providing insights into those differences. The University of Alabama at Birmingham (UAB) Center for Clinical and Translational Science (CCTS) serves a region with a population with a heavy burden of cardiometabolic, vascular, and cancer-related diseases. UAB follows the larger NCATS vision of creating a national network of institutions capable of making translational science more efficient. For the CCTS, this network includes connecting the national CTSA network to a regional network of ten institutions that make up the CCTS' Partner Network among a three-state region (Alabama, Louisiana, and Mississippi) in the Deep South. The Partner Network consists of: Auburn University, Hudson Alpha Institute for Biotechnology, Louisiana State University Health Sciences Center, Pennington Biomedical Research Center, Tulane University, University of Alabama at Tuscaloosa, University of South Alabama, University of Mississippi Medical Center, and two Historically Black Colleges Universities: Tuskegee University and Southern University.

To support its vision, the CCTS has identified five aims: (1) ensure their research and training efforts serve the region's special populations; (2) promote a diverse workforce that reflects multiple disciplines; (3) support ethical clinical trials conducted among their Partner Network among the 10 universities and three neighboring states; (4) engage communities in planning and conducting research; (5) evaluate CCTS activities to ensure goals are attained. The primary vision of the CCTS is to ameliorate disparities in these and other conditions that disproportionately affect minority and special populations represented within the region and

across the nation. One strategy used to achieve the various aims established for the CCTS is by providing didactic and experiential training in translational investigation. In addition, through the hub's ***One Great Community*** program, the CCTS has demonstrated commitment to community engagement through the Community Health Innovation Awards (CHIA) and the Community Engagement Institute, a regional assembly that seeks to increase dialogue among academic and community partners.

Another way that NIH supports research on health disparities experienced by underserved populations in the South is by building partnerships among academic and community partners. An example of this is the NIH-supported Mid-South Transdisciplinary Collaborative Center (TCC) for Health Disparities Research, a consortium of academic institutions including UAB, Jackson State University, the University of Mississippi Medical Center, Louisiana State University Health Sciences Center New Orleans, and Dillard University. The institutions in the Mid-South TCC are working together to reduce the burden of chronic disease experienced by minorities in Alabama, Louisiana, Mississippi, Arkansas, Tennessee, and Kentucky. This region includes many of the country's most impoverished rural and inner-city communities, which carry exceptionally high burdens of obesity, chronic disease and high mortality rates. This program has developed a coalition of over 120 community members, organizational and institutional partners, policy makers, and stakeholders, to establish a regional infrastructure to support research, implementation, and dissemination activities. In addition, the Mid-South TCC supports research projects about social determinants that impact obesity and chronic illness, and has developed a mentored research program to support early-stage investigators who are researching health disparities in the South.

Accelerating Medicines Partnership

Roby 2: Dr. Collins and any of the other IC Directors who would like to respond: Public-private partnerships are proving to be invaluable in overcoming some of the most complex scientific challenges we face today. A great example of this kind of unique collaboration is the Accelerating Medicines Partnership (AMP), which brings together the NIH, the FDA, several biopharmaceutical companies, as well as several non-profit organizations, to develop new diagnostics and promising targets for treating Alzheimer's disease, type 2 diabetes, and lupus. By all accounts this pre-competitive partnership has been very successful thus far, with a unique governance and structure that enables valuable sharing of both expertise and resources. What attributes of this partnership are making it successful, and how are each of the partners helping to fuel advances?

Response:

NIH is very pleased at the progress made so far by the Accelerating Medicines Partnership (AMP), a public-private partnership. Launched in 2014, the AMP partners include NIH, the U.S. Food and Drug Administration (FDA), 10 biopharmaceutical companies and multiple non-profit organizations. The Foundation for the NIH (FNIH) manages the partnership. The AMP partners aim to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics, thereby reducing the time and cost of developing new therapeutics.

A critical feature of AMP is that all partners agreed to make the AMP data and analyses publicly accessible to the broad biomedical community. NIH and industry partners share expertise and resources in an integrated governance structure that enables scientific contributions to inform all participants. AMP is strengthened by the robust commitment and ongoing participation from senior leadership of all partner organizations. AMP projects have well-developed work plans, with clear milestones and detailed budgets. Furthermore, all partners have made significant financial contributions.

AMP's initial projects have focused on Alzheimer's disease, type 2 diabetes (T2D), and the autoimmune disorders rheumatoid arthritis and systemic lupus erythematosus (RA/Lupus). Accomplishments to date for the Alzheimer's project include multiple public data releases from target discovery and preclinical validation projects and the inclusion of tau imaging in two National Institute of Aging-supported clinical trials. T2D project accomplishments include the development of the T2D Knowledge Portal, with publically available datasets from many sources worldwide. The RA/lupus project is beginning its phase 2 clinical work of collecting RA synovium (a thin membrane lining joints implicated in RA) and lupus kidney biopsies, and will be releasing its phase 1 data in the fall of 2017.

Prioritizing Resources

Roby 3: Dr. Collins: Would you please describe for us how the NIH will prioritize its resources in the coming year to ensure that the NIH supports the most promising and potentially highest-impact research?

Response:

NIH prioritizes its resources through a process that considers multiple factors. Outlined in the [NIH-Wide Strategic Plan for FY2016-2020](#), each factor is weighed carefully in order to ensure that the agency funds research with the greatest potential for impact. These factors include:

- **Peer Review:** NIH is committed to funding the most rigorous proposals with the most scientific merit. NIH's two-stage peer review process leverages the expertise of its scientific community to ensure that it funds the best science.
- **Public Health Needs:** NIH is committed to supporting research towards its mission to enhance health, lengthen life, and reduce illness and disability. To this end, NIH responds to public health needs, from emerging infectious diseases like Zika, to growing burdens of chronic disease like opioid addiction and obesity.
- **Scientific Opportunity:** As different fields mature at different rates, new findings and new technologies can often open up new experimental possibilities for breakthrough research. NIH seeks to capitalize on these new opportunities for rapid, high-impact advancement in scientific fields, especially when they come from unexpected directions.
- **Portfolio Balance:** Since new scientific breakthroughs often come from unexpected directions and public health emergencies are often difficult to predict, NIH believes it is important to cast a broad net and maintain a careful balance within its portfolio in order to be nimble enough to respond to new threats and promising opportunities. This includes a balance of basic, translational, and clinical research, a balance among diseases and model systems, and a balance between supporting research and supporting the infrastructure and training that keep research sustainable.

The NIH-Wide Strategic Plan also identifies key efforts to be more transparent about our priority setting process. NIH is confident that this process combines the necessary breadth and steady progress to move biomedical research forward across a wide range of research topics with the nimbleness required to capitalize on unexpected opportunities and address public health threats as they arise.

Collaboration with Private Industry

Roby 4: Dr. Collins: While NIH supports a great deal of biomedical research on its campuses and at universities across the US, private industry- including pharmaceutical companies, as well as many nonprofit organizations and foundations, also conduct and support research. Can you please tell us more about how NIH collaborates with private industry and nonprofit research funders to maximize the impact of its available funding on advancing biomedical research?

Response:

NIH collaborates with industry and nonprofit research funders when there is more to gain in scientific output than would be possible by each working separately. For some collaborations, NIH partners with industry and other organizations directly, but it also can leverage its partnership with the congressionally-established, nonprofit Foundation for NIH (FNIH), whose purpose is to forge public-private partnerships in support of NIH's mission.

Some of NIH's collaborations are pre-competitive research, meaning the outcomes benefit an area of research and collaboration rather than one company's proprietary product. For example, the Biomarkers Consortium, managed by FNIH, has supported the development of indicators of osteoarthritis and sarcopenia that would benefit any researcher or company developing interventions to treat these diseases. The Biomarkers Consortium is a public-private partnership that seeks to discover, develop, and seek regulatory approval for biological markers that can be used for diagnosis, prevention, or to support development of new treatments. It has supported projects in 13 disease areas thus far.

Other collaborative programs at NIH support researchers in gaining access to companies' proprietary compounds to test new ideas or find new therapeutic uses. For instance, the new National Cancer Institute (NCI) agent formulary (NCI Formulary),¹⁷ launched in January 2017, will enable investigators at NCI-designated Cancer Centers to have quicker access to approved and investigational agents for use in preclinical studies and cancer clinical trials. This public-private partnership between the NCI and pharmaceutical and biotechnology companies will expedite the start of clinical trials by alleviating the lengthy process for investigators to obtain access to agents on their own. The NCI Formulary is particularly focused on agents (often from different companies) that can be used in combination to generate better outcomes, a strategy that is being applied more frequently as the use of genomic sequencing is becoming more common in selecting cancer therapies.

NIH also often works with other funders to focus on research for rare and neglected diseases. Therapies for these diseases tend to have limited commercial value, making it difficult for industry to justify investment in this area. NIH's Therapeutics for Rare and Neglected Diseases (TRND) program stimulates collaborations among academic scientists, nonprofit organizations, and pharmaceutical companies to develop new therapies. NIH supports development as the drugs move through pre-clinical testing and submission of an Investigational New Drug application to the Food and Drug Administration, making the drug candidates more appealing to outside

¹⁷ <https://nciformulary.cancer.gov/>

partners to develop further. NIH uses this and many other collaborative models to leverage public funds with support from other partners to advance biomedical research and obtain a better return on the research investment.

Maternal Mortality

Herrera Beutler 1: Last week NPR did a story on maternal mortality, after teaming up with ProPublica for a six month investigation on maternal mortality. It highlighted the fact that “every year in the US, 700 to 900 women die from pregnancy or childbirth-related causes, and some 65,000 nearly die — by many measures, the worst record in the developed world.” While addressing this issue is going to take action on multiple levels, including State based Maternal Mortality Review Committees - and part of the solution will come from the medical professional community, and other agencies such as CDC - what is NIH and NICHD planning to do to address and reduce maternal mortality and maternal morbidity?

Response:

More women in the United States are dying of pregnancy-related complications than any other developed country. In fact, U.S. rates are rising, unlike other developed countries, where they are falling. 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. The prevalence and potential severity of pregnancy complications make research to inform better treatment and prevention interventions to protect maternal health a high priority.

Pregnancy-related health outcomes are influenced by a woman's general health and other factors like race, ethnicity, age, income and potential complications of co-existing conditions. The National Institute of Child Health and Human Development (NICHD) supports a large portfolio of research on the diverse aspects of maternal health, including complications of pregnancy, gestational diabetes, and incontinence. The NICHD-supported Maternal-Fetal Medicine Unit (MFMU) Network 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. For example, a major clinical study, which is focused on 10,000 women expecting their first child, will yield critical information on several common adverse pregnancy outcomes, which can be unpredictable in women who have no pregnancy history to help guide their treatment. This valuable network infrastructure and data also are being shared with other NIH Institutes and Centers to conduct collaborative studies. One such collaborative project, with the National Heart, Lung, and Blood Institute, is following women who participated in this study and who had preeclampsia during their pregnancies to evaluate them for maternal cardiovascular health.

NICHD's Obstetric-Fetal Pharmacology Research Network 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. A recent clinical study showed that women who were known to be at high risk of preeclampsia who had been given the cardiovascular drug, Pravastatin, did not develop preeclampsia. In addition, NICHD is leading the new, congressionally mandated Task Force on Research Specific to Pregnant Women and Lactating Women, which will be providing

recommendations to the HHS Secretary on how to address research gaps on prescription medications commonly used by these populations, but not tested or labeled for them.

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. One project, known as 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 and/or a mobile application. This project will help researchers better understand the range of physical and emotional alterations that women experience during pregnancy and after giving birth, the impact of these experiences on women's lives, and the challenges encountered by special sub-populations of women before and after childbirth. This portfolio of research is aimed at helping to understand and address the causes of maternal mortality and morbidity.

Kidney Research

Herrera Beutler 2: In December, the Government Accountability Office (GAO) released a report entitled, Kidney Disease Research and Priority Setting. This report found that Medicare spends \$103 billion on patients with kidney disease, of which \$32.8 billion is spent on those patients in kidney failure. The dollars spent annually on those in kidney failure is almost as much as the entire NIH budget. NIH's FY2015 investment in kidney research was \$564 million, which is less than 1 percent of the amount Medicare spent on the disease. Enhanced research on kidney disease could deliver improved detection and treatments to patients, and provide solutions to reduce this cost burden to the healthcare system. In addition to the recent launch of the Special Kidney Program at the NIDDK, what innovative opportunities does NIH foresee to fund research that will lead to a better understanding of kidney disease and deliver improved treatments?

Response:

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is vigorously supporting research to identify causes of kidney diseases, slow or stop disease progression, develop treatments, and prevent kidney diseases and kidney failure in adults and children. A growing consensus suggests that different disease pathways lead to different subgroups of acute kidney injury (AKI) and chronic kidney disease (CKD); thus, the future of kidney disease clinical care lies in individualized treatment plans based on a patient's disease subgroup. Recent advances in multi-scale interrogation of human tissue and single cells have set the stage for precision medicine to be applied to AKI and CKD. In 2016, NIDDK released three funding opportunity announcements to establish the Kidney Precision Medicine Project (KPMP), which aims to obtain ethically, and evaluate, human kidney biopsies from participants with AKI or CKD; create a kidney tissue atlas; define disease subgroups; and identify critical cells and pathways that will lead to targets for novel therapies. The KPMP will start in August 2017. Additional technology development in support of the KPMP will be supported by small business research programs.

In 2018, the NIDDK will renew the Chronic Renal Insufficiency Cohort (CRIC) Study, which seeks to gain a better understanding of how CKD advances. CRIC is one of the largest and longest ongoing studies of CKD in the United States. The aims of the study are to better understand what makes CKD progress to kidney failure, and to understand the link between CKD and cardiovascular disease (CVD), or heart-blood vessel disease. Another study goal was to find ways to pinpoint groups of people who are at high risk for CKD and CVD. The latest phase of the study builds on the results of the past 10 years and will look at the illnesses that older people with CKD have. CRIC researchers have made important discoveries. In collaboration with other researchers, they reported that *APOL1* gene variants significantly contributed to the faster CKD progression in African Americans compared with Caucasians. In another study, CRIC investigators reported that high levels of a hormone called FGF-23, which regulates phosphate metabolism, are associated with an increased risk of CVD in patients with CKD.

Also being renewed in 2018 is the multi-center Chronic Kidney Disease in Children (CKiD) study, led by the NIDDK in collaboration with other Institutes, which is examining children with

mild to moderately decreased kidney function to investigate risk factors for further kidney decline, as well as closely monitoring neurocognitive development, examining, risk factors for heart disease, and following long-term effects of poor growth in this group.

Strategies to enhance renal repair and promote the generation of new nephrons in the postnatal organ could have a significant impact on the prevalence and progression of kidney disease. NIDDK continues to support the (Re)Building a Kidney consortium, which will optimize approaches for the isolation, expansion, and differentiation of appropriate kidney cell types and their integration into complex structures that replicate human kidney function.

Pediatric Kidney Disease

Herrera Beutler 3: Children with kidney disease will face significant health challenges throughout their life. NIDDK has done important research on its impact on a child's development and maturation through its multicenter research on pediatric kidney disease. However, health disparities significantly influence the progression of the disease in children. African Americans and Hispanics are 3.4 and 1.5 times, respectively, more likely to develop kidney failure. What steps is NIH undertaking to better understand and address these health disparities on the progression of kidney disease in pediatric patients? How does NIH plan to advance and coordinate the work done on this topic at the relevant institutes, including NIDDK, NIMHD, and NICHD?

Response:

The National Institute of Diabetes and Digestive and Kidney Diseases's (NIDDK) multi-center Chronic Kidney Disease in Children (CKiD) study, also supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Heart, Lung, and Blood Institute, is examining children with mild to moderately decreased kidney function to investigate risk factors for further kidney decline, as well as closely monitoring neurocognitive development, examining risk factors for heart disease, and following long-term effects of poor growth in this group. To better understand the health disparities associated with kidney disease in children, the CKiD study cohort included 23 percent African American and 15 percent Hispanic participants. CKiD is providing valuable insights; for example, the study has already found that growth is more stunted in lower-income youth with kidney disease. NIDDK has renewed the CKiD study, which will continue to follow current study participants, and is recruiting new subjects.

One project supported by the National Institute on Minority Health and Health Disparities (NIMHD) examines the genetic mechanisms underlying kidney disease across the life cycle. Previous work supported by NIH indicated that variations in the Apolipoprotein L1 (APOL1) gene account for much of the excess risk of chronic and end-stage kidney disease, which results in a health disparity for people with African ancestry. These APOL1 risk alleles are associated with 5-29 times higher odds of severe kidney disease in African Americans than Whites. NIMHD is supporting a clinical trial to examine the factors that lead from having the risk alleles to the development of kidney disease, with roughly 5 percent of the participants representing the pediatric population. This research may generate new insights into the biological mechanisms underlying the relationship between risk alleles and future development of kidney disease from childhood to adulthood, providing insight into prevention and treatment, and allow for precision medicine approaches in the future.

Implantable or Wearable Kidneys

Herrera Beutler 4: Kidney dialysis has enabled millions of Americans to extend their lives, including more than 600,000 who are on dialysis currently. However, kidney transplantation remains the preferred therapy for most patients but the demand exceeds the current supply of kidneys. One promising way to replace kidney function is through the development of implantable or wearable kidneys. Could you comment on the status of current research in these areas, including your general assessment of their viability? Is there more NIH could do to move this forward? Is the private sector sufficiently engaged?

Response:

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is supporting research on an implantable kidney device through its Quantum Grant program which supports projects that have a highly focused, collaborative, interdisciplinary, milestone-driven approach targeted at solving a major medical or public health challenge through technological innovation. Kidney dialysis is not only costly and inconvenient for patients, but exposing blood is inherently risky for infection. The NIBIB-supported project is working to develop an implantable bioartificial kidney for patients who suffer from kidney failure who are currently on dialysis. The device will combine a nanoscale filter with a bioreactor of cells to mimic normal kidney function. The device is designed to be driven by normal blood flow wherein blood is filtered under circulatory system pressure to selectively remove waste products and other materials, the same manner as healthy kidney function. Researchers are developing this project and working with the Food and Drug Administration (FDA) through its Innovation Pathway Program 2.0. In a proof of concept study in a large animal to test the design, blood could flow and there were no clotting difficulties using a small model of the device. Early testing also demonstrated that the device worked continuously in an animal for 30 days. Preliminary stage progress is also being made on improving the function of isolated kidney cells to be included in the device. Although advances are being made on development of an implantable device, many scientific challenges remain and need to be overcome before the device can be tested in humans.

In addition, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) launched the (Re)Building a Kidney Consortium. The research protocols and improved understanding of basic kidney biology from this research will help optimize the biologic components of wearable and implantable kidneys, thereby accelerating their development and increasing likelihood of viability. All protocols and resources developed through the (Re)Building a Kidney program will be accessible through a public website so that the entire scientific community, including the private sector, can benefit from the investment in this program.

Other private sector engagement is occurring through NIDDK's support of several grants to small businesses through the Small Business Innovation Research (SBIR) program to improve vascular access for hemodialysis—a critical aspect of implantable or wearable dialyzer viability. For example, in one project, researchers are optimizing a working design of a novel hemodialysis needle that was engineered to reduce the risk of bleeding upon needle dislodgement.

Rare Disease Research and Precision Medicine

Herrera Beutler 5: I would like to see more progress and focus on discovering treatments for rare diseases. As we develop the field of precision medicine, common disease categories will subdivide into smaller and smaller groups. How do you see the role of rare disease research, which already looks at small group diseases, impacting precision medicine and how does the NIH propose to take advantage of this linkage?

Response:

The translation of a discovery into a treatment that benefits the public is a multi-step process. Not only does the development of a therapy help those impacted by the disease, but often the research itself leads to additional insights in our basic understanding of the disease as well as others like it. Approximately 80 percent of rare diseases are genetic disorders, which are frequently diagnosed by genomic analysis. This type of precision medicine is having an impact on all disease-related research by expanding the toolbox by which doctors diagnose, evaluate, and treat diseases. In addition to identifying the genetic basis of a disorder, genomic analysis can also help to assess disease severity (including type of mutation, such as a gene deletion, which tends to be the most severe), identify individual patients who are at higher or lower risk of disease progression or severe manifestations, and identify who may be more responsive to a therapeutic agent. Genomic analysis can also identify where to “target” an intervention, which can guide research, such as identifying and optimizing potential therapies. Recent data from FDA has shown that the number of “targeted” therapies (e.g., those that make use of blood tests, images, or other technologies to determine who may benefit from a treatment, or at risk of a side effect) being approved are increasing, and many of these therapies are for rare disease indications.^{18,19}

Both rare and common diseases are increasingly being subdivided into smaller populations, based on our growing knowledge about the underlying pathophysiology of the disease, such as through identification of biomarkers (e.g., lab markers), mutations (as noted above) or other factors. Together, this information improves the targeting or precision of therapeutic interventions. Several common cancers, such as lung cancer, are now being targeted based on specific mutations in the tumor.

NIH's Office of Rare Diseases Research (ORDR), which is housed within the National Center for Advancing Translational Sciences, was established in 1985 to help develop a national scientific agenda to conduct and support research in rare diseases. ORDR currently supports and advances rare diseases research through a number of programs, including the Rare Diseases Clinical Research Network (RDCRN) and the Genetics and Rare Diseases information center

¹⁸ Woodcock J. FDA Voice. FDA Continues to Lead in Precision Medicine. March 23, 2015.

<https://blogs.fda.gov/fdavoice/index.php/2015/03/fda-continues-to-lead-in-precision-medicine/>

¹⁹ Moscicki R, CDER 2016 Update for Rare Diseases. Slides 18-19.

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM542141.pdf>

(GARD), and by supporting scientific conferences, among others. Precision medicine and other innovative approaches are supported and advanced through these and other NIH programs.

Youth Suicide

Herrera Beutler 6: In 2015, suicide was responsible for over 44,000 deaths in the U.S., which is approximately one suicide every 12 minutes. Overall suicide rates increased 28% from 2000-2015. It is the third leading cause of death for youth 10-14 years of age (now exceeding motor vehicle deaths), and the second leading cause of death among people 15-24 and 25-34 years of age, but it is a problem that exists throughout the lifespan. Dr. Gordon, you have outlined suicide prevention as one of your top three research priorities that will yield benefits on a short-term timescale. We have a youth suicide issue in our district, and these children and their families need help now. For adolescents who are suicidal, they are typically not being seen in behavioral health settings, but primary health care settings. What is NIMH doing to improve screening and care for adolescents at risk, and how is NIMH balancing research funding that will address current mental health needs - meaning benefitting people who need help now - with investments that yield benefits over a longer term, perhaps 10, 15, or 20 years from now.

Response:

Suicide prevention research is a top priority for NIMH, and current investments are aimed at reducing suicide events in the short-term.²⁰ “Zero Suicide” is a commitment to suicide prevention led by the National Action Alliance for Suicide Prevention and its partners, including NIMH. Through Zero Suicide efforts, NIMH is expanding research to determine the best ways to implement effective suicide prevention services for youth in multiple health care settings, including emergency care and primary care.²¹

In terms of identifying youth at risk for suicide, researchers in the NIMH intramural programs, together with pediatric emergency staff, developed an emergency department suicide risk screening tool for pediatric patients. The 4-item Ask Suicide Screening Questions (ASQ)²² significantly increased suicide risk detection for youth who presented with psychiatric concerns, as well as for youth who presented with medical/physical concerns.

Once a child or adolescent is identified to be at risk for suicide, appropriate treatment levels (i.e., inpatient or outpatient) must be determined. NIMH funds the Emergency Department Screen for Teens at Risk for Suicide (ED-STARS) study in 14 sites across the United States to examine innovative approaches for risk detection and to determine appropriate treatment levels for youth at risk for suicide.^{23,24}

After treatment levels are determined, effective interventions need to be available and implemented. NIMH funds intervention studies aimed at increasing positive mood among high-risk youth, increasing social support, reducing negative emotions, improving adolescents' sleep

²⁰ <https://www.nimh.nih.gov/about/director/messages/2016/the-push-for-suicide-prevention.shtml>

²¹ <https://www.nimh.nih.gov/news/science-news/2016/nimh-funds-3-zero-suicide-grants.shtml>

²² <https://www.nimh.nih.gov/news/science-news/ask-suicide-screening-questions-asq.shtml>

²³

https://projectreporter.nih.gov/project_info_description.cfm?aid=9203948&icde=32467332&ddparam=&ddvalue=&ddsub=&cr=1&cscb=default&cs=ASC&pball=

²⁴ <https://www.nimh.nih.gov/news/science-news/2014/personalized-screen-to-id-suicidal-teens-in-14-ers.shtml>

quality and adherence to treatments, and reducing substance use.^{25,26} Based on work with the NIH Office of Disease Prevention in their Pathways to Prevention program, NIMH has promising indications that early efforts to build youths' coping skills and supportive relationships with family and peers can lower risk for suicidal thoughts and behavior.²⁷

²⁵

https://projectreporter.nih.gov/project_info_description.cfm?aid=8968866&icde=32483259&ddparam=&ddvalue=&ddsub=&cr=3&csb=default&cs=ASC&pball=

²⁶

https://projectreporter.nih.gov/project_info_description.cfm?aid=8967226&icde=32483259&ddparam=&ddvalue=&ddsub=&cr=7&csb=default&cs=ASC&pball=

²⁷ <https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/suicide-prevention>

Down Syndrome

Herrera Beutler 7: "Dr. Collins, I want to ask you about progress on the NIH Research Plan for Down syndrome. I understand it has been a great catalyst for expanding our understanding of Down syndrome, particularly in the area of Alzheimer's disease. It also seems to provide a clear road map for how studying many of the other coexisting conditions in Down syndrome, such as congenital heart disease and mental health disorders, as well as studying conditions that are rare in people with Down syndrome, such as solid tumors, can provide new insights into how best to treat all people with those conditions, not just those with Down syndrome. At this point, however, much the plan still seems to be aspirational. What more can be done to advance the important research priorities identified in the NIH Research Plan for Down syndrome?"

Response:

NIH published the *DS Directions: The NIH Down Syndrome Research Plan* in late 2014. The public-private Down Syndrome Consortium, which includes the Trans-NIH Working Group, 13 national and international organizations whose missions focus on Down syndrome, and individuals with Down syndrome and family members, provided valuable input and a link to the Down syndrome community during development of the plan. The plan has had an impact on the field of Down syndrome research; in submitting their grant applications, many researchers have cited one of its objectives. While life expectancy for people with Down syndrome who are living in the United States has increased dramatically over the last 50 years, the coexisting conditions, such as congenital heart disease, and hearing, vision, and intestinal problems still require more research.

The NICHD and NIH continue to fund a wide-range of research projects and other efforts to improve the health of people with Down syndrome. For example, to address the dementia akin to Alzheimer's disease, a recent NICHD-funded study showed that inefficient breakdown of proteins in individuals with Down syndrome could lead to the build-up of damaged proteins, which could be harmful for brain cells and be a contributory factor for dementia. The Alzheimer's Biomarkers Consortium – Down Syndrome (ABC-DS), co-funded in FY16 by the National Institute of Aging (NIA) and NICHD – is aimed at a better understanding of the link between Down syndrome and Alzheimer's Disease. The HHS National Plan to Address Alzheimer's Disease promotes improving care for populations disproportionately affected by Alzheimer's disease and for populations facing care challenges, including individuals with Down syndrome.²⁸

Some NICHD-supported research on autism spectrum disorders will also benefit individuals with Down syndrome who also have autism. One recent study showed that brain changes at age 6 or 12 months may help predict the development of autism spectrum disorders (ASD) by age 2 years among infants with a high family risk, an important finding since early diagnosis and appropriate intervention can ease symptoms and improve social, emotional and cognitive skills. Other NICHD-funded researchers showed metal toxicant uptake (lead) and deficiency in essential elements (manganese, zinc) during fetal development may increase ASD risk and severity.

²⁸ <http://aspe.hhs.gov/daltcp/napa/NatlPlan.shtml>

NIH also assists the research community by providing research resources that might otherwise prove cost prohibitive for them to support individually. To advance research on Down syndrome, NICHD supports a contract for the leading repository of mouse models for Down syndrome. The Cytogenetic & Down Syndrome Models Resource²⁹ at Jackson Laboratory maintains and distributes mouse models for Down syndrome, as well as the study of chromosomal aneuploidy, and has recently funded a new research project to develop new mouse models for Down syndrome. Together with NIMH and NINDS, NICHD encourages studies that develop, validate, and/or calibrate informative outcome measures for use in clinical trials for individuals with intellectual and developmental disabilities (IDD), including Down syndrome. And *DS-Connect*®, a Web-based DS patient registry that was established in 2013 and now includes about 3,500 participants, provides researchers with a new tool to recruit for their research studies. The registry benefits families, too; ultimately, the registry will link to biorepositories of tissue samples and other resources, making it easier for participants to take part in clinical studies for new medications and other treatments for Down syndrome.

²⁹ <http://www.jax.org/cyto/index.html>

Rare Disease Research

Herrera Beutler 8: The indirect cost rate for extramural research has risen over the years and may have lead universities to pursue quantity of funding over quality of projects that may include rare diseases. What changes, if any, are needed in this system with the understanding that the NIH has underwritten significant portions of the infrastructure at these institutions?

Response:

The total cost of a grant award generally consists of direct and indirect costs. While direct costs are directly attributable or assignable to a specific project, indirect costs, commonly known as Facilities and Administrative (F&A) costs, are incurred for the general support and management of research. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity. F&A costs are those which are necessary to support research but cannot be readily identified with an individual research project. Examples of these costs are facilities operation and maintenance, utilities, maintenance of scientific equipment and tools, libraries, and administrative expenses, which include the costs of complying with Federal policies and regulations. F&A costs are real expenses incurred to support research activities.

For most of NIH grant awards to educational institutions and non-profit organizations, the HHS Cost Allocation Services negotiates and approves F&A cost rate proposals. Once negotiated, all Federal agencies, including NIH, must accept and apply the negotiated F&A cost rates for its grant recipients, as required by regulation at 45 CFR 75.414 (c)(1). Indirect costs as a proportion of the NIH budget have remained below 30 percent for nearly 30 years.

Not all recipient institutions receive a negotiated F&A cost rate. For example, F&A costs for training and foreign grant awards are capped at 8 percent, in recognition that these types of awards do not incur the same level of indirect expenses as do other research projects. NIH also does not pay any F&A costs for awards to Federal institutions.

NIH Organization

Herrera Beutler 9: The NIH Centers and Institutes are now structured around organ systems, disease models (like cancer) and targeted groups. Would there be a benefit from examining this system periodically to avoid overlap, duplication and potential waste? Are some of these Centers and Institutes the best and most efficient models for targeting research given the newer models of disease?

Response:

As a public science agency, NIH uses transparent, data driven approaches in its decision making to ensure that it maximizes efficiencies and exercises optimum stewardship of taxpayer funds. NIH is strengthening its leadership in developing and validating the methodologies that are needed to evaluate scientific investments, and prevent potential overlap and duplication in research. For example, new tools for portfolio analysis can be used to identify scientific opportunities, high-performing areas of research, and areas of potential overlap among NIH Institutes and Centers (IC). Such analyses help to ensure NIH investments are complementary and maximize synergies. As outlined in the NIH Strategic Plan, the portfolio of each IC has been analyzed and compared to one another to better assess what value each grant in its portfolio provides and to guide optimal decision-making and collaborations.

To undertake these portfolio analyses, NIH developed *iSearch*, a portfolio analysis platform that provides comprehensive, easy-to-use access to a carefully curated, extensively-linked data set of grants, patents, publications, clinical trials, and drugs. *iSearch* enables immediate insight into current and emerging areas of research, as well as provides new understanding of the translational potential and impact of NIH-supported research. NIH is also interested in examining how NIH-funded research is making an impact in research and healthcare communities. For example, NIH recently developed the Relative Citation Ratio (RCR), a new metric which can measure the influence of a scientific article, regardless of publication and scientific field. The RCR is one way for NIH to ensure that the research it funds is scientifically impactful. The RCR tool is free and available to the public through NIH's *iCite* website (<https://icite.od.nih.gov/>).

In addition to portfolio analysis tools, NIH is enhancing trans-NIH collaborations to reduce potential overlap and duplication between ICs and to leverage the unique strengths of each IC when faced with complex and multi-faceted biomedical research issues. One example is the Longitudinal Study of Adolescent Brain and Cognitive Development (ABCD Study), a landmark study on brain development and child health examining how biology and environment interact with and relate to developmental outcomes such as physical and mental health and life achievements. The ABCD Study is led by three ICs³⁰, in partnership with five additional ICs and Office of the Director (OD) Offices³¹. This multi-IC collaboration ensures that many different

³⁰The National Institute on Drug Abuse, the National Cancer Institute, and the National Institute on Alcohol Abuse and Alcoholism.

³¹ The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Institute of Mental Health, the National Institute of Minority Health and Health Disparities, the National Institute of Neurological Disorders and Stroke, and the NIH Office of Behavioral and Social Sciences Research.

aspects, from genetic factors to behavioral responses, are included in the scope of the ABCD Study.

Another example of trans-NIH collaboration is the Human Microbiome Project (HMP), which develops research resources to enable the study of the microbial communities that live in and on our bodies and the roles they play in human health and disease. Led by the NIH Common Fund, the HMP involves 18 ICs and OD Offices to coordinate human microbiome research across NIH. Current HMP projects focus on: gaining a better understanding of how microbiome and host profiles change throughout pregnancy and influence the establishment of the nascent neonatal microbiome, understanding how the human gut microbiome changes over time in adults and children with inflammatory bowel disease, and a detailed analysis of the biological processes that occur in the microbiome and human host in patients at risk for Type 2 Diabetes.

Finally, NIH regularly examines its administrative processes for ways in which to increase efficiencies and reduce duplication of effort, both for NIH-funded researchers and within the agency itself. For example, NIH is currently in the process of streamlining grant application and reporting requirements and simplifying the biographical information that scientists are required to submit with grant applications, as well as taking a number of administrative actions to consolidate facility and IT resources for both cost and time savings.

NIH Role in Research

Herrera Beutler 10: Given the massive increases in biomedical research at America's universities and colleges, do you see the NIH's role more as an organizer, funder, and motivator for science or as a primary site for research in the NIHs internal programs. How do you see this evolving in the next ten years?

Response:

While it began as an intramural research facility in the late 19th century, NIH has transitioned most of its resources to support research across the vast and diverse academic, industrial, and non-profit biomedical research sectors in the United States following World War II. In recent years for example, NIH awarded approximately 81 percent³² of its funding to extramural researchers and institutions across the country, with about 10-12 percent of the budget supporting innovative research on-going at its intramural facilities. Throughout these changes, NIH has been essential for organizing, funding, and motivating research across the country and within the laboratories managed on its campus. Moving forward over the next decade, NIH will strive to continue balancing these roles through the goals outlined in our strategic plan and with continued and evolving feedback from researchers, advocates, Congress, and the public.

Organizer

Each year, NIH organizes thousands of peer review meetings involving scientists from across the country aimed at identifying the most promising research to fund. NIH recruits outstanding scientific experts to serve as reviewers and coordinates the logistics of these peer review meetings to ensure that NIH grant applications receive fair, independent, expert, and timely reviews. In addition to peer review, NIH plays a key role in convening experts for evaluating progress and determining future directions of specific fields.

In 2014, following concerns surrounding the rigor and reproducibility of biomedical research, NIH further demonstrated its utility as an organizer by bringing together editors from basic and pre-clinical science journals to identify a set of goals to enhance rigor, which numerous journals have since endorsed. In 2016, NIH followed through with updated application instructions and review criteria to enhance reproducibility of research findings through increased scientific rigor and transparency.

The NIH strategic plan further demonstrates our organizing potential to improve research through its implementation of interdependent objectives that will guide priorities over the next five years.³³ These goals include:

- 1) Focusing on how basic, translational, and clinical research intersect to accelerate discovery
- 2) Fostering innovation by setting priorities that are both flexible and based on the best science
- 3) Enhancing scientific stewardship and striving for the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science

³² <https://officeofbudget.od.nih.gov/pdfs/cjs/2017/Final%202017%20CJ.pdf.pdf>

³³ <https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf>

- 4) Managing for results by assessing scientific investments, balancing outputs and outcomes, and evaluating NIH policies and decision-making processes

Funder

Approximately 81 percent of NIH's budget has funded extramural research across the United States for many decades. This trend will continue as extramural scientists provide a wealth of diverse ideas to address the difficult issues associated with improving health of people in the United States and across the world.

NIH also funds an intramural research program known for its interdisciplinary approach to biomedical science. The flagship Clinical Center currently supports about 1,600 clinical research studies. Intramural researchers have won international recognition and countless awards for conducting transformational science that advances biomedical knowledge³⁴. Many projects focus on rare diseases, the results of which often add to the basic understanding of common diseases affecting the larger population.

Motivator

One approach NIH uses to motivate science is through funding opportunity announcements (FOAs), which solicit research applications targeted to a specific research area or program. Targeted announcements often highlight areas of scientific interest with promise for advancement and the potential to fill knowledge gaps. As an example, the National Heart, Lung, and Blood Institute recently released a FOA to encourage basic, translational, and clinical proof-of-concept research projects that are needed for the advancement of bioengineering approaches for heart, lung, blood, and sleep diseases.³⁵

In addition, NIH continues to implement policies and programs to motivate early career scientists to embark upon and sustain independent research careers, including through the recently announced Next Generation Researchers Initiative, which will enhance support for early-stage and mid-career investigators.

Moving Forward Over the Next Decade

Among several provisions, the recently enacted 21st Century Cures Act authorizes multi-year funding to NIH to support several innovative scientific initiatives over the next 10 years. These efforts have the promise to shape long-term research outcomes in precision medicine, neuroscience, cancer biology, and regenerative medicine.

NIH also identified bold aspirational goals in its most recent strategic plan that spotlights areas of research that are ripe for continued support throughout the coming decade. Examples include enhancing survival of cancer patients by applying precision medicine and advancing development of a universal flu vaccine.

³⁴ <https://irp.nih.gov/accomplishments>

³⁵ <https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-015.html>

The roles NIH will take to achieve each of these objectives may vary between organizer, funder, and motivator. Regardless of the approach, the overall importance of these many moving parts working in concert to produce biological breakthroughs will endure.

Pregnancy-Related Research

Herrera Beutler 11: Pregnancy-related discoveries that might translate into insights related to pregnancy. Research in pregnancy is largely supported by the NIH through the NICHD's research networks, including the maternal-fetal medicine units network. These networks leverage multi-center sites so that trials can be conducted with larger populations. These networks have contributed to improving clinical practice of obstetrics and have helped work toward lessening the burden of pre-term birth. Unlike chronic conditions that attract industry investment, pregnancy does not, and these networks are essential to moving toward breakthroughs in treatment and discovery. Can the NIH take the idea behind utilizing networks and encourage cross-institute collaboration to gain more insight into pregnancy? If so, how?

Response:

The *Eunice Kennedy Shriver National Institute of Child Health and Human Development* (NICHD) has long made effective use of multi-site networks to conduct clinical studies that are ethnically and geographically diverse, working closely with other NIH Institutes and other federal agencies to answer critical research questions and develop evidence for clinical practice. Randomized clinical trials of sufficient size are often the best way to answer research questions that will inform clinical practice, whether those answers stop the use of an unproven practice or encourage the effective use of new treatment.

Pregnancy-related health outcomes are influenced by a woman's health and other factors like race, ethnicity, age, income and potential complications of co-existing conditions. NICHD supports a large portfolio of research on the diverse aspects of maternal health, including complications of pregnancy, gestational diabetes, and incontinence. The NICHD-supported Maternal-Fetal Medicine Unit (MFMU) Network 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. A major clinical study, which is focused on 10,000 women expecting their first child ("nulliparous" women), will yield critical information on several common adverse pregnancy outcomes, which can be unpredictable in women who have little or no pregnancy history to help guide their treatment. NICHD partnered with the National Heart, Lung, and Blood Institute (NHLBI) to support the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b) sleep study to estimate the prevalence of sleep apnea among 3,700 women during their first pregnancy and to determine whether sleep apnea is a risk factor for adverse pregnancy outcomes. Initial analysis showed that sleep apnea during pregnancy was associated with the development of hypertensive disorders of pregnancy and gestational diabetes. This valuable network infrastructure and data also are being shared with other NIH Institutes and Centers to conduct collaborative studies. For example, the National Institute on Neurological Disorders and Stroke (NINDS) provided funding through the MFMU for the Beneficial Effects of Antenatal Magnesium Sulfate (BEAM) study, which helped to establish that providing magnesium sulfate therapy to pregnant women at risk of preterm birth helped to reduce the incidence of cerebral palsy in their infants. Study data are being deposited into NICHD's new Data and Specimen Hub (DASH), a centralized resource that allows investigators across the country to access NICHD-funded study data for secondary analyses.

NICHD's Obstetric-Fetal Pharmacology Research Network 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. A recent clinical study showed that women who were known to be at high risk of preeclampsia who had been given the cardiovascular drug Pravastatin did not develop preeclampsia.

In addition, NICHD is leading the new Task Force on Research Specific to Pregnant Women and Lactating Women authorized through the 21st Century Cures Act, which will provide recommendations to the HHS Secretary and Congress on how to address research gaps on prescription medications commonly used by, but not tested or labeled for, these populations. A broad range of NIH Institutes, Centers, and Offices, as well as other federal agencies, are participating in the Task Force. Another large, collaborative research endeavor, the "Human Placenta Project," will continue advancing research on the least understood human organ. Working with the National Institute of Biomedical Imaging and Bioengineering (NIBIB), industry, and others, this project is aimed at assessing placental development in real time and developing interventions to prevent abnormal placental development and improve pregnancy outcomes and long-term health. NICHD will continue to look for opportunities to expand cross-institute collaborations.

Implementation of Safe Medications for Moms and Babies Act

Herrera Beutler 12: The 21st Century Cures Act, enacted late last year, created a federal task force to examine gaps in research around safe medications for pregnant and nursing women, and make recommendations to Congress on how to address these gaps. Where is NIH on implementing that task force? What additional resources would NIH need to fully carry out this provision of law?

Response:

Most prescription medications have not been tested in, nor are labeled for, use by pregnant and lactating women. To address this issue, in the 21st Century Cures Act (P.L. 114-255), Congress mandated the establishment of a new Task Force on Research Specific to Pregnant Women and Lactating Women. The Task Force is charged with providing “advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.” Its findings and recommendations must be reported to the HHS Secretary and Congress by September 2018. The Secretary must then decide whether regulatory and other changes might be needed to facilitate the inclusion of pregnant and lactating women in clinical research.

In January 2017, NIH was delegated the authority to establish the Task Force, and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) was asked to take the lead. A Charter establishing the Task Force was filed within the required 90-day timeframe, on March 13, 2017. As a Federal Advisory Committee, a slate of nominees has been prepared for the Secretary’s approval. Each federal agency listed in the law has designated a representative to the Task Force. The first meeting took place on August 21-22, 2017, with three other meetings scheduled over the next year (see <https://www.nichd.nih.gov/about/advisory/PRGLAC>), and all meetings are open to the public. Part of the Task Force’s charge is to create a compendium of federal research activities on therapeutics used by pregnant and lactating women; the findings will be part of the report to the Secretary. This analysis is underway. Further, new, public-facing reporting categories are being developed for NIH-funded research to capture projects in two areas: Pregnancy; and Breastfeeding, Lactation, and Breastmilk.

In addition, NICHD continues to support the Obstetric-Fetal Pharmacology Research Network, which is aimed at improving the safety and effective use of therapeutic drugs in women during pregnancy and lactation through enhanced understanding of obstetric pharmacokinetics and pharmacodynamics. The Network includes pharmacology, clinical research, and multidisciplinary components to explore the mechanisms of drug disposition and response in pregnancy and during lactation. For example, for a medication to treat a pregnant woman’s illness effectively, doses recommended for non-pregnant patients may not be appropriate because pregnancy can significantly change the way the human body processes medicine. Recently, NICHD-funded researchers reported that pregnant women being treated with buprenorphine for opioid dependence need more frequent daily doses of the medicine than currently recommended

dosing for non-pregnant patients. Because a pregnant woman's body "clears" the drug more rapidly, three to four daily doses may be required, according to the researchers, to protect from opioid withdrawal symptoms and enable the patient to adhere to her treatment regimen. This and similar findings from the Network may help to improve clinical practice and promote the health of pregnant women.

Zika Vaccine

Herrera Beutler 13: As you know, NIAID and a variety of private sector partners have made tremendous progress toward developing a Zika vaccine. However, it appears it won't be available commercially until at least 2020. Is that correct? What is the timeline for getting it to people who need it? What are the greatest barriers you face? What additional resources are necessary for this Zika vaccine work to continue as rapidly as possible?

Response:

It is not possible to determine exactly when a commercial Zika vaccine will be available; however, it is unlikely to be prior to 2020 because additional evaluation is required. A full evaluation of the Zika vaccine candidates requires several, phased trials. Initial human studies, or Phase I clinical trials, are safety and immunogenicity studies performed in a small number of closely monitored healthy volunteers. Phase II studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase III trials typically enroll thousands of individuals and provide the critical documentation of efficacy and important additional safety data required for licensing.

The National Institute of Allergy and Infectious Diseases (NIAID) is supporting the development of several leading Zika vaccine candidates, including the NIAID Vaccine Research Center's DNA-based vaccine candidate, which is furthest along in clinical testing. NIAID recently launched a multi-site Phase II/IIb clinical trial of the DNA-based vaccine candidate in March 2017 following positive results in Phase I testing. This Phase II/IIb study will further evaluate whether the experimental vaccine is safe and able to stimulate an adequate immune response, and importantly, whether it can prevent disease in areas with ongoing mosquito-borne Zika virus transmission. The study is expected to conclude in 2019, although the exact timing of the trial will depend on the intensity of Zika virus transmission and the efficacy of the vaccine candidate. A low level of Zika transmission may lengthen the amount of time required to obtain sufficient efficacy data from the clinical trial. If successful, this Phase II trial would be an important step toward licensure and eventual commercial availability of a Zika vaccine. However, additional evaluation and documentation (especially with regard to manufacturing processes) would likely be needed to support eventual FDA licensure or approval for use. The development of a partnership with a commercial entity or entities that could produce and market the vaccine also would be required to make any Zika vaccine available to the general public.

The remaining NIH supplemental funds provided by the Zika Response and Preparedness Appropriations Act, 2016 (Pub. L. No. 114-223) will be obligated by the end of FY 2017. NIH anticipates that these funds will be sufficient to support Zika-related activities.

Zika-Related Birth Defects

Herrera Beutler 14: Recently, the Centers for Disease Control and Prevention released a Vital Signs report finding that 10 percent of babies whose mothers were infected with the Zika virus have some kind of Zika-related birth defect. Is NIH currently doing any research into birth defects or developmental or intellectual disabilities associated with Zika? What are opportunities for continued research into Zika during pregnancy and its effects on women and babies long-term?

Response:

Zika infection, and its consequences, continues to be an emerging, urgent public health issue. Between 2015 and 2017, the Zika virus spread rapidly to 70 countries globally, including countries in South and Central America, the U.S., and U.S. territories, especially Puerto Rico. One of the most serious outcomes of infection during pregnancy is Congenital Zika Syndrome, which may include microcephaly, intracranial calcifications, and many other brain, eye, motor, and learning abnormalities in infants. The risk of an infected woman's infant being born with microcephaly is estimated to be between 1 and 15 percent.

NIH is supporting a wide range of research to understand how Zika affects fetal cells and causes birth defects. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), together with the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Environmental Health Sciences (NIEHS) and Fundação Oswaldo Cruz (Fiocruz), a national scientific research organization linked to the Brazilian Ministry of Health, began a multi-country study, the Zika in Infants and Pregnancy (ZIP) Cohort Study, to evaluate the magnitude of health risks posed by Zika virus infection. Plans are to enroll as many as 10,000 pregnant women ages 15 years and older at up to 15 sites; more than 2,300 participants have been enrolled to date. These women will be followed throughout their pregnancies to determine if they become infected with the Zika virus and, if so, what the health outcomes are of both mother and child. To provide additional information about health outcomes, the participants' infants will be carefully followed for at least one year after birth.

NICHD has launched another new study, the Prospective Cohort Study of HIV and Zika in Infants and Pregnancy, to determine the potential risks that infection with the Zika virus might pose for pregnancies in which the mother is infected with HIV. Researchers hope the new study will provide information on whether infection with one of these viruses might increase the risk of infection with the other. Other concerns include whether Zika might interfere with medications that prevent HIV from being passed from mother to child, and whether infection with the two viruses might increase the risk of damage to the brain seen with the Zika virus. The study is currently enrolling participants in Puerto Rico and will also recruit from the continental U.S. and Brazil. Participants will be provided with appropriate treatment. Mothers will be followed throughout pregnancy and for six months after giving birth, and infants will be followed for a year after birth.

Basic science studies also can improve our understanding of how Zika may cause birth defects. Recently, NICHD-funded researchers discovered that the Zika virus infects and crosses the

placentas of pregnant mice, causing severe damage or death in fetal mice. Recent data in mice indicate that Zika infection affects the testes and sperm quality, so the ZIP study is being expanded to include the male partners of women already enrolled in ZIP. In another NICHD-funded study, Hydroxychloroquine, a drug approved by the Food and Drug Administration (FDA) to treat malaria and certain autoimmune diseases in pregnant women, appears to reduce the transmission of Zika virus from pregnant mice to their fetuses.

The National Institute of Dental and Craniofacial Research (NIDCR) is supporting research exploring how the molecular pathways of two Zika virus proteins (NS4A and NS4B) work together to stunt brain development. Another NIDCR-supported team is investigating how the Zika virus infects cranial neural crest cells, which are the cells that give rise to most of the bones of the craniofacial complex, and whether that contributes to the disruption of normal fetal development of cranial and facial structure. In addition, NIDCR intramural researchers are conducting basic studies on how cell surface proteins interact with their surrounding environment and whether an FDA-approved drug (Hemin) can be repurposed to modify these interactions to suppress Zika virus infection. NIDCR also supports research to develop rapid, non-invasive, point-of-care diagnostic tools for Zika virus infection to improve detection in pregnant women and other vulnerable individuals. These research efforts include a U.S.-Panama collaboration and a small business grant to apply rapid HIV detection technologies to the Zika virus.

Foster Care

Herrera Beutler 15: More than 400,000 children are in the foster care system due to abuse or neglect. Sadly, child welfare agencies in most states are reporting increases in foster care placements due to the substance abuse epidemic affecting communities all across the country. Recently the National Institute of Child Health and Human Development announced a grant for the first national center for maltreatment studies at Penn State.

- a. Can you speak to how you believe this will help inform treatment for maltreatment and prevention and treatment of children?
- b. How will the Center for Healthy Children inform health practitioners, child welfare agencies, social workers etc. as you move forward? How will the Center inform policymakers?
- c. What other work on prevention in child maltreatment is NICHD supporting, and is there collaboration with other Institutes?

Response:

With 1.2 million victims of child maltreatment in the U.S. each year, childhood abuse and injury is a public health issue of far-reaching importance to children and their families. Despite the breadth of this problem, few rigorous studies of effective interventions have been conducted to date.

The purpose of the new NICHD P50 Centers program is to foster collaborative research across multiple disciplines to promote better identification, treatment and care of maltreated children, design effective interventions, and provide opportunities for training for researchers who focus on child abuse. NICHD's goal is to ultimately support at least one center in every region of the country focusing on an important theme in child maltreatment research. The Capstone Child Maltreatment Research Center at Penn State is the first Center to be funded. One of the Center's studies will focus on the child welfare system in Pennsylvania with the goal of identifying and eliminating health disparities in child maltreatment. Another central goal of this Centers program is to help bridge research to policy; each Center is required to propose an Outreach and Dissemination Core to ensure that the knowledge generated from the Center projects is disseminated to the broader community working with this population. For example, the Center at Penn State is partnering with state policymakers to identify and select participants for one of its studies.

In addition, NICHD chairs the NIH Child Abuse and Neglect Working Group, comprising eight NIH Institutes, Centers, and Offices, to identify shared research interests and to foster more collaboration within the NIH on this topic. NICHD also participates in the Federal Interagency Working Group on Child Abuse and Neglect, which is led by the Children's Bureau at the HHS Administration for Children and Families.

Trauma and the Adolescent Brain Cognitive Development Study

Herrera Beutler 16: The Adolescent Brain Cognitive Development Study will examine how biology and environment interact and relate to developmental outcomes of children such as physical health, mental health, and life achievements including academic success. Can you explain how the impact of trauma, such as child abuse, might have on the study results? How is the NICHD involved in this research?

Response:

The Adolescent Brain Cognitive Development (ABCD) Study is the largest long-term study of brain development and child health in the U.S. Previous research has demonstrated that adverse childhood experiences (ACEs) negatively impact numerous health outcomes.³⁶ The ABCD Study provides a unique opportunity to increase understanding of how ACEs, including child abuse, impact brain, social, emotional, and cognitive development. The study will be collecting information on family history of substance use and mental illness, loss of family members, family environment, neighborhood and school safety, and child exposure to violence, sexual abuse, or other trauma. Because the ABCD Study is also collecting information about youth substance use, mental health, physical health, brain development, as well as cognitive and academic performance, scientists will be able to gain new insight into how these adverse childhood experiences alter life trajectories and myriad life outcomes.

The study is a collaboration among several components of the National Institutes of Health including the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Cancer Institute (NCI), the *Eunice Kennedy Shriver* National Institute on Child Health and Human Development (NICHD), the National Institute on Neurological Disorders and Stroke (NINDS), the National Institute of Mental Health (NIMH), National Institute of Minority Health and Health Disparities (NIMHD), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Research on Women's Health (ORWH). The Centers for Disease Control and Prevention Division of Adolescence and School Health (CDC-DASH) and the National Institute of Justice (NIJ), part of the Department of Justice, are also collaborating on this study. In doing so, each of these organizations lends their expertise to the development and management of this large comprehensive study.

In particular, the NICHD has been involved since the study's conception to provide guidance on initial study design and continue to be involved to ensure their interests in healthy brain development, the interactions between environmental factors and brain development, and the effects of childhood sports participation are integrated into the study. In addition, NICHD funds the **CAPSTONE Centers for Multidisciplinary Research in Child Abuse and Neglect**, allowing researchers to assess the efficacy and effectiveness trials of child abuse and neglect interventions, examine the long-term impact of child maltreatment, and study the neurobiology of abuse and neglect and implications for health outcomes. In 2017, the Center for Healthy

³⁶ Campbell JA, Walker RJ, Egede LE. Associations Between Adverse Childhood Experiences, High-Risk Behaviors, and Morbidity in Adulthood. Am J Prev Med 2016;50:344-52. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/26474668>

Children at Penn State University was funded to serve as a national resource for child maltreatment research and training.

The Adolescent Brain Cognitive Development Study and Adverse Childhood Experiences

Herrera Beutler 17: The Centers Disease Control Adverse Childhood Experiences (ACEs) research has laid a foundation about childhood experience and the impact on future violence victimization and lifelong health and opportunity. ACEs have been linked to risky health behaviors, chronic health conditions, low life potential and early death. Can you discuss how the Adolescent Brain Cognitive Development Study might complement the foundational research of ACEs? How might both studies inform policy makers, practice in public health, and child welfare, for example?

Response:

The Adolescent Brain Cognitive Development (ABCD) Study is the largest long-term study of brain development and child health in the U.S., repeatedly assessing more than 10,000 children across the country beginning at age 9 or 10 over 10 years. The study includes comprehensive assessments of physical and mental health, cognitive function, substance use, culture and environment, structural and functional brain imaging, as well as biospecimen collection for environmental, hormonal, and genetic analyses. Included among these assessments are questionnaires that directly address adverse childhood experiences (ACEs). For example, parents answer questions about family history of substance use and mental illness, loss of family members, family environment, neighborhood and school safety, and child exposure to or being a victim of violence or sexual abuse (i.e., within the home or in the community). As the youth participants age, they will be asked these questions directly and repeatedly throughout the course of the study. Because the ABCD Study is also collecting information about youth substance use, mental health, physical health, and cognitive and academic performance, scientists will be able to examine the relationship between adverse childhood experiences (ACEs) and myriad life outcomes.

The prospective nature of the ABCD Study will greatly complement the work of the Centers for Disease Control and Prevention (CDC) work in ACEs, which has demonstrated associations between these experiences and lifelong health. By collecting such comprehensive information about health and life experiences throughout childhood, the ABCD Study has the potential to reveal new detail about how these experiences alter life trajectories to contribute to some of the outcomes observed by the CDC. Collectively, these studies can identify additional opportunities for policy and programmatic intervention to improve the health and success of future generations. For example, if the ABCD Study identifies specific cognitive deficits among children with adverse childhood experiences that may predispose them to engage in risky behaviors (e.g., drug use, risky sexual behaviors), tailored interventions could be developed and implemented to strengthen those cognitive abilities to reduce or prevent risky behaviors and their long-term health consequences.

Substance Abuse Prevention for Children

Herrera Beutler 18: One of the hardest questions we can ask ourselves is how we can help break the cycle of substance abuse and the issues that come with it. Congress has been examining how to help support addiction treatment, but there are concerns about how to help children so they don't fall into the same pattern of addiction.

- a) The National Institute on Drug Abuse has done some work on Substance Abuse Prevention for Early Childhood and I wonder if you can speak to what type of interventions can you provide early on to children to increase resiliency and reduce risk for drug abuse?
- b) Can you speak a little about the comorbidity of drug addiction and mental illness, and potential to address these issues early on?

Response:

Prevention is a critical component of efforts to combat drug use and addiction. Research has identified many risk and protective factors that influence the likelihood that a person will use substances and develop a substance use disorder. The earlier communities, schools, and families intervene in a child's life to reduce risk factors and enhance protective factors, the more of an impact the intervention is liable to make—not only for preventing substance use but also in averting related outcomes like behavioral problems, delinquency, poor academic performance, and mental illness.³⁷

Interventions aimed at pregnant mothers or very young children (infants and toddlers), such as the Nurse Family Partnership or Early Steps, Family Check-Up,³⁸ are often home-based, involving visits by nurses to give guidance to soon-to-be or new parents. These interventions can help parents build the necessary knowledge and skills—for instance in setting age-appropriate expectations for children, appropriate management of bad behavior, and developing warm, supportive relationships to promote attachment. Early attachment difficulties are a risk factor not only for later substance use but for many other mental and behavioral problems.³⁹ Pregnant mothers and new parents may also be counseled on their substance use and smoking, as these too are risk factors for a child's later use of substances.

For preschool- and school-aged children, interventions are often given in the classroom or both in the classroom and at home. Interventions may focus on addressing risk factors like aggressive or disruptive behavior, poor emotional control or social skills, and academic difficulties. They may aim to improve school climate, resources, and policies as well as enhance teachers' skills and parent-teacher communication. Changing classroom environments from those that react to problem behavior to those that encourage pro-social behavior can be achieved through supporting teacher training in constructive classroom management strategies. Just one example

³⁷ NIDA. Principles of Substance Abuse Prevention for Early Childhood. 2016. Available from: <https://www.drugabuse.gov/publications/principles-substance-abuse-prevention-early-childhood/index>.

³⁸ NIDA. Principles of Substance Abuse Prevention for Early Childhood A Research-Based Guide (In Brief). 2016. Available from: <https://www.drugabuse.gov/publications/principles-substance-abuse-prevention-early-childhood-research-based-guide-in-brief/nida-funded-early-interventions>.

³⁹ Schindler A, Bröning S. A Review on Attachment and Adolescent Substance Abuse: Empirical Evidence and Implications for Prevention and Treatment. *Substance Abuse* 2015;36:304-13. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/25424652>

of several that have been shown successful, the Classroom-Centered Intervention, enhances teachers' behavior management and instructional skills using an effective classroom behavior management program called the "Good Behavior Game".

Many childhood risk factors for substance use also increase risk for other psychiatric and behavioral problems, including conduct disorder, depression, and delinquency.⁴⁰ Shared genetic or biological risk factors may contribute to the emergence of mental illness and substance use, and symptoms of one may influence the development of the other. Prevention interventions often target these shared risk factors and have been shown to reduce risk for both substance use and addiction, as well as a range of behavioral health problems.⁴¹

⁴⁰ National Research Council (US) and Institute of Medicine (US) Committee on the Prevention of Mental Disorders and Substance Abuse Among Children, Youth, and Young Adults: Research Advances and Promising Interventions; O'Connell ME, Boat T, Warner KE, editors. Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities. Washington (DC): National Academies Press (US); 2009. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK32775/>; doi: 10.17226/1248

⁴¹ NIDA. Principles of Substance Abuse Prevention for Early Childhood. 2016. Available from: <https://www.drugabuse.gov/publications/principles-substance-abuse-prevention-early-childhood/index>.

NIMH
Chronic Conditions and Mental Health

Herrera Beutler 19: Mental health is a critical challenge for many, especially those with chronic health conditions like cystic fibrosis, a rare, life threatening genetic condition that impacts the lungs and digestive system. A study conducted by the Cystic Fibrosis Foundation showed that depression and anxiety are two to three times greater among people with cystic fibrosis and family caregivers than the general population and concluded that mental health treatment and assessment should be a regular part of care and treatment for cystic fibrosis.

What do you see as the path forward for integrating mental health care with regular, physical health care for those with chronic conditions? How can the federal government support mental health screening and services for those with all chronic conditions?

Response:

NIMH recognizes that some risk factors for mental illnesses, like depression and anxiety, can be directly related to having a physical illness. As well, illness-related anxiety and stress can trigger symptoms of depression.⁴² NIMH is committed to research that aims to identify and treat mental illnesses among all individuals who experience them, including people with other chronic conditions.

For over two decades, NIMH has invested in research to support systems of care that integrate mental and physical health care. NIMH views the implementation of Collaborative Care as a path forward for integrating mental and physical health care for chronic conditions. In a Collaborative Care system, patient populations are screened and closely tracked in a registry that is used to monitor symptoms and inform evidence-based practices. A care manager, a psychiatric consultant, and other mental health professionals work collaboratively to support mental health treatment within primary care. Essential services include outreach to patients, treatment monitoring, and communication among members of the treatment team. These systems keep patients engaged in care, and alert the treatment team when patients are not improving as expected.

Collaborative Care models have been shown to improve mental disorders among people with co-occurring medical problems treated in primary care settings.⁴³ This is critical because untreated mental disorders are common in patients seen in primary care settings; so much so that primary care is considered the de facto mental health service system in the United States. Findings from over 80 randomized controlled trials robustly support the effectiveness of the Collaborative Care model to improve depression, anxiety, PTSD, suicide prevention, and other mental disorders in pediatric, adult, and geriatric populations.⁴⁴

Routine screening is essential for early detection of mental illnesses and subsequent referral to treatment. In 2016, the United States Preventive Services Task Force updated its recommendations regarding depression to include screening for depression in the general adult

⁴² <https://www.nimh.nih.gov/health/publications/chronic-illness-mental-health/index.shtml>

⁴³ <https://www.ncbi.nlm.nih.gov/pubmed/16675360>

⁴⁴ <https://www.ncbi.nlm.nih.gov/pubmed/23076925>

population, and especially among persons with chronic illnesses. NIMH supports research on effective methods for identifying individuals with depression and other mental disorders, and on effective interventions for treating mental disorders in both general medical and specialty care settings. For example, NIMH funds studies on integrating depression detection and care into OB/GYN settings for pregnant women with depression, and delivering online therapy for depression and anxiety to adult primary care patients.^{45,46,47}

NIMH also supports the Mental Health Research Network (MHRN), which works to improve the speed, efficiency, generalizability, and uptake of mental health research and treatment.⁴⁸ MHRN is comprised of 13 health care systems, reaching 13 million beneficiaries across the country. MHRN serves as NIMH's prototype of a learning healthcare system, and includes large-scale pragmatic trials and services research.

These NIMH-supported efforts are intended to cast a wide net to identify and treat mental illnesses in many settings and among many populations.

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https://projectreporter.nih.gov/project_info_description.cfm?aid=9253314&icde=35019783&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=

⁴⁶

https://projectreporter.nih.gov/project_info_description.cfm?aid=9046911&icde=35019783&ddparam=&ddvalue=&ddsub=&cr=3&csb=default&cs=ASC&pball=

⁴⁷

https://projectreporter.nih.gov/project_info_description.cfm?aid=9086425&icde=35019827&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=

⁴⁸ <http://hcsrn.org/mhrn/en/>

Engineering and Biomedical Research

Herrera Beutler 20: NIH funding goes to nearly all colleges and units across Universities, such as the University of Washington in my home State. NIH funds go to the Medical School and Pharmacy school to Engineering, to fund cross-collaborations in Alzheimer, cancer, epilepsy, precision medicine and more. The technical skill of engineers to develop ways to understand the body's proteins and create new ones for personalized treatments and therapies through precision medicine or to create instruments to implant in the human brain or place on our skin to respond to electrical activity in the brain eliminating tremors from Parkinson's disease. The importance of NIH research funding on the discipline of engineering is critical. The application of engineering principles and concepts in medicine and healthcare have made significant contributions and brought about innovation in prevention, diagnostics, and therapeutic systems. NIH research bridges the boundaries between engineers and healthcare practitioners by integrating research, student projects, clinical practice, and commercialization that result in cutting-edge discoveries. If NIH's budget were significantly cut, how does the administration plan to ensure the United States retains its competitive advantage in biomedical research?

Response:

Bioengineering research has broad applications from developing therapeutic immune cells, to creating point-of-care diagnostic devices, to designing prosthetic limbs with a sense of touch. The National Institute of Biomedical Imaging and Bioengineering (NIBIB) and NIH have been leaders in this area, supporting interdisciplinary research that applies engineering approaches to solve biomedical problems. A recent example is the development of a microneedle patch for administering the influenza vaccine. The patch delivers vaccines painlessly, does not require refrigeration, and could be self-administered. With this technology, vaccines could be delivered in the mail to anyone that needs them. A Phase I clinical trial was successfully completed to test the influenza vaccine using the patch.⁴⁹ This engineered approach could potentially be used to deliver other vaccines and is a game changer for reaching rural and underserved populations. Engineering plays a major role in developing technologies that allow early detection, precise diagnostics, mobile health, and data-sharing for the realization of precision medicine. NIH has steadily increased funding for biomedical engineering at a higher rate than the overall NIH budget, reflecting the growing importance of engineering in making advances against the nation's toughest health challenges. From 2000 to 2016, NIH funding to biomedical engineering departments across the U.S. grew more than five-fold.⁵⁰ The expanding role of engineered technologies in biomedical research is transforming our ability to detect, monitor, and treat disease.

NIH will continue to use its priority-setting process to ensure that NIH funds the most promising research in service of its mission to enhance health, lengthen life, and reduce illness and disability, including potentially breakthrough approaches in bioengineering. NIH uses peer review to ensure that it funds the most meritorious scientific proposals. NIH also considers

⁴⁹ The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomized, partly blinded, placebo-controlled, phase 1 trial. Roush, Nadine G. Beck, Allison et al. *The Lancet*.

⁵⁰ Updated unpublished data based on previous data in: Engineering as a new frontier for translational medicine (Apr 2015) Chien S, Bashir R, Nerem RM, Pettigrew R. *Science Translational Medicine*.

public health needs, responding to both emerging threats and chronic health challenges. In addition, given that scientific fields mature at different rates, NIH seeks to capitalize on promising scientific opportunities as they arise within all biomedical fields. However, because scientific opportunities often arise from unexpected avenues and public health threats are often unforeseen, NIH also strives to maintain a balanced portfolio of basic, translational, and clinical research across a variety of scientific areas, as well as a balance between supporting research and supporting the training and infrastructure that research depends on. NIH believes that, together, these principles allow it to cast a wide net to support the most high-quality, rigorous science with the nimbleness to address public health needs and capitalize on scientific opportunities in all areas of biomedical research, including bioengineering.

NICHD
Breastfeeding

Herrera Beutler 21: A 2016 study of both maternal & pediatric health outcomes showed that if 90% of infants were breastfed according to medical recommendations, 3,340 deaths, \$3 billion in medical costs, and \$14.2 billion in costs of premature death would be prevented, annually. Yet to achieve these savings, substantial change is still needed across multiple sectors to better support breastfeeding families.

Because of these profound impacts, the Surgeon General's Call to Action to Support Breastfeeding called for the convening of a national consortium on breastfeeding research: to identify key priorities in a national research agenda*, promote the dissemination of research findings, and foster the timely translation of research into practice. In 2013, nominations were solicited and collected for this National Breastfeeding Research Consortium (NBRC), yet the group was never convened and no subsequent communication was received by applicants. Can you speak to any barriers holding up the convening of this critical group? Do you plan to complete the formation and launch of this consortium soon – as in 2017 or 2018 – or when do you expect it to be functioning?

Response:

NICHD provided scientific input into the Surgeon General's Call to Action to Support Breastfeeding. Notably, 17 of the 27 NIH Institutes and Centers support research on various aspects of breastfeeding. Recently funded research projects include basic physiology (such as sucking, swallowing, and digestion); breastfeeding and HIV; the effects of prescription and over-the-counter drugs, and pollutants, on breastmilk; health needs of preterm babies and infants with cleft palate; breastfeeding among health disparity populations; and the effects of breastfeeding on the mothers' health (neuropsychiatric, bone, cardiometabolic, diabetes, and obesity).

NICHD's current research efforts include the development of a "Bili-hut" that will provide a low-cost bilirubin light so that infants needing phototherapy can be discharged from the hospital to go home, thus avoiding the risk of disruptions in breastfeeding. If successful, thousands of infants who develop jaundice shortly after birth can avoid lengthy hospital stays. In addition, the NICHD's Neonatal Research Network (which has 18 sites at academic institutions across the United States) is currently running a clinical trial comparing donor breastmilk to infant formula in babies that are extremely preterm. The goal is to determine whether donor milk is superior to formula by testing infant cognition at two years of age. The infants are enrolled in the study if they are preterm and if their mothers do not produce enough milk, or if they have a medical contraindication to breastfeeding, such as receiving chemotherapy.

Additionally, the health of lactating women will be the focus of the new Task Force on Research Specific to Pregnant Women and Lactating Women discussed in previous responses. Most prescription medications have not been tested in, nor are labeled for, use by pregnant and lactating women. To address this issue, in the 21st Century Cures Act (P.L. 114-255), Congress mandated the establishment of a new Task Force on Research Specific to Pregnant Women and Lactating Women; the Task Force is charged with providing "advice and guidance to the

Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.” It must report findings and recommendations to the HHS Secretary and Congress by September 2018. The Secretary then has six months to decide whether regulatory and other changes might be needed to facilitate the appropriate use and development of therapies for pregnant and lactating women.

In January 2017, NIH was delegated the authority to establish the Task Force, and NICHD was asked to take the lead. A Charter establishing the Task Force was filed within the required 90-day timeframe, on March 13, 2017. As a Federal Advisory Committee, a slate of nominees has been prepared for the Secretary’s approval. Each federal agency listed in the law has designated a representative to the Task Force. The first meeting will take place on August 21-22, 2017, with three other meetings scheduled over the next year, and all meetings are open to the public. NICHD will provide updates about the Task Force on its website (<https://www.nichd.nih.gov/about/advisory/PRGLAC>).

Substance Abuse Treatment During Pregnancy

Herrera Beutler 22: Rates of opioid use disorders have risen dramatically over the past few years. Especially important are pregnant women at risk for opioid use disorder during pregnancy, and infants born with neonatal abstinence syndrome (NAS). Data indicate that the prevalence of opioid use disorder among pregnant women increased from 1.7 per 1,000 delivery admissions in 1998 to 3.9 in 2011. Further, the incidence of NAS in the United States increased 400 percent between 2000 and 2012. Does NIDA plan to further explore the finding that access to substance use disorder treatment that supports the family unit has proven effective for maintaining maternal sobriety and child well-being? Additionally, are there efforts underway to better understand the efficacy of non-residential treatment options that are responsive to women's complex responsibilities, often as the primary or sole caregivers for their families? Can you discuss NIDA's research into buprenorphine and other medication assisted treatment and their benefits for pregnant women and their infants?

Response:

Research on the unique needs of pregnant and parenting women with opioid use disorder (OUD) and their children is a priority for both the National Institute on Drug Abuse (NIDA) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). In 2016, NIH convened a workshop along with Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Society for Maternal-Fetal Medicine, and the March of Dimes Foundation to identify key scientific opportunities to advance the understanding of opioid use disorders in pregnancy and to improve outcomes for affected women, their children, and their families. Identified priorities for research included better methods to screen for and identify NAS, as well as research on non-drug treatments and long-term outcomes for infants who were exposed to opioids in utero.⁵¹

NIDA and NICHD support a robust research portfolio on the prevention and treatment of NAS, including research to:

- validate screening tools to identify pregnant women in need of treatment⁵²
- elucidate the clinical, demographic, and genetic factors that increase a baby's risk of developing NAS after exposure to opioids⁵³
- analyze mother and infant outcomes to identify optimal treatment strategies for opioid use disorder during pregnancy^{54,55}

⁵¹ Reddy UM, Davis JM, Ren Z, Greene MF. Opioid Use in Pregnancy, Neonatal Abstinence Syndrome, and Childhood Outcomes: Executive Summary of a Joint Workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, Society for Maternal-Fetal Medicine, Centers for Disease Control and Prevention, and the March of Dimes Foundation. *Obstetrics and gynecology* 2017;130:10-28.

⁵²https://projectreporter.nih.gov/project_info_description.cfm?aid=9193487&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=17&csb=default&cs=ASC&pbali=

⁵³https://projectreporter.nih.gov/project_info_description.cfm?aid=9102516&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=21&csb=default&cs=ASC&pbali=

⁵⁴https://projectreporter.nih.gov/project_info_description.cfm?aid=8858597&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=41&csb=default&cs=ASC&pbali=

⁵⁵https://projectreporter.nih.gov/project_info_description.cfm?aid=9034137&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=47&csb=default&cs=ASC&pbali=

- optimize behavioral interventions for opioid misuse and addiction during pregnancy⁵⁶

In the future, NIDA would like to build a research portfolio on intervention strategies to ensure continuity of treatment for OUD after delivery and to evaluate the effect that continued medication-assisted treatment post-pregnancy has on mother and infant outcomes.

On the specific topic of treatment that supports the family unit, NIDA is supporting the development of a parenting intervention to help mothers in treatment for substance use disorder maintain abstinence and foster secure child attachment. In addition, NIDA is funding research to determine how the incorporation of housing and supportive services into treatment for homeless mothers with substance use disorders influences outcomes for both the patient and their children. NIDA also funded the Maternal Opioid Treatment: Human Experimental Research (MOTHER) project, a multicenter, randomized, controlled trial comparing buprenorphine with methadone for the treatment of opioid-dependent pregnant patients. This study supported the safety and usefulness of buprenorphine treatment in pregnancy.⁵⁷ Ongoing research seeks to determine longer term infant outcomes and to determine which patients will respond better to buprenorphine or methadone treatment.

A recent NICHD-funded study on buprenorphine indicated that pregnant women need more frequent daily doses of the medicine than currently recommended for non-pregnant patients.⁵⁸ Researchers reported that the standard dosing of once or twice daily does not produce a high enough blood concentration of buprenorphine in pregnant women to prevent opioid withdrawal symptoms who may, because they ‘clear’ the drug more rapidly; three to four daily doses may be needed.

The NICHD also is leading the Task Force on Research Specific to Pregnant Women and Lactating Women focused on medications used by these populations.

⁵⁶[https://projectreporter.nih.gov/project_info_description.cfm?aid=9233984&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=36&csb=default&cs=ASC&pbali=36&csb=default&cs=ASC&pbali](https://projectreporter.nih.gov/project_info_description.cfm?aid=9233984&icde=33373994&ddparam=&ddvalue=&ddsub=&cr=36&csb=default&cs=ASC&pbali=36&csb=default&cs=ASC&pbali=)

⁵⁷ Jones HE, Kaltenbach K, Heil SH, et al. Neonatal abstinence syndrome after methadone or buprenorphine exposure. *N Engl J Med* 2010;363:2320-31. Available from: <http://www.nejm.org/doi/full/10.1056/NEJMoa1005359#t=article>

⁵⁸ Caritis SN, Bastian JR, Zhang H, et al. An Evidence-Based Recommendation to Increase the Dosing Frequency of Buprenorphine During Pregnancy. *American Journal of Obstetrics and Gynecology*. Available from: <http://www.sciencedirect.com/science/article/pii/S0002937817307986>

Grant Support Index

DeLauro 1: The NIH is discussing a “Grant Support Index” (GSI) to limit the amount of support a single investigator can receive and to free up funding for early career investigators and those struggling to keep their labs open. My understanding is that the GSI is still in draft form, but you are planning to implement it in September, just months away.

Given the complexity of the proposed metric, the need to ensure that NIH continues to fund the best science, and the importance of managing the implementation of this major change in policy:

Does the NIH intend to establish a formal reporting mechanism to collect and consider comments on the GSI?

How specifically does the NIH intend to incorporate stakeholder feedback into the final version of the new metric and communicate those changes to the broad research community?

What is NIH’s policy for special exceptions to the new limit on awards?

Response:

NIH and its stakeholder community have for many years been concerned about the long-term stability of the biomedical research enterprise. Too many researchers vying for limited resources have led to a hypercompetitive environment, with many highly meritorious applications going unfunded. In some cases, the hypercompetitive environment has also resulted in the loss of NIH investments in research training, as emerging investigators are unable to establish stable careers. This has too often resulted in misaligned incentives and unintended consequences for talented researchers at all career stages who are trying to succeed and stay in science.

NIH has implemented a variety of programs over the past decade to help stabilize the biomedical research workforce, especially for new and early-stage investigators. While the percentage of NIH awards that support early-career investigators has stabilized over this time, these gains have been offset by a decline in the percentage of NIH awards that support mid-career investigators. To continue addressing these issues, NIH proposed the Grant Support Index (GSI) policy in May 2017, which aimed to limit the total NIH grant support provided to an individual principal investigator. NIH received many comments from the biomedical research and advocacy communities, as well as from outside members of various Institute and Center advisory councils. The community raised valid concerns about the potential unintended consequences of implementing the GSI policy as proposed, including effects on team science and training grants. As a result, NIH shifted toward a more focused approach to bolster support to early-stage⁵⁹ and early-established investigators⁶⁰. In recognition of the call for such action in the 21st Century Cures Act, this effort is named the Next Generation Researchers Initiative (Next Gen). NIH

⁵⁹ An investigator is considered an Early Stage Investigator (ESI) if he/she is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent).

⁶⁰ Applicants who are within 10 years of receiving their first major NIH competing award, who received their first major competing NIH award as an ESI (or ESI equivalent), and who:

- Are at risk for losing all NIH funding if they receive no competing awards this year, OR
- Have only one active award (potential “rising stars”)

anticipates funding an additional ~200 grants to early stage investigators and another added ~200 grants to early-established investigators in 2017.

NIH will track the impact of NIH Institute and Center funding decisions for early-stage and early-established investigators with fundable scores to ensure this new strategy is effectively implemented. Additionally, NIH, working with outside experts, will also encourage multiple approaches to develop and test metrics that can be used to assess the impact of NIH grant support on scientific progress. An Advisory Committee to the Director working group is currently being established to refine and implement Next Gen, and includes investigators at all levels – from graduate student to full professor. NIH will communicate progress on the Initiative through traditional mechanisms (e.g., public meetings and conferences), as well as through the Next Gen Initiative website: <https://grants.nih.gov/ngri.htm>.

Interagency Autism Coordinating Committee

DeLauro 2: Dr. Gordon, you chair the Interagency Autism Coordinating Committee (IACC), which is revising its strategic plan for autism spectrum disorder.

Can you share some of the priorities for the new strategic plan?

Is additional funding needed to accomplish the IACC's goals?

Response:

The Autism Collaboration, Accountability, Research, Education and Support (CARES) Act of 2014 requires the IACC to provide annual updates on its Strategic Plan for Autism Spectrum Disorder (ASD). The IACC developed its new Strategic Plan update over the past several months. The updated plan includes a broader set of objectives that encompass research, services, and supports to meet the requirements of the law. The 2016-2017 update to the IACC Strategic Plan for ASD provides guidance to federal agencies and partner private organizations regarding ASD research and services priorities, information about the current state of research and services activities, and progress made since the last Strategic Plan update.

The updated plan is organized around seven consumer-based questions related to the following topics:

1. Screening and Diagnosis
2. Underlying Biology of ASD
3. Risk Factors
4. Treatments and Interventions
5. Services
6. Lifespan Issues
7. Infrastructure, Surveillance, Workforce and Outreach

The IACC developed 23 objectives that correspond to the seven topic areas listed above. Input from the autism community and invited external experts ensures that the objectives reflect critical areas of community need, and scientific and service opportunities. The objectives describe priority areas for future research and services, including:

- Strengthening the evidence base for the benefits of early detection;
- Reducing disparities in early detection, access to services, and outcomes for underserved populations;
- Fostering research to better understand the processes of early development, molecular, and neurodevelopmental mechanisms, and brain circuitry that contribute to ASD;
- Supporting large scale long term studies of ASD to better understand health and service needs across the whole lifespan;
- Increasing understanding genetic and environmental mechanisms of risk and resilience in the development of ASD;
- Development of pharmacological, psychosocial, and technological interventions for ASD to address both core symptoms and comorbid conditions;
- Successfully scaling up interventions for use in community settings;
- Improving service models to maximize outcomes;

- Supporting development and coordination of integrated services to help youth with ASD make a successful transition to adulthood; and,
- Expanding surveillance efforts to include the adult population and better understand co-occurring physical and mental health conditions that affect people on the autism spectrum.

The draft IACC Strategic Plan, including 23 new objectives for research and services activities, was shared publicly at the IACC meeting on July 26, 2017. During this meeting, the Committee made final revisions to the Strategic Plan and approved the plan for publication.

Integrating Mental Health Care:

DeLauro 3: Mental health is a critical challenge for many, especially those with chronic health conditions like cystic fibrosis, a rare, life threatening genetic condition that impacts the lungs and digestive system. A study conducted by the Cystic Fibrosis Foundation showed that depression and anxiety are two to three times greater among people with cystic fibrosis and family caregivers than the general population and concluded that mental health treatment and assessment should be a regular part of care and treatment for cystic fibrosis. What do you see as the path forward for integrating mental health care with regular, physical health care for those with chronic conditions like cystic fibrosis? How can the federal government support mental health screening and services for those with all chronic conditions?

Response:

NIMH recognizes that some risk factors for mental illnesses, like depression and anxiety, can be directly related to having a physical illness. As well, illness-related anxiety and stress can trigger symptoms of depression.⁶¹ NIMH is committed to research that aims to identify and treat mental illnesses among all individuals who experience them, including people with other chronic conditions.

For over two decades, NIMH has invested in research to support systems of care that integrate mental and physical health care. NIMH views the implementation of Collaborative Care as a path forward for integrating mental and physical health care for chronic conditions. In a Collaborative Care system, patient populations are screened and closely tracked in a registry that is used to monitor symptoms and inform evidence-based practices. A care manager, a psychiatric consultant, and other mental health professionals work collaboratively to support mental health treatment within primary care. Essential services include outreach to patients, treatment monitoring, and communication among members of the treatment team. These systems keep patients engaged in care, and alert the treatment team when patients are not improving as expected.

Collaborative Care models have been shown to improve mental disorders among people with co-occurring medical problems treated in primary care settings.⁶² This is critical because untreated mental disorders are common in patients seen in primary care settings; so much so that primary care is considered the de facto mental health service system in the United States. Findings from over 80 randomized controlled trials robustly support the effectiveness of the Collaborative Care model to improve depression, anxiety, PTSD, suicide prevention, and other mental disorders in pediatric, adult, and geriatric populations.⁶³

Routine screening is essential for early detection of mental illnesses and subsequent referral to treatment. In 2016, the United States Preventive Services Task Force updated its recommendations regarding depression to include screening for depression in the general adult population, and especially among persons with chronic illnesses. NIMH supports research on

⁶¹ <https://www.nimh.nih.gov/health/publications/chronic-illness-mental-health/index.shtml>

⁶² <https://www.ncbi.nlm.nih.gov/pubmed/16675360>

⁶³ <https://www.ncbi.nlm.nih.gov/pubmed/23076925>

effective methods for identifying individuals with depression and other mental disorders, and on effective interventions for treating mental disorders in both general medical and specialty care settings. For example, NIMH funds studies on integrating depression detection and care into OB/GYN settings for pregnant women with depression, and delivering online therapy for depression and anxiety to adult primary care patients.^{64,65,66}

NIMH also supports the Mental Health Research Network (MHRN), which works to improve the speed, efficiency, generalizability, and uptake of mental health research and treatment.⁶⁷ MHRN is comprised of 13 health care systems, reaching 13 million beneficiaries across the country. MHRN serves as NIMH's prototype of a learning healthcare system, and includes large-scale pragmatic trials and services research.

These NIMH-supported efforts are intended to cast a wide net to identify and treat mental illnesses in many settings and among many populations.

⁶⁴

https://projectreporter.nih.gov/project_info_description.cfm?aid=9253314&icde=35019783&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=

⁶⁵

https://projectreporter.nih.gov/project_info_description.cfm?aid=9046911&icde=35019783&ddparam=&ddvalue=&ddsub=&cr=3&csb=default&cs=ASC&pball=

⁶⁶

https://projectreporter.nih.gov/project_info_description.cfm?aid=9086425&icde=35019827&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=

⁶⁷ <http://hcstrn.org/mhrn/en/>

Antimicrobial Resistance

DeLauro 4: Please describe the NIAID resources currently allocated to antibiotic resistance R&D—and, in particular, how those resources have fluctuated as the crisis has escalated. How would antibiotic resistance R&D be impacted by the proposed cut in overall NIH funding in FY 2018, as proposed by the Administration?

Please describe how NIAID is working with agencies such as the CDC, FDA, BARDA, and the Department of Defense on the federal response to antibiotic resistance. Additionally, how effectively is NIAID engaging private industry in efforts to generate new antibiotics and rapid diagnostics?

Please describe NIAID's accomplishments and planned efforts in regards to advancements in diagnostic tools to address bacterial, viral, and fungal infections.

Response:

The National Institute of Allergy and Infectious Diseases (NIAID) continues to make antibacterial research a key priority. NIAID has strengthened and expanded its antibacterial resistance research program in response to a 2014 Executive Order on Combating Antibiotic-Resistant Bacteria (CARB), the 2014 National Strategy for CARB, and the 2015 National Action Plan for CARB, which outline federal actions to combat the rise of antibiotic-resistant bacteria. Along with partners in the CARB initiative including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD), NIAID is pursuing research and development of novel strategies to address antimicrobial resistance in the areas of diagnostics, vaccines, and therapeutics.

Funding for CARB efforts has been, and will continue to be, instrumental in addressing the growing global public health threat of antimicrobial resistance. In FY 2016, NIH funding for antimicrobial resistance research was \$420 million, including \$100 million in additional funding provided by Congress to NIAID for its CARB research activities. In FY 2017, NIH funding for antimicrobial resistance research is estimated to be \$473 million, including an additional \$50 million for NIAID antibiotic resistance research provided by Congress. In FY 2018, NIH funding for antimicrobial resistance is estimated to be \$327 million under the President's budget request. NIAID will continue to make antimicrobial resistance a priority in FY 2018.

NIAID actively engages in cross-agency partnerships to address the issue of antimicrobial resistance. NIAID, along with the other NIH Institutes and Centers, works closely with CDC, FDA, and other agencies to establish and maintain the National Database of Resistant Pathogens in response to the goals and objectives of the National Action Plan for CARB. NIAID is supporting the sequencing of high-priority reference strains of bacteria identified by CDC and FDA for inclusion in the database. These genomic data will be used to help advance the development of new diagnostics and therapeutics, improve surveillance and monitoring methods, and increase our knowledge of the underlying mechanisms of antibiotic resistance.

NIAID and other Federal agency partners also are engaging with private industry in efforts to generate effective antimicrobial resistance countermeasures. For example, NIAID engages

private industry through its Partnership Program, which stimulates collaborative efforts to advance promising candidate products or platform technologies, and through preclinical services it provides to the community. Through these mechanisms, NIAID is supporting the advancement of promising broad-spectrum antibacterial therapeutics, including a novel tetracycline (CUBRC/Tetraphase) and beta-lactamase inhibitor (VenatoRx). In addition, NIAID is collaborating with BARDA on the CARB Biopharmaceutical Accelerator, or CARB-X, a new global public-private partnership to advance the preclinical development of promising antibacterial drugs and other products. CARB-X has announced \$24 million in funding to 11 research teams and biotechnology companies to develop new antibacterials and diagnostics. These funds will leverage up to \$24 million in additional milestone-based funding and additional private funds from the companies for a total of more than \$75 million dedicated toward novel strategies to combat resistance. NIAID will provide in-kind services, including preclinical services, as well as technical support to CARB-X awardees.

NIAID is continuing to support the development of diagnostics to combat antibiotic resistance, including multiplex platforms. Using small business grants and partnerships, NIAID supported the development of a polymerase chain reaction (PCR)-based system, which has been cleared by FDA to simultaneously detect multiple pathogens in approximately one hour. This panel tests for 24 Gram-positive bacteria, Gram-negative bacteria, and yeast microbes that cause bloodstream infections. NIAID also has provided support for the development of the Xpert® MTB/RIF (Cepheid) test, addressing the urgent need for new tools to rapidly diagnose tuberculosis (TB) and drug-resistant TB. The Xpert test platform has been expanded to develop diagnostics for healthcare-associated infections, sexually transmitted infections, and influenza. In addition, researchers at the NIAID-supported Antibacterial Resistance Leadership Group (ARLG) are developing a simple blood test that analyzes patterns of gene expression to determine if a patient's respiratory symptoms stem from a bacterial infection, viral infection, or no infection at all.

The development of rapid, point-of-care diagnostics that can specifically identify the microbe causing an infection is an important step in combating antibiotic resistance. NIH has partnered with BARDA to launch the Antimicrobial Resistance Diagnostic Challenge that will award up to \$20 million in prizes for innovative, rapid, point-of-need diagnostic tests to combat the emergence and spread of drug-resistant bacteria. The Challenge was developed with technical and regulatory expertise from CDC and FDA. The first phase of the Challenge selected ten semifinalists based on a technical evaluation and programmatic assessment of the submissions. The semifinalists will each receive \$50,000 to develop their concepts into prototypes to compete in the second phase of the Challenge. Final awards following three phases of the Challenge are expected in 2020.

NIAID continues to place a high priority on antibiotic resistance research and will continue to support robust research efforts in this area. This includes ongoing support for NIAID partnerships with other Federal agencies to advance critical research on the identification, characterization, and treatment of antibiotic-resistant pathogens. NIAID will continue to leverage the knowledge gained through this research to develop new rapid diagnostics, therapeutics, and vaccines to address the challenge of antimicrobial resistance.

Agency for Healthcare Research and Quality

DeLauro 5: A list of all AHRQ authorities, functions, and/or programs that would be transferred to the new National Institute for Research on Safety and Quality; and

A list of all AHRQ authorities, functions, and/or programs that would be discontinued after the proposed consolidation.

Response:

For FY 2018, the President's Budget transitions AHRQ to an Institute at the NIH – the National Institute for Research on Safety and Quality (NIRSQ). NIRSQ will be poised to ensure that NIH's investments in biomedical science are translated into knowledge and practical tools that can be adopted by physicians and other health care professionals to benefit patients.

In FY 2018, NIRSQ will continue AHRQ's focus on patient safety research; quality improvement, including support of doctors and nurses in using data to improve care delivery to create learning health care systems; and data initiatives to continue to help identify priorities for health care improvement and monitor trends over time.

Investigator-initiated research project grants, including those addressing prescription drug and opioid misuse and abuse, are a funding priority for NIRSQ in FY 2018. NIRSQ will also provide extramural predoctoral and postdoctoral educational and career development grants and opportunities in health services research to develop the next generation of health services researchers. In support of the National Strategy for Combatting Antibiotic-Resistant Bacteria, NIRSQ will fund research grants to further expand efforts to develop improved approaches to antibiotic stewardship, with a focus on ambulatory and long-term care settings, as well as hospitals. NIRSQ will also provide support to continue conformance with administrative requirements of The Patient Safety and Quality Improvement Act of 2005 (PSQIA) (P.L. 901-41) which provides protection (legal privilege) to health care providers throughout the country for quality and safety improvement activities. NIRSQ will continue supporting the Evidence-Based Practice Center (EPC) program, which reviews all relevant scientific literature on a wide spectrum of clinical and health services topics to produce various types of evidence reports. Going forward, NIRSQ will continue to support the Extension for Community Healthcare Outcomes initiative (Project ECHO), a telehealth program that links specialists at an academic hub to primary care providers working on the frontlines in rural communities, to treat opioid abuse by delivering remote training and expert consultation on medication-assisted treatment. The Medical Expenditure Panel Survey (MEPS), a national source of comprehensive annual data on how Americans use and pay for medical care, will be supported to ensure it meets steady state precision levels in survey estimates. The Healthcare Cost and Utilization Project (HCUP), which will be continued in FY 2018, is the Nation's most comprehensive source of hospital care data, including information on in-patient stays, ambulatory surgery and services visits, and emergency department encounters.

The Comprehensive Unit-based Safety Program (CUSP) involves improvement in safety culture, teamwork, and communication, together with a checklist of evidence-based safety practices.

NIRSQ will continue funding the nationwide expansion of the CUSP projects focused on central line-associated blood stream infections, antibiotic stewardship, and enhanced recovery following surgery. While CUSP will receive a reduced level of support, it is related to attendant start-up costs from the ICU expansion project in FY 2017; whereas in FY 2018, this project and the other two CUSP projects will be continued with slightly lower continuation costs. NIRSQ will continue to support the US Preventative Services Task Force at a reduced scope, with plans to make recommendations on seven topics in FY 2018. NIRSQ will efficiently close-out activities for all currently funded grants and contracts supporting the health information technology program, and end support for contract projects supported in prior years, including Quality Indicators, Consumer Assessment of Healthcare Providers and Systems, and all dissemination and implementation support contracts.

NIRSQ will partner with others by producing evidence-based research and tools and by working with Federal and non-Federal partners to make sure the evidence developed is easily applied and used in health care settings. Accelerating learning and innovation in health care delivery will also be a priority for NIRSQ as it seeks to build practical tools that take the “what” of scientific advances and translate it into the “how” for use by physicians and nurses to improve care.

Sex Gender Balance in Biomedical Research

DeLauro 6: "Please provide an update on NIH's efforts to ensure that research includes both male and female animals in preclinical studies. Please provide an update on NIH's efforts to ensure that pre-clinical research includes both male and female tissues and primary cells.

Response:

NIH is committed to improving the health outcomes of males and females through support of rigorous science that advances fundamental knowledge about the nature and behavior of living systems. Sex and gender play a role in how health and disease processes differ across individuals. Moreover, considering these factors within research studies informs the development and testing of preventive and therapeutic interventions in both sexes.

In June 2015, NIH introduced the NIH Policy on Consideration of Sex as a Biological Variable in NIH-funded Research (NOT-OD-15-102)⁶⁸. The policy focuses on NIH's expectation that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies, including studies using primary cells and tissues. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. To ensure a sex/gender balance in biomedical research, NIH-funded investigators are encouraged to (1) consider sex in study designs or explain why it is not being incorporated; (2) collect and tabulate sex-based data; (3) characterize sex-based data; and (4) communicate, report, and publish sex-based data.⁶⁹

Assessment of the applicant's plans to consider sex as a biological variable should be reflected in an application's priority score. NIH application instructions and review criteria have been updated to reflect this policy, effective for applications submitted for due dates on or after January 25, 2016. Currently, NIH is assessing how applicants adhere to the policy requiring consideration of sex as a biological variable.

⁶⁸ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html>

⁶⁹ <https://orwh.od.nih.gov/resources/pdf/ACRWH2015springfordistribution-508.pdf>

Multiple Sclerosis Update

Lee 1: With regard to multiple sclerosis (MS), where are we in terms of finding a cure for multiple sclerosis and how the BRAIN Initiative will engage patients living with MS?

Response:

Although no cure exists for multiple sclerosis (MS), more than a dozen immunotherapies have been shown to improve symptoms and slow immune-mediated disease processes in relapsing-remitting MS. Most of these therapies were made possible by an NIH discovery using a chemical compound and magnetic resonance imaging (MRI) to identify active brain lesions that indicate inflammation is present. Researchers found that active brain lesions occurred commonly in persons with MS. Multiple drugs that blocked these lesions from appearing were found to effectively prevent the exacerbation of MS in most patients. In addition, a recent study funded by the National Institute of Allergy and Infectious Diseases showed that high-dose chemotherapy to suppress the immune system, followed by a transplant of a person's own purified blood stem cells, can induce sustained remission in relapsing-remitting MS, and may be an alternative treatment for some people who don't respond well to existing therapy or prevent the secondary progressive form of MS. Unfortunately, we have learned that even when exacerbations are blocked, patients with MS can slowly worsen over decades. The challenge for future MS research is to understand the root cause of this progressive phase of MS. In March 2017, the FDA approved ocrelizumab (brand name Ocrevus, developed by Genentech, Inc) to treat adult patients with primary progressive MS, as well as patients with relapsing forms of MS. This is the first drug approved by the FDA to treat primary progressive MS. Although NIH was not directly involved in the development of ocrelizumab, the foundational knowledge necessary to develop this drug emerged in large part from NIH-funded basic research on MS and the immune and central nervous systems.

These treatments can dramatically improve the lives of people with MS; however, they do not work for all people with MS, they can have significant side effects, and none cure the disease. NIH is funding a broad array of basic, translational, and clinical research aimed at improving our understanding of MS and developing better ways to prevent, treat, or cure it. National Institute of Neurological Disorders and Stroke (NINDS)-funded scientists are currently investigating genetic and environmental risk factors for MS; causes of higher MS incidence in women compared to men; immune system function and dysfunction in the brain; blood-brain-barrier breakdown in MS; formation and destruction of myelin (the fatty sheath that insulates axons) in MS; and factors that repair or protect against neurodegeneration. NINDS-funded preclinical therapy development is focused on finding treatments that modulate immune system function, repair damaged myelin, or protect neurons. As part of a public-private partnership, the NINDS NeuroNEXT phase II clinical trials network is testing a potential neuroprotective drug for progressive MS called ibudilast (MN-166). Within the NIH Clinical Center, NINDS clinical trials are assessing the safety and effectiveness of treatments for MS, including studies of the drug idebenone in people with progressive MS.

NINDS intramural researchers continue to develop MRI techniques to detect immune-mediated lesions in MS. Most recently, they were able to identify collections of immune cells on the

surface of the brain, which is now considered a potential source of inflammation in MS. Progressive MS has become the major challenge and, unfortunately, as opposed to exacerbating/remitting MS, structural imaging has not revealed a target for therapeutics.

The technologies to detect the circuit dysfunction that underlies the symptoms and disability in progressive MS patients are quite rudimentary. The NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is currently funding scientists to develop new brain imaging tools and techniques capable of examining the circuit activity of millions of nerve cells, networks, and pathways in real time, and is beginning to apply those tools to better understand the functional organization of the brain. The BRAIN Initiative is not focused on specific diseases; however, the tools and technologies developed through the Initiative will enable a deeper understanding of how the brain functions normally and what goes wrong in diseases like MS. Researchers whose labs study MS have received BRAIN Initiative funding to improve upon MRI technologies. BRAIN Initiative investigators are developing imaging techniques to generate accurate ultra-high resolution brain images that reflect brain activity as opposed to structure. Others are working to visualize fine structures within the brain and map brain activity with an unprecedented spatial and temporal resolution. These and other tools developed through the BRAIN Initiative can provide the breakthrough technologies critical for progressive MS research, as well as for many other brain diseases and disorders. As MRI technology enabled the discovery of over a dozen approved drugs for exacerbating/remitting MS, we look to the technologies coming from the BRAIN Initiative to make a difference in the battle to slow or prevent the slow and insidious progressive form of MS.

Inclusion of Women in Research Studies at the Institutes and Funding Concerns

Pocan 1: There have been several studies over the years regarding the lack of inclusion of women in various research studies and clinical trials in the same proportions as their incidence rates in the diseases being studied. Between FY 2010 – FY 2013, the National Cancer Institute had reduced expenditures allocated to clinical trials by \$175 million. Given this proposed FY 2018 budget, how will the NCI respond and what will it mean for cancers that have high incident rates in women and clinical trial opportunities for them. What about for other NIH institutes, like NHLBI and NIDDK?

Response:

Ensuring inclusion of women in clinical research studies is a priority for the National Institutes of Health (NIH) and the National Cancer Institute (NCI). As reflected in the NIH biennial report⁷⁰ addressing inclusion, there has been historically strong participation of women in NCI-supported cancer clinical trials, even without considering clinical trials focusing on cancers of the female reproductive system and most breast cancers. The most recent data on gender enrollment for NCI's extramural research studies (excluding enrollments to "all male" and "all female" studies such as prostate cancer and uterine cancer), show that women represented over half the enrollment into NCI's clinical trials during FY 2013 and FY 2014 (57.8 percent and 56.0 percent, respectively).⁷¹

NCI maintains a strong commitment to supporting clinical trials through its national network of academic research centers and community partners, and has continued to adapt and support this research infrastructure as both the science and types of clinical trials being conducted evolve. In March 2014, after several years of extensive consultation and coordination with many stakeholders, NCI transformed its longstanding Cooperative Group program into the National Clinical Trials Network (NCTN). Guided by recommendations in a 2010 Institute of Medicine (IOM) report, the design and implementation of the NCTN incorporated feedback from Cooperative Group investigators, NCI Comprehensive Cancer Center directors, several NCI working groups, leading cancer researchers, industry representatives, and patient advocates.

Changes to NCTN focused on merging operational and administrative infrastructure, not on reducing resources for scientific research in any particular disease area. The overall NCTN budget for these awards in FY 2014 - 2016 was \$151 million per fiscal year. This amount is approximately the same as the total budget provided to the Cooperative Groups for awards in each of fiscal years 2010-2013, despite reductions in the overall NCI budget that resulted from sequestration in FY 2013.

NCTN is structured so that sites – cancer centers, hospitals, academic medical centers – can belong to more than one group, and membership in any one group allows a site to participate in trials led by any NCTN group for which their investigators are qualified. The new NCTN

⁷⁰ https://report.nih.gov/recovery/inclusion_research.aspx

⁷¹ <https://dcainfo.nci.nih.gov/advisory/ncab/0215/abrams.pdf>

structure allows any qualified site to enroll patients into a trial, meaning that more patients will have access to these trials closer to where they live.

The NCI Community Oncology Research Program (NCORP), which includes 46 main sites, seven research bases, and more than 900 affiliated component sites across the country, extends the reach of NCI's clinical trials network even further, and facilitates patient and provider access to NCTN treatment and imaging trials in the community setting. NCORP also represents an NCI investment in addition to NCTN to support the conduct of clinical trials. NCORP has been funded since FY 2014, and was funded at approximately \$93 million in FY 2014, \$93 million in FY 2015, \$82 million in FY 2016.

Together, NCTN and NCORP help to ensure that all cancer patients, regardless of gender, have access to state of the art cancer clinical trials. This is true for cancers that are often specific to women, such as female reproductive cancers and breast cancers, as described above, as well as other cancer types. For example, lung cancer is the second leading cancer diagnosis for both men and women, and colon and rectum cancers are the third most common cancer diagnosis for both men and women. NCTN and NCORP have several clinical trials currently accruing patients to evaluate promising treatment approaches for these cancers.

NCTN and NCORP are also making innovative precision medicine clinical trials possible. For example, the NCI MATCH (Molecular Analysis for Therapy Choice) trial is the first NCI-supported clinical trial to assign cancer treatments according to the molecular abnormalities of the tumor, rather than according to the tumor site of origin. More than 60percent of patients enrolled to the NCI MATCH trial were women, and the trial was open to accrual at more than 1,000 NCTN and NCORP sites across the country. Most patients enrolled in the trial through a community-based site rather than an academic medical center.

Precision medicine trials like NCI MATCH, as well as trials focusing on specific cancer types, continue to provide options to evaluate treatments for cancers that are not diagnosed as frequently as cancers of the breast, lung, colon and rectum, and prostate, but still claim the lives of thousands of cancer patients, including women, each year. Support for cancer clinical trials, including important investments in NCI's clinical trials network, continues to be a priority for NCI and will remain a priority in the coming fiscal year.

Like all components of the NIH, NIDDK and NHLBI are also committed to scientifically appropriate enrollment inclusion (including consideration of gender, race, and ethnicity) in all clinical research projects we support. According to the latest biennial report on the inclusion of women and minorities in clinical research, representation of women enrolled in clinical studies supported by the NHLBI and NIDDK extramural research programs was over 50 percent. Women also comprised 64percent of participants in all NHLBI-funded cardiovascular clinical trials in FY 2015, including the Women's Health Initiative (WHI), a long-term national health study focused on strategies for preventing heart disease, breast and colorectal cancer, and osteoporotic fractures in postmenopausal women. Supporting and coordinating high-impact clinical research remains a priority for NIDDK and NHLBI. In another example of a coordinated project, NIDDK, NCI, NHLBI, and NIA are now jointly supporting follow-up of participants (68percent female) in NIDDK's landmark Diabetes Prevention Program to determine the effects

of the commonly used diabetes drug metformin on breast, uterine and other cancers, cardiovascular disease, and cognition. We hope to continue in this and other important clinical studies in FY 2018.

National Institutes of Drug Abuse (NIDA) and Commonly Abused Drug List

Pocan 2: NIDA publishes a document referenced as “Commonly Abused Drug Charts” – published in January 2016, and revised in May 2017, that lists kratom in a category where “there is enough scientific evidence to connect the drug use to specific negative effects.” Can you provide the “scientific evidence” that shows kratom results in “anorexia, weight lost, insomnia, skin darkening, dry mouth, frequent urination, constipation, and hallucination and paranoia with long-term use at high doses?

Response:

Research on kratom’s health effects is limited. The effects listed in the Commonly Abused Drug Charts are noted as “possible” health effects and have been reported by chronic users in Southeast Asia including Malaysia and Thailand.^{72, 73,74, 75,76} A 2014 cross-sectional study among regular kratom users found more than half developed kratom use disorder and experienced physical and psychological symptoms such as insomnia, decreased appetite, diarrhea, restlessness and nervousness.¹ In a 1975 study, Thai persons with kratom dependence reported experiencing anorexia, weight loss, insomnia, and darkening of the skin, particularly on the cheeks. Other side effects included dry mouth, frequent urination, and constipation.⁴ Another small study of 30 persons described five cases of long-term kratom users displaying psychotic symptoms, two of which experienced hallucinations.⁴ Negative acute effects of kratom exposure, including tachycardia, hypertension, and hallucinations, were also noted in a report of data from Texas poison centers.⁷⁷

⁷² Darshan Singh, Christian P. Müller, and Balasingam K. Vicknasingam. Kratom (*Mitragyna speciosa*) dependence, withdrawal symptoms and craving in regular users. *Drug and Alcohol Dependence*, Volume 139, 1 June 2014, Pages 132-137. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24698080>

⁷³ Dessa Bergen-Cico and Kendra MacClurg. Chapter 89 – Kratom (*Mitragyna speciosa*) Use, Addiction Potential, and Legal Status. *Neuropathology of Drug Addictions and Substance Misuse Volume 3: General Processes and Mechanisms, Prescription Medications, Caffeine and Areca, Polydrug Misuse, Emerging Addictions and Non-Drug Addictions*. 2016, Pages 903–911.

⁷⁴ Drug Enforcement Administration. Kratom (*Mitragyna speciosa* korth). (Street names: Thang, Kakuam, Thom, Ketum, Biak). Drug Enforcement Administration, January 2013. http://www.deadiversion.usdoj.gov/drug_chem_info/kratom.pdf (accessed July 3, 2017).

⁷⁵ Suwanlert, S. 1975. A study of kratom eaters in Thailand. *Bull Narc*, 27: 21–7. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/1041694>

⁷⁶ Trakulsrichai S. et al. Kratom Abuse in Ramathibodi Poison Center, Thailand: A Five-Year Experience. *J Psychoactive Drugs*. 2013 Nov-Dec;45(5):404-8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24592666>

⁷⁷ Forrester MB. Kratom Exposures Reported to Texas Poison Centers. *J Addict Dis* 2013;32:396-400. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24325774>

WEDNESDAY, MAY 24, 2017.

DEPARTMENT OF EDUCATION

WITNESS

HON. BETSY DEVOS, SECRETARY, SECRETARY OF EDUCATION

INTRODUCTION OF FOSTER YOUTH SHADOW DAY GUEST

Mr. COLE. Good to have you here, Madam Secretary.

Before we begin formally, I want to recognize Ms. Roybal-Allard for the purposes of an introduction.

Ms. ROYBAL-ALLARD. Thank you, Mr. Chairman, for this courtesy.

I would like to introduce Tommy Diaz, who is a former foster care youth, who is shadowing me today for the Sixth Annual Congressional Foster Youth Shadow Day. Tommy is a resident of Downey, California, in my 40th Congressional District. His educational aspirations are to earn a master's in architecture and have a career in designing sustainable green houses in the community.

I just want to thank him for coming to D.C. to help ensure that the voices of current and former foster care youth are involved in the child welfare reform discussion, particularly efforts to support the well-being, talents, and educational aspirations for every child involved in foster care.

And Tommy is the one with the blue around him.

Mr. COLE. Why don't you stand up real quick? Yes, stand up. [Applause.]

There he is.

CHAIRMAN'S OPENING REMARKS

Good morning, Madam Secretary. It is genuinely my pleasure to welcome you here to the Subcommittee on Labor, Health and Human Services, and Education. We are looking forward to hearing your testimony.

Madam Secretary, you have one of the most important jobs in Washington, and that is ensuring that all young people will have access to the education they need to be successful in coming decades. And frankly, I know it is a cause that you have devoted your life to quite selflessly.

Many of our schools do fantastic jobs, some need some support, and others are in need of significant improvement and reform. But one fact remains, and that is we need to do the right thing for all America's children, and your job is to ensure that that happens.

The budget blueprint that came out in March was further detailed yesterday and proposes some dramatic shifts in the way your agency does business. It has a goal of opening doors for more edu-

cational choices to families, whether those schools be regular public schools, charter schools, or private schools.

I applaud your investment in high-quality charter schools as a way to give options to many students who have had no options in the past. I support high-quality education options for all students, and I believe the neediest among us have the most to gain from an excellent education. I have long supported programs that help level the playing field for Indian children, for disabled children, first-generation college students, and poor children. I think that is a common objective on this committee.

Today, I will have some questions about how your school choice proposals would work and how they would mesh with the reauthorization of the Elementary and Secondary Education Act that was just completed over a year ago and was nearly a decade in the making.

I also appreciate that your budget aims to protect the most vulnerable populations—students with disabilities, English language learners, and Minority Serving Institutions. It is unfortunate that the timing of the final consolidated appropriations bill and the production of the full budget coincided such that the final fiscal year 2017 budget figures were not known at the time your funding proposal decisions were finalized. And I understand that makes apparent—or makes sometimes cuts appear that, frankly, were not intended to be cuts at all.

In many cases, it is obvious that the policy of your administration was to maintain current funding for programs. But Congress increased for particular programs, sometimes after the fact, such that your proposal would appear to be a cut when, in fact, that was not the intention at all. We simply need to carefully explain ourselves when discussing proposed increases and decreases today.

Your budget also shifts the way higher education student financial assistance flows by proposing dramatic changes in the Supplemental Educational Opportunity Grant (SEOG) and college Work Study programs. I look forward to learning more about how you believe these reforms will increase student access to and completion of college programs.

Your budget consolidates and proposes over 20 programs for elimination. Many of these are cited as being duplicate, ineffective, or not a key Federal mission. I look forward to discussing those, and your budget also proposes cuts in TRIO and GEAR UP, which, frankly, I will advise you I have a different point of view on. But I will be interested in discussing this with you and learning your rationale.

I will also have questions about your proposed funding levels for individuals with disabilities, particularly in light of the recent Supreme Court decision, which found that schools must provide a meaningful education opportunity to all children with disabilities and not just a bare minimum level of services. And again, I want to commend you for making a special effort to protect these populations in your budget.

Finally, ultimately, this subcommittee needs to know the specific details of how your cuts impact schools and students and how new programs would be implemented. The budget provides some of

these details, and I know some are still being developed, but we look forward to hearing what you are able to share with us today.

As a reminder to the subcommittee and our witnesses, we will abide by the 5-minute rule so that everyone will have a chance to get their questions asked and answered. Obviously, we have both the big Chairman and the Ranking Member here. So I am going to move next to my Ranking Member, but we will certainly be calling on them for whatever remarks they care to make as well.

Ms. DELAUR. Thank you very much—

Mr. COLE. I recognize the gentlelady from Connecticut.

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

And I want to welcome the Secretary. I will take one second, if I will, because like my colleague Congresswoman Roybal-Allard, I, too, have a young woman who is shadowing me today. Justina Rosario, from the City of New Haven, Connecticut, who, as with Tom, is part of the program that is dealing with foster children and making it through the system, which they both have.

So I want to welcome her. Thank you, Justina. [Applause.]

RANKING MEMBER'S OPENING REMARKS

Ms. DELAUR. Again, thank you, Secretary DeVos, for joining us today and offer my congratulations to you. But let me launch right in as we spoke about recently.

I believe the proposals contained in President Trump's budget are alarming, and quite frankly, this puts us on a path towards the privatization of public education. This budget intends to shift public school funding and to advance an agenda that transfers taxpayer dollars out of local community schools.

Education is the great equalizer in our country. At the signing ceremony for the original Elementary and Secondary Education Act, President Lyndon Johnson described education as "the only valid passport out of poverty."

Decades later, he is still right. The economic benefits that are accrued for the individual and society are indisputable. That is why our Government must be committed to providing every child with access to a high-quality public education. We need to focus our policies on strengthening public schools, reducing class sizes, supporting the teaching profession, providing more one-on-one attention, boosting student enrichment opportunities, supporting parental involvement, and making high-quality preschool available to all.

ACHIEVEMENT GAP IN HIGH-POVERTY AREAS

We have an achievement gap in this country, and it is worse in high-poverty areas, both urban and rural. Yet these are the very areas we would starve with this budget. I note that a concerted Federal investment has helped students of color and low-income students make gains since the Department of Education was created.

National Assessment of Educational Progress (NAEP) reading and math scores have improved. I won't go into it now, but later in the hearing will read you the success percentages of our students with the NAEP scores.

At the same time economic inequities grew, high-poverty districts received less funding. Their students are more likely to be taught by novice teachers and less likely to take an Advanced Placement (AP) course for which they have shown potential.

FUNDING FOR PUBLIC SCHOOL CHOICE

Ninety percent of our kids are in public schools. We need more resources to help them succeed. You can't do more with less. You do less with less. And we certainly should not be siphoning off taxpayer dollars to pay for vouchers. Vouchers, in my view, will destabilize not only our schools, but our communities, and I will fight at every step against any attempt to take public money away from public schools.

Cutting funding for critical programs to increase Federal investments in charter schools also raises public accountability questions. I support charter schools, but I do not believe that they should supplant the public education system.

Transferring limited resources from public schools to private schools is wrong. It creates a false choice for families. When Congress completed the bipartisan reauthorization of the Elementary and Secondary Education in 2015, it soundly rejected efforts to decimate neighborhood schools, and we expect the administration to implement the new law as written.

The Trump budget request includes \$1.4 billion in new funding to expand so-called choice. At the same time, the budget puts \$9.2 billion in cuts on the table, slashing or eliminating funding for many programs that benefit kids in public schools to pay for this ill-conceived proposal.

Despite budget documents and rhetoric claiming the request maintains funding for core formula grant programs, it cuts \$578 million from Title I and \$114 million from the Individuals with Disabilities Education Act (IDEA).

The budget also eliminates \$1.2 billion for after school enrichment programs that help keep nearly 2 million kids safe, \$2 billion for teacher professional development and class size reduction, which would result in more than 7,000 teachers losing their jobs.

Literacy is a mark of a civilized society. We spend money to spread literacy internationally. Yet we are eliminating \$190 million from the largest reading program for low-income children and youth and \$96 million from grants that help low-skilled adults become literate.

Despite promises by the administration to champion the American worker, the budget slashes funding by 15 percent for Career and Technical Education programs that help prepare high school and community college students for in-demand jobs. The list goes on and on.

CUTS TO HIGHER EDUCATION

The budget also proposes deep cuts to or eliminations of programs that help students access and succeed in higher education that have enjoyed bipartisan support, and bipartisan support on this subcommittee, for many years. Ten percent cut to TRIO, which would end academic support services for more than 130,000 college students.

Fifty percent cut to work study, which would punish thousands of students who are working their way through college. The complete elimination of both the SEOG, Supplemental Education Opportunity Grants, that 1.5 million students rely on, grants that allow schools to tailor programs to students' needs, and the Strengthening Institutions program that helps nearly 200 community colleges and other institutions serve working-class students.

The budget calls for an end to Public Service Loan Forgiveness (PSLF) for police officers, teachers, nurses, and raids \$4,000,000,000 from Pell without taking any steps to help students access the economic freedom they deserve, such as increasing the maximum Pell award.

Those in the administration claim to support Historically Black Colleges and Universities (HBCUs) but refuse to admit or simply ignore the fact that these disastrous budget proposals would harm the very programs that HBCUs and their students rely on.

I want to be clear. Fraught and painful history of segregation in this country, HBCUs were not the product of school choice. They were a product of our Nation's racist segregation.

PROTECTING STUDENTS FROM POOR QUALITY FOR-PROFIT COLLEGES

Aside from your budget, I have questions about how you plan to protect students from low-quality, high debt, for-profit colleges. These companies prey on low-income students—students of color and the honorable men and women who serve in our military and sacrifice their lives for this country.

Students at for-profits represent only about 1 in 10 of the total higher education population, yet they represent more than a third of all Federal student loan defaults, calling into question the quality and the value of education provided by this sector. The borrower defense and gainful employment regulations are critically important steps in reining in these abuses. That is why I am alarmed that one of your first actions as Secretary was to delay the gainful employment rule.

Failure to fully implement this regulation will not only hurt students, it would be expensive. The Congressional Budget Office estimated a \$1.3 billion cost over 10 years to taxpayers.

President George H.W. Bush once said, and I quote, "Think of every problem, every challenge we face. The solution to each starts with education."

We owe it to the future of our society to make a commitment to all of our children that they get the best start in life possible, and that cannot happen if we make misguided cuts to education.

I look forward to a robust discussion today, and I thank you for being here.

And I thank you, Mr. Chairman.

Mr. COLE. I thank the gentlelady.

And we are very privileged to have the distinguished chairman of the full committee here today. So, Chairman, we would love to hear whatever opening remarks you would care to make.

Mr. FRELINGHUYSEN. Well, thank you, Chairman Cole.

And I also want to welcome Madam Secretary DeVos here to the Appropriations Committee. We look forward to your testimony and hearing your frank and candid views on any number of issues.

CHAIRMAN FRELINGHUYSEN'S OPENING REMARKS

Today's hearing is an important part of the oversight duties of this committee. Now that we have formally received the administration's budget request, the committee will undertake a thorough analysis of each and every budget. We will go through each and every budget line, question every witness, and demand credible spending justifications, and only then will we make our own determinations on the best use of those tax dollars.

We intend to put forward a complete set of appropriations bills that adequately fund important programs while working to reduce and eliminate waste and duplication. I will work with Mrs. Lowey, Chairman Cole, Ranking Member DeLauro to move rapidly in the coming weeks and months to complete the fiscal year 2018 appropriations bills.

Again, today's hearing is part of a process we follow to determine the best use of taxpayers' dollars. After all, the power of the purse lies in this building. It is the constitutional duty of Congress to make spending decisions on behalf of the people we represent at home.

ACCESS TO HIGH QUALITY EDUCATION

We owe it to our young people to ensure that they have access to the best education possible, and your Department is vital in keeping that promise. Many programs administered by the Department of Education, like Pell Grants and those established by the Individuals with Disabilities Education Act (IDEA) ensure young people receive a quality education.

I visit many wonderful schools in my district in New Jersey, some of the best in the Nation, throughout the school year, and I hear from students, teachers, and parents on a range of issues. In middle schools and high schools, I often hear about the benefits of a well-rounded education that is afforded by the Every Student Succeeds Act, which allow students to pursue interests in the arts, music, and physical education, as well as science, technology, engineering and math (STEM) education and English.

In colleges and universities in my district, many students remind me that they would not have the opportunity to attend without programs like Pell and Federal Work Study. I am eager to hear how your Department will ensure opportunity for these students under proposed reductions, including the elimination of the Supplemental Education Opportunity Grants.

Further, these goals can only be met by ensuring the next generation of teachers have access to quality higher education and the necessary tools in their careers. We need to work, as we have in the past, in a bipartisan way to ensure that every child in America is well educated.

In conclusion, Madam Secretary, I welcome you. I look forward to working with you and this committee to make sure that we have the best possible legislation possible.

Thank you, Mr. Chairman.

Mr. COLE. Thank you, Mr. Chairman.

And again, we are very fortunate to have the ranking member of the full committee, my good friend from New York is recognized for whatever remarks she cares to make.

Mrs. LOWEY. And I want to thank Chairman Cole, and it is good to have Chairman Frelinghuysen here, my partner. And always good to have my friend Congresswoman DeLauro here. Thank you both for holding this hearing. And I am very pleased to welcome Secretary DeVos before this subcommittee for the first time.

Madam Secretary, I will get right to it. I believe that your budget proposal would do great harm to students in every facet of education, from kindergarten through graduate school and, for those with student loan debt, years beyond. It is just another example of the broken promises in the Trump budget that would harm hard-working Americans and set us back in preparing a 21st century workforce.

PROPOSED CUTS TO DEPARTMENT'S 2002 LEVEL

To me, this budget reflects the views that do not represent the majority of people in my district and people throughout the country. Your budget would cut \$9.2 billion from the Department of Education, a cut of 13.6 percent, taking us back to 2002 levels.

It would siphon money from public schools to pay for private school vouchers, eliminate more than 22 education investments, including teacher training and after school programs, leaving 1.6 million children without a safe enrichment environment. And I want to say that has always been one of my favorite programs because if you can't convince people that they are enriching their children, at least they are keeping them safe while their parents are both working.

It would make higher education more expensive by cutting Federal Work Study in half, eliminating Perkins Loans for needy students; preventing inflationary increase for Pell Grants, robbing its surplus; ending Public Service Loan Forgiveness; and more.

In my district, Rockland Community College is currently taking part in a Department of Education initiative that provides childcare for low-income parents taking college courses, allowing students to earn a degree and enter the workforce more quickly with less debt. Your budget would eliminate this program, destroying the dreams of these hard-working people who are trying to build a better life for themselves and their children.

And I hope, by the way, before this budget is completed, you would come to the district, meet these families, meet these parents who are working jobs, going back to school so they can have a positive, bright future.

This budget reflects the views of an administration filled with people who, frankly, never had to worry about how they were going to pay for their children going to college. And yet I am most upset that this budget would undermine our public education system and the working families who depend on them by reallocating funding for disadvantaged students, including the Pell surplus and Title I funding through private school vouchers.

EVIDENCE BASE AND RATIONALE FOR VOUCHERS

Study after study shows these vouchers go to families who would likely send their kids to private school anyway, yet this budget would deplete public schools to fund them. It is clear to me that you do not have the necessary understanding of our education system, between this proposed budget and your comments referring to public schools as a “dead end” and public school teachers as being in “receive mode.”

Please come. Come spend some time in schools in my school district, where the teachers I know don’t stop working when the final bell rings. They work for hours every night getting prepared for the next day. Many of these teachers and administrators are on the front line, identifying the best way to reach each student and at times being a parent, counselor, teacher, and more.

And I am not saying that it is all perfect, but let us improve the system rather than destroy the system. The teachers I represent were angered and demoralized after hearing your statements on public education. I hope that as you lead the Department, you will see the hard work and good that most public school teachers do every day and do better than this budget proposal to empower them to succeed.

Thank you, Mr. Chairman.

Mr. COLE. I thank the gentlelady.

INTRODUCTION OF THE WITNESS

And Madam Secretary, again, it is a genuine pleasure to have you here. You are recognized for whatever opening remarks you care to make.

OPENING STATEMENT OF SECRETARY OF EDUCATION BETSY DEVOS

Secretary DEVOS. Thank you, Mr. Chairman, Chairman Frelinghuysen, Ranking Member Lowey.

Mr. Chairman, Ranking Member DeLauro, and members of the subcommittee, thank you for this opportunity to testify on behalf of the administration’s budget proposal for fiscal year 2018.

I look forward to talking about how we can work together to improve educational opportunities and outcomes for all students while also refocusing the Federal role in education. While today’s hearing is meant to focus on the numbers and mechanics of the budget, I hope we will all remember our goal and our purpose, how to best serve America’s students. Allow me to share just one example.

I recently met a young man, Michael, whose story truly spoke to me. Michael grew up in East Hartford, Connecticut, in a low-income neighborhood. He was an average student throughout elementary and middle school, but all that changed when he reached the district high school.

Michael described a school where students were the real ones in charge of the class, and they would make it impossible for the teacher to teach. He was constantly bullied to the point he was afraid to even go to the school’s bathroom, and this constant fear made him hate school. He described the school he was assigned to as, and I quote, “nothing more than adult daycare, a dangerous daycare.”

But even though he was failing his classes, the school simply passed him along from year to year, giving him Ds and sending the not-so-subtle message that they didn't think Michael would amount to much. Michael got a diploma, but not an education.

Michael followed the path he thought he was destined for, working in a low-skill, low-wage job. But with the encouragement of his wife, Michael took a course at the local community college to see what was possible for him. He found an environment that was invested in his success, and much to his surprise, Michael earned an A.

He thought it was a fluke. So he took more classes. Lo and behold, he earned more As. He is now in the school's honors program with the goal of working as an emergency room nurse. His success is America's success.

Access to a quality education is the path to the American dream. So I ask you to keep Michael and countless other students like him in mind as we go about our shared work to support America's students. No student should feel they attend a dangerous daycare. No child's dream should be limited by the quality, or lack thereof, of the education they receive.

EQUAL OPPORTUNITY AND DECENTRALIZING CONTROL

This budget lays out a series of proposals and priorities working toward ensuring every student has an equal opportunity to receive a great education. It focuses on returning decision-making power and flexibility to the States, where it belongs, and giving parents more control over their child's education.

Parents deserve that right, and frankly, that right has been denied for too long. We cannot allow any parent to feel their child is trapped in a school that isn't meeting his or her unique needs.

The budget also reflects a series of tough choices. If taxpayer money were limitless, we wouldn't need a budget at all. But by its very definition, a budget reflects the difficult decisions of how best to appropriate the limited taxpayer dollars we have. This budget does so by putting an emphasis on the programs that are proven to help students while taking a hard look at programs that are well-intended, but simply haven't yielded meaningful results.

This is why the President's fiscal year 2018 budget would reduce overall funding for Department programs by \$9 billion or 13 percent. I have seen the headlines and I understand those figures may sound alarming for some. However, this budget refocuses the Department on supporting States and school districts in their efforts to provide high-quality education to all our students. At the same time, the budget simplifies funding for college while continuing to help make a higher education more accessible to all.

PRINCIPLES GUIDING 2018 BUDGET

I would like to outline the principles that guided our decision-making. First, our request would devote significant resources toward giving every student an equal opportunity for a great education. It emphasizes giving parents more power and students more opportunities.

Second, the administration's request recognizes the importance of maintaining strong support for public schools through longstanding

State formula grant programs focused on meeting the educational needs of the Nation's most vulnerable students, including poor and minority students and students with disabilities.

Third, our request maintains funding for key competitive grant programs that support innovation and build evidence of what works in education. This also means strong support for the research and data collection activities of the Department.

Fourth, our request reduces the complexity of funding for college while prioritizing efforts to help make a college education accessible for low-income students. As Congress prepares to reauthorize the Higher Education Act, I look forward to working with you to address student debt and higher education costs while accelerating and improving student completion rates through such efforts as year-round Pell and reducing the complexity of student financial aid.

And fifth, consistent with our commitment to improve the efficiency of the Federal Government, our request would eliminate or phase out 22 programs that are duplicative, ineffective, or are better supported through State, local, or philanthropic efforts. Six additional programs were already eliminated in the reauthorization of the Elementary and Secondary Education Act. All told, taxpayers will save \$5 billion.

In total, the President's budget fulfills his promise to devolve power from the Federal Government and place it in the hands of parents and families. It refocuses the Department on supporting States in their efforts to provide a high-quality education to all of our students.

Research shows that increasing education options can have positive effects on students generally and an even greater impact on poor and minority students. If we truly want to provide better education to underserved communities, then we must start with giving parents and students the power to select high-quality schools that meet their needs.

We want to unleash a new era of creativity and ingenuity in the education space. My hope is that working in concert with each of you, we can make education in America the envy of the rest of the world.

Thank you again for the opportunity to share the administration's vision for improving education across the country. I look forward to respond to your questions.

[The information follows:]

Biography of Betsy DeVos, U.S. Secretary of Education

Betsy DeVos serves as the 11th U.S. Secretary of Education. She was confirmed by the U.S. Senate on February 7, 2017, after being nominated by President Donald J. Trump.

Secretary DeVos has been involved in education policy for nearly three decades as an advocate for children and a voice for parents. She is especially passionate about reforms that help underserved children gain access to a quality education.

DeVos' interest in education was sparked at an early age by her mother, a public school teacher. It grew when she sent her own children to school and was confronted with the reality that not every child in America is granted an equal opportunity to receive a great education. DeVos saw firsthand the work leaders in her hometown were doing to increase educational opportunities for students and choices for parents, and she has been involved in the fight to provide better educational options across the nation ever since.

For 15 years, DeVos served as an in-school mentor for at-risk children in the Grand Rapids (Michigan) Public Schools. Her interactions there with students, families and teachers, according to DeVos, "changed my life and my perspective about education forever."

A leader in the movement to empower parents, DeVos has worked to support the creation of new educational choices for students in 25 states and the District of Columbia.

As Secretary, DeVos will work with President Trump to advance equal opportunities for quality education for all students. DeVos firmly believes that neither the ZIP code in which a child lives nor a child's household income should be the principal determinant of his or her opportunity to receive a world-class education. As secretary, she will advocate for returning control of education to states and localities, giving parents greater power to choose the educational settings that are best for their children and ensuring that higher education puts students on the path to successful careers.

Prior to her confirmation, DeVos served as chairman of The Windquest Group, an enterprise and investment management firm. In addition to her leadership in the education arena, DeVos has also served on the boards of numerous national and local charitable and civic organizations, including the Kennedy Center for the Performing Arts, Kids Hope USA, ArtPrize, Mars Hill Bible Church, and the Kendall College of Art and Design.

DeVos is a graduate of Calvin College in Grand Rapids, Michigan, where she earned a Bachelor of Arts degree. She is married to entrepreneur, philanthropist and community activist Dick DeVos, and together they have four children and five grandchildren.

Mr. COLE. Thank you, Madam Secretary, and I am delighted again to have you here and appreciate your testimony.

Let me begin with the first of the many unfair questions you are going to get. Unfair in this case because you will have had so little time in your Department to react to it.

MEANINGFUL OPPORTUNITY MANDATE FOR STUDENTS WITH DISABILITIES

But as I am sure you are well aware, we recently had a Supreme Court decision, Endrew F. versus Douglas County School District, an 8–0 decision, which found that school districts must provide a truly meaningful level of educational opportunity for students with disabilities and not simply more than a *de minimis* level of basic services.

I think it is early, obviously, to tell what the full ramifications and implications of this are. But as you know, this is a tremendous cost to local school districts. Obviously, it is a major item in your budget as well, which, again, I appreciate you defending.

Have you had a chance to think about what the impact of this decision will be on local school districts and, obviously, you know, how the Department might be able to assist the local areas in addressing it?

Secretary DeVos. Well, thank you, Mr. Chairman, for that question.

And this is an issue about which I have definitely become aware and followed closely. Let me just begin by saying how important I believe it is—the Federal Government's role is to support the IDEA program supporting students with special needs, with disabilities, and this budget does, in fact, anticipate level funding IDEA.

What the implications are of this decision, obviously, remain to be seen. We are looking closely at the decision and the directive to help provide guidelines and are in the process of working through that now.

But I would come back to, I think, the original reason for the case, and that was that these parents felt their son was not getting the kind of education that he needed. And they, as any parent would do, fought hard to make sure that their child was getting the support that he needed.

And I think that this is an area that is very ripe for broader discussion around empowering parents more in these decisions around their children.

Mr. COLE. This has been an area that this committee has really focused on. As a matter of fact, with all due respect to the last administration, they flat funded IDEA in their last couple of budgets, and it was this committee, honestly, that put more money for IDEA than either the Senate or the House. So as you develop your strategies, it is a scenario that we are going to want to visit with you about again. Because, again, we know this is a challenge for a lot of districts, and obviously, we want to make sure these young people are well taken care of.

PROPOSED TRIO AND GEAR UP REDUCTIONS

Let me also ask you and give you an opportunity, and in full disclosure, I am a big TRIO fan. I have seen the impact in my district.

And it is a program, actually, I first found a lot about when I was an academic back in the 1970s. It has been around a long time. It is a Great Society-era program.

But it has produced over 5 million college graduates. So it has served its purpose well. And again, that is an area that had been flat funded, and this subcommittee has been the leader on restoring funding there.

So I know you have proposed some reductions to that—and to GEAR UP, if you care to address it in the time we have got. I would love to have your thinking on this and your assessment of the program.

Secretary DeVos. Thank you. Agreed there are portions of the TRIO program that have been very effective and very important for students who are aspiring to go to college who may not have had that opportunity.

The focus of this budget and the portion of the TRIO program that we are proposing to be eliminated are the McNair Scholars and the Education Opportunity Center (EOC) portions. McNair being focused on postbaccalaureate program students and not—you know, sort of outside of the original intent of the TRIO programs to begin with. And then the EOC program being more of an ancillary activity to help support or market the TRIO program.

So we felt that, again, with tough choices to be made, that these were areas that probably were not really focused on the original intent, as Congress intended the TRIO programs originally. So we have proposed those be eliminated but continue to fund the Upward Bound Program, Talent Search, and the Student Support Services Program.

Mr. COLE. I appreciate that very much, and we will continue to have a dialogue. I think you will find, if you look at McNair in particular, it has helped a lot of students get graduate school that otherwise couldn't because, again, they are quite often coming from families of very limited means.

Secretary DeVos. Granted, it is just a high cost per student in terms of its application.

Mr. COLE. And you are absolutely correct. It is much more expensive per student, but that is partly because it is a graduate degree as opposed to an undergrad. But you are correct in your assessment in the cost.

With that, let me go to my good friend the ranking member.

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

TITLE II-A TEACHER TRAINING FUNDS

Madam Secretary, you have previously stated that funding designated for professional development in Title II, Part A of the Every Student Succeeds Act (ESSA) is redundant and duplicative. Eliminating Title II, Part A sends the message that either teachers, school staff, and principals have hit all the benchmarks and they do not need to improve, or teachers, school staff, and principals are doing so poorly that there is no need to invest in them. Which category do you believe teachers, paraprofessionals, and principals fall into?

Secretary DeVos. Well, Madam Congresswoman, first of all, the Title II-A program, we believe, has been spread—it has been

spread very thinly. It has been more prescriptive in nature, and as the States go to implement their ESSA programs and plans, they have great latitude with how to use other funding sources and to devote them to the kinds of activities that IIA has been intended for.

Twenty percent of the grants that have gone through that program are of \$10,000 or less, and so the efficacy of them has been very much in question. We believe that with the flexibility granted to the States that they are going to be able to use the other funding streams in support of these programs, if that is what is right for the plan and programs and the students in their States.

Ms. DELAUBRO. I don't know these days that States have a lot of leeway in other funding streams. I just point to the State of Connecticut, which is in very serious financial difficulty.

Now when teachers feel prepared and supported, they stay in the profession. Standards and curriculum change based on research. Teachers need to improve and change as well. Do you believe that that is true?

Secretary DEVOS. Absolutely.

Ms. DELAUBRO. Okay.

Secretary DEVOS. And that a good and effective teacher is invaluable.

TITLE II—A CUTS AND POTENTIAL STAFF CUTS IN SCHOOLS

Ms. DELAUBRO. And they need the resources to do it. Okay. So having the resources there is critically important in order to deal with teacher development.

Many schools use their Title II, Part A funds to keep classes from being overcrowded. So parents do not want their first grader to be in a class of 30 with one teacher. Eliminating this funding could mean firing approximately 8,000 teachers. How do you explain this decision to parents?

Secretary DEVOS. Well, again, we believe with the implementation of ESSA that States are going to be best equipped and best able, along with their local education agencies and authorities, to be able to make these decisions on behalf of students closer to the decision—

Ms. DELAUBRO. Decisions, though, without resources.

Secretary DEVOS. Well, there is resources through Title I that are very flexible in that regard.

TITLE I—FUNDING FOR TEACHER QUALITY

Ms. DELAUBRO. Well, we have got a serious shift in funds from Title I. We can get that in another round. Shifting of the money out of Title I to school choice. That is part of where you all want to go with Title I. So Title I isn't going to be at the level that it necessarily needs to be in order to be able to accommodate these efforts.

You talked about in your fiscal year 2018 budget that it refocuses the Department's mission on supporting the efforts of States to provide high-quality education. My view that eliminating of Title II, Part A contradicts this mission. How do you square this circle?

TITLE II—ELIMINATION AND DEPARTMENT MISSION

Secretary DEVOS. Again, we believe that these decisions are best made at the State and the local level, and their ability to target the resources to where the needs are for their State, for their students, and for their schools is the most important. The flexibility afforded through ESSA is a very important element in consideration of this whole budget process.

Ms. DELAUBRO. Should every student—again, you can't do less with less. That is my view. I don't know what everyone else's view is. And we are cutting back significantly in the resources to education and dealing with the notion that we do not have to invest in teacher training or in reduced class size in order to help better to have kids learn.

Should every student have access to a highly qualified teacher? I am sure your answer is—

Secretary DEVOS. Absolutely.

Ms. DELAUBRO [continuing]. Absolutely. How does the eliminating Title II funding impact the belief? We know that the Supporting Effective Educator Development (SEED) exists, the Teacher Incentive Fund (TIF) exists. There are competitive grants that don't reach every State and every school district. So how do you—by eliminating Title II, how do you back up your view that every student should have access to a highly effective teacher?

Secretary DEVOS. Again, reprioritizing the dollars that go to the States for their flexibility to be used in the best manner—that they deem the best manner possible for—on behalf of the students they are serving.

And just with respect to your question and comment about reducing class size, that portion of that program only was effective or implemented for 8,000 teachers out of more than 3 million. So the number of teachers that are actually being benefited or impacted through that is really very minimal.

Ms. DELAUBRO. Eight thousand. I guess if you are one of those 8,000, you don't see yourself as minimal.

Secretary DEVOS. Indeed.

TITLE I—EXPENDITURES AT DISTRICT LEVEL

Ms. DELAUBRO. Just one final comment. And you can—is there evidence that States and districts aren't spending all of their Title I money? Because you have claimed that they can use Title I.

Mr. COLE. If the gentlelady would please—

Ms. DELAUBRO. There is no room to accommodate elimination of these programs.

Thank you for your courtesy, Mr. Chairman.

Mr. COLE. And please, if you would care to respond?

Secretary DEVOS. That is okay.

Mr. COLE. Okay. Thank you.

And again, we will try and be generous with the clock, but please.

Ms. DELAUBRO. Thank you.

Mr. COLE. Okay. If we can, we next go to the full chairman. Mr. Chairman.

Mr. FRELINGHUYSEN. Madam Secretary, I visit some years as many as 80 schools, juniors and seniors in high school, seventh and eighth graders, some of whom may trek down here for their Washington trip, and elementary schools promoting obviously literacy, Read Across America, things that put a sort of a human face on what we do as Members of Congress to support public education.

IDEA AND FULL AUTHORITY SPECIAL EDUCATION FUNDS

I have had a particular focus, as has Chairman Cole on IDEA, and I am hugely impressed and actually in awe of anyone who teaches special ed. They are, should be ordained for sainthood.

We have never met our full obligation. I think the law was passed in 1975.

Secretary DEVOS. Forty percent.

Mr. FRELINGHUYSEN. Forty percent partnership. Could you talk a little bit about—where you are relative to greater participation in terms of that partnership? I think it is absolutely essential.

And may I just say for the record, and maybe it is true of New York as well for Mrs. Lowey, that there are a number of people who come to New Jersey because of court decisions which require a thorough and efficient education for every child, regardless of their circumstance. And many families with disabilities, or who have children with severe disabilities, the whole spectrum of disabilities, come to our State.

We have, obviously, a great public school system. We have a supportive number of other schools maybe dealing with autism, particular challenges. Where do you feel we are going, and how supportive does this budget represent?

Secretary DEVOS. Thank you, Mr. Chairman.

I share your concern and heart for both these students as well as those who help teach them, and they have a tremendous dedication to a wide range of needs and a wide range of students. And your reference to the fact that when IDEA was originally passed, the goal was to fund it at or to support 40 percent of the cost of it, if Congress were to actually fully fund it, it would be \$31.5 billion for IDEA.

We are—the budget and what you have traditionally funded it the last number of years is at about the 15 percent range. So you can see we are proposing to continue the budget funding as has been done in the last number of years.

But I think, you know, it is a matter for robust conversation. If Congress believes that the commitment to this program should be at a much higher level financially, there is certainly an opportunity there.

Mr. FRELINGHUSYSEN. I think at one point, Mr. Chairman, we were up to 18 percent, and now we are down to, I think, 15 percent. I think we need to do better, and I just want to put my oar in the water because I think it is very important.

Thank you, Mr. Chairman.

Mr. COLE. I thank the gentleman.

We will now go to the ranking member of the full committee.

Mrs. LOWEY. Thank you, Mr. Chairman.

DIRECTING PUBLIC SCHOOL FUNDS TO PRIVATE SCHOOLS

As you have heard, I am extremely disappointed that your budget proposes to take funding from public education and transfer it to private schools. In my judgment, we need to increase the resources. Remember, the Federal Government just provides about 9 percent of resources for public schools. Most of it comes from State and local taxes.

So what we have to do is increase resources for public schools, not put an increased burden on the State and local and, again, continue to work together to improve them, not diminish them. So I think it is imperative that this committee and the American people really understand just what this proposal would do. So a couple of quick questions you can just answer yes or no.

VOUCHER RECIPIENT RIGHTS TO IDEA DUE PROCESS

Under your proposal, would a student with disabilities receiving a voucher for a private school have due process rights under IDEA?

Secretary DeVos. Ranking Member Lowey, I thank you for the question and thank you for being here today. Before responding yes or no to your question, allow me to just address one of the things that you said earlier about shifting funding.

We are not proposing any shifting of funding from public schools to private schools. In fact, all of the proposals that have been set forth in the budget continue to fully fund and commit to funding public schools as we have. And so I want to make sure that we are very clear on that, and if we are misunderstanding numbers somehow, let us talk about that.

Mrs. LOWEY. Aren't you talking about vouchers? Who is paying for the vouchers?

Secretary DeVos. That is an additional program to the Title I funds that have been carried forward in the budget.

Mrs. LOWEY. Where—

Secretary DeVos. The Title I funds in the budget are consistent from—

Mrs. LOWEY. This is clearly a misunderstanding, so maybe at another time, we could talk about that. If you are funding with vouchers private school, the money is coming from someplace, and there is an overall cut in the budget.

Secretary DeVos. There is a small—there is a proposal for a \$250 million investment in the innovation portion of the budget that would help fund some pilot test programs around school choice, and we talk about—everybody talks about vouchers. What we also have to understand is that there are many different mechanisms to provide parents choices, and vouchers are but one mechanism.

The \$250 million does not prescribe a method or a mechanism. That remains to be discussed and decided upon if that is funded as part of the appropriations process.

PERFORMANCE AND ACCOUNTABILITY IN PRIVATE VOUCHER SCHOOLS

Mrs. LOWEY. We will have to continue this discussion because I would be interested in knowing whether private schools funded with public taxpayer dollars will be held to the same performance

standards as public schools, and do you believe that private schools that enroll voucher students should be accredited and have to provide evidence of the quality of their programs?

Secretary DeVos. Each State deals with this issue in their own manner, and I can refer to the program in Florida where there are 40,000 parents whose children are deemed students with disabilities who have chosen to take what is called the McKay Scholarship and take it to a private school of their choice. Those parents are very happy with and satisfied with that decision. They have made that choice to do that.

And I refer to that as a specific example of a State addressing an issue in a way that is working for the students and parents in their State. Each State has to deal with this, I believe, in their own way.

CLARIFYING IDEA DUE PROCESS REGARDING VOUCHERS

Mrs. LOWEY. Maybe I misunderstood, but can you clarify, a student with disabilities receiving a voucher for a private school have due process rights under IDEA. What is the law unto that?

Secretary DeVos. Due process rights with regard to—

Mrs. LOWEY. IDEA.

Secretary DeVos [continuing]. IDEA. They—if a parent chooses to go to a school that is not a public school, then that is a decision made and a contract made with that private provider or that other provider.

Mrs. LOWEY. But what is—will they have access to IDEA? Will they have due process rights? Or is that—I mean, the public should know that it is optional. Correct?

Secretary DeVos. The way that they handle it in Florida is one approach. But again, each State has to—I believe if they are going to offer choices to parents and to students, they are going to deal with those issues in the way that works best for their State.

Mrs. LOWEY. Let me just say I see I have no time left, but there are many questions I have—after school programs, Pell Grants. We have worked very, very hard on this committee to support public education all the way up, and I am very concerned, when the Federal Government only pays 9 percent of the budget, that you are supporting further cuts.

So I think we need increased dialogue here because education for me is probably one of our most important responsibilities if we are going to have a workforce that is strong, healthy.

Secretary DeVos. I couldn't agree with you more.

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

Mr. COLE. Certainly. We are going to go a little bit out of order, if we may, because our friend Ms. Herrera Beutler has another engagement. So Mr. Harris has graciously agreed to allow us to go to her, and then we will resume our normal rotation.

YOUTH SUICIDE PREVENTION

Ms. HERRERA BEUTLER. Very gracious. Thank you, Mr. Chairman. And I thank the good doctor from Maryland.

So I will make it as succinct as I possibly can. In 2014, suicide was the second-leading cause of death among young people 13 to 19. And youth suicide is a problem in certain areas of my district

and across the country, quite frankly, and I have made a commitment to helping our schools address this problem.

I have a kind of a two-part question, Madam Secretary. The first one is, how does the Department plan on partnering with local school districts as well as other agencies to effectively and swiftly address the mental health crisis that we are seeing evolve in our Nation's youth?

And secondly, the second part, in many cases, school resource officers, or SROs, play an important role in this effort. They engage with students on a daily basis. They get to know them and are critical in identifying depression and suicidal behavior among these school-age kids or young people.

And for the last few years, the Community Oriented Policing Service (COPS) hiring program has given additional resources—or additional consideration to SRO grant applications, so the school districts who make application for this. And I wanted to hear what your thoughts are on the practice of school-based policing through school resource officers, and is it something you will be supporting?

Secretary DEVOS. Well, thank you, Congresswoman.

First, let me say I share your concern about this crisis in our youth, and I think, to start with, those issues, that crisis is best addressed at the most local level possible. And so to the extent that ESSA again allows States and local communities great flexibility in how to invest the resources, hopefully, that they will—in an area where that is a very specific issue in crisis, they will certainly devote the resources necessary.

From the Department level, we do have a program, the Office of Safe and Healthy Students, that is involved with helping to meet some of these needs. But again, it is a very distant relationship there. And I think to the extent that local communities have this issue as very high on their radar screen, I hope and trust that States in implementing their plans will account for that and address those needs very specifically there.

Ms. HERRERA BEUTLER. Do you think the Department of Justice should continue to promote the hiring of school resource officers within the COPS program?

Secretary DEVOS. I am sorry. Could you say that again?

Ms. HERRERA BEUTLER. Do you think the Department of Justice should continue to promote the hiring of school resource officers within the COPS hiring program?

Secretary DEVOS. I think certainly school resource officers are a very viable and important solution in some places. And I think, again, that is best determined at the State and local level.

CHRONIC STUDENT ABSENTEEISM

Ms. HERRERA BEUTLER. Okay, with a little bit of time left, in a 2014 Department of Education report, over 6 million students were chronically absent or missed 10 or more percent of school days. And in my State, we have the highest rate of chronic absenteeism by school district in the Nation.

And unfortunately, that the research shows that the student who is chronically absent is seven times more likely to drop out of school than their peers who are not. There are reasons. I had recently held a roundtable, and there are very important reasons

around why students—it is not just a random student playing hooky, which is what we used to think of it. There are home environments. There are community environments.

There are reasons, you know, I think in high school, when I think about some of the young men who dropped out, they dropped out because they go, get a better job, and they couldn't see the relevance of being in class, right? So there are a lot of issues here.

And I have recently introduced the Chronic Absenteeism Reduction Act with Congressman Tim Ryan, which would give the school districts the flexibility to implement strategies that would combat the chronic absenteeism because it is different per region and what the needs are.

And my question for you is how does the Department plan to empower the local school districts to address this issue effectively?

Secretary DeVos. Well, thank you for that question. I mean, it is a very real issue in many areas. And so often it is a matter of the student and the school not being a good fit for one another, but yet the student doesn't have a choice or another alternative.

And I think about a letter that the Department recently received from an individual who is in the correctional facility in Minnesota who really was lamenting the fact that he didn't have the kind of fit that he needed in school. He went down a bad path and ends up in jail and in prison. And now is getting an education, but saying—

Ms. HERRERA BEUTLER. With just a little bit of my time left, I agree. Sometimes it is the fit. I totally agree with you. But sometimes there are also extenuating circumstances.

Secretary DeVos. And again, I think it goes back to the local districts and the State that really need to work together to address the issues at the local level, closest to the students that need the support and the help.

Ms. HERRERA BEUTLER. Thank you, Mr. Chairman. I thank you again, Dr. Harris.

Mr. COLE. You are certainly welcome.

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

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

LEGALITY OF TITLE I PORTABILITY PROPOSAL

And welcome, Secretary DeVos. I want to go back to a topic that was raised by the ranking member, which is how your department treats Title I. Quite frankly, I was disappointed to see your budget request includes focus grants, which is, in essence, a \$1 billion Title I portability proposal.

This request for an unauthorized, unproven carve-out from Title I is alarming, especially in light of your request to cut \$578 million from other parts of Title I. As you know, Title I portability was soundly rejected by Congress during negotiations for Every Student Succeeds Act.

During the debate surrounding ESSA, numerous nonpartisan experts and stakeholders ranging from the Brookings Institution to the Association of School Superintendents concluded that portability would result in more funding for wealthier school districts at the expense of poorer districts.

My first question is, in your view, should high-poverty schools receive more funding resources than schools that have lower levels of poverty?

Secretary DEVOS. Congresswoman, yes, I think the reality is that they do receive higher levels of funding.

And if I could just actually refer back to one of Chairwoman—Ranking Member Lowey's questions or the question around Title I funding and the assumption that Title I funding for vouchers was going to be a part of Title I. It is Title I-B that is for a voluntary school choice program. It is not any kind of a mandatory or imposed program. I just wanted to make sure to clarify that.

And with respect to the funding for Title I, let us make sure we are clear that the budget that we are working from was prior to the omnibus changes in April. So we are working from that, those funding levels, and the proposal is to carry forward the Title I funding the same level and to fully fund Title I around support to and through public schools.

Ms. ROYBAL-ALLARD. Just to be clear, so that you do agree that high-poverty schools should receive more Federal resources than lower-level poverty schools? Was that your testimony?

Secretary DEVOS. I think—yes. I mean, I think that that is the case.

Ms. ROYBAL-ALLARD. Well, as the ranking member said, they don't. But my next question is, then, do you accept the basic premise by experts that high-poverty schools face disproportionate challenges when compared to moderate income and wealthy schools?

Secretary DEVOS. Yes, I do.

Ms. ROYBAL-ALLARD. Okay. Well, quite frankly, I am relieved that you do acknowledge that. And then based on your answer then, I find it curious that then you would endorse a proposal that shifts more funding away from highest-need schools. So I think there is a conflict there.

Secretary DEVOS. We actually are proposing to protect all of the Title I dollars to public schools, and the additional \$1 billion is for a voluntary program that would allow students to choose between public schools.

Ms. ROYBAL-ALLARD. But that money has to come from somewhere, and we can—because of lack of time, we can maybe explore this a little bit further. But any shifts in money, given limited budget, have to come from somewhere, and it appears that it is coming from areas that could truly help these low-income kids and from programs that—

Secretary DEVOS. Yes, and the reality is that it is intended to help low-income kids, and it is intended to give some more choices to them and their parents in finding schools that fit for them.

Ms. ROYBAL-ALLARD. I think where the disagreement comes in is that maybe the intentions are good, but the actual impact is not meeting those intentions.

EFFECTS OF SCHOOL CHOICE ON SCHOOL DISTRICTS

This administration has made clear that restoring local control is a major tenet of its approach to K-12 education. Yet your budget violates that premise. Instead, your request would incentivize dis-

tricts to adopt portability in spite of warnings that portability would undermine local control in limiting districts from using the funds in ways they believe to be most effective.

Has your Department considered the financial implications that portability will have on districts, and has the Department considered how it would mitigate the disruption a portability structure would impose for public school districts, if enacted?

Secretary DEVOS. Let me just say again, this is proposed to be a voluntary program, an opt-in on the part of States and local communities. And I would also kind of try to take us back to the notion that we are talking about students and their education, and I think we spend a lot of time talking instead about schools and buildings and systems. I think we should be focused on doing what is right for individual students.

And if a school is not working for a student, and a parent doesn't have the economic means to do something different, I think we should help find them ways to be able to make that decision on behalf of their students and their children.

Ms. ROYBAL-ALLARD. Well, perhaps a better way would be, though, is in these poor minority schools is maybe to invest more and to bring all the schools up to a level, rather than take away from schools that need these funds and putting them into wealthier schools.

Secretary DEVOS. Well, and you know, the Federal Department of Education has invested a lot of funds in trying to do just that. In fact, the last administration invested \$7 billion in school improvement grants specifically targeted at the lowest-performing schools and areas with zero results and zero improvement.

So we have tried that. I think it is time to try something different.

Ms. ROYBAL-ALLARD. We may have a disagreement on that.

Mr. COLE. Well, the chair is going to gently admonish Members. Please don't ask a question at the end of your 5 minutes. It puts the Secretary in a very difficult spot, and it will inhibit our ability to reach a second round, which I would like to do, a second shorter round.

So, with that, I go to my good friend from Maryland, Dr. Harris, who was kind enough to delay his questions so that Ms. Herrera Beutler could ask hers. Thank you.

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

EFFECT OF SCHOOL CHOICE ON STUDENT ACHIEVEMENT

And welcome, Madam Secretary. It is a pleasure to have you in front of the committee.

As you know, every Secretary I have questioned in the past few years, I have always made known my preference for giving parents the choice of where to send their students. Because in the end, the parents are the taxpayers. The parents are the ones who probably know best.

With that, I just want to read a sentence from your testimony. I am sorry I wasn't here for your testimony, but you said, "In part, my support for educational choice is based on my strong belief in the power of markets and competition as drivers of educational quality and accountability."

Well, let us start with educational quality. I am sure you are aware that in international testing, the OECD nation tests done, I guess, in 2015 or 2016, in math, reading, and science, we didn't crack the top 10. In fact, we didn't crack the top 15. In fact, in math, we didn't crack the top 25.

So I think there is no question that we don't get a bang for our buck in the American educational system. Because we see education spending going up, we think that, I guess, the measure on how effective education is how much money you spend on it, and yet in all these objective tests, we are failing in a global education economy.

And I welcome things like the Opportunity Scholarship Program in D.C. It is interesting because, and I might ask for a brief comment from you on it because they said, well, you know, the latest report is that, well, the people—the children in those schools don't do as well compared to the ones in public schools in the latest one. Because, of course, the study several years ago showed the graduation rate much higher, things like that.

One possible explanation is, you know, competition actually works. That actually when you do give people the choice, that the public school system actually figures they better—they better turn out a better product because now there is competition. So, I mean, is that a reasonable reading of those results?

Secretary DeVos. I think it is, indeed, Congressman. I think that the NAEP scores for all of the District and the students in the traditional schools in the District have shown remarkable improvement in the last few years. And I think it is directly relatable to the fact that there are robust choices now within the District for all of the students.

Mr. HARRIS. There certainly are. I wish it were more robust because the new scholarship awards for school year 2016 and 2017, as you are probably aware, was only 234 students. Now interestingly enough, there were 2,349 applications for those 234 slots, a 10:1 ratio.

So these are parents deciding, you know, 10 times more than slots are available, which actually correlates to what a really good university gets in terms of its applicant to accept, you know, an Ivy League kind of thing. So to somehow suggest that these parents have no idea what they are talking about, and we know better—you know, Federal Government knows better—is kind of crazy. So I hope you are a strong advocate of the Opportunity Scholars Program (OSP) and fully fund it.

FEDERAL IMMIGRATION ENFORCEMENT IN SCHOOLS

There are just two other things I wanted to bring up. One is because Federal funds do flow directly to institutes of higher education is this trend that I think is waning now of these higher education institutions that come to the Federal Government for billions of dollars, declaring themselves sanctuary campuses. So we want the billions of dollars, but you know, we are not going to comply with Federal immigration authorities.

And I hope that you follow the lead of the DHS, Department of Homeland Security, in their budget and write things or request things written into law that suggest that, you know, if you are

coming to the Federal Government for dollars, you better cooperate with our Federal immigration—with our Federal law enforcement for immigration because in the end, that is the only immigration enforcement we have at the Federal Government.

State and local governments are not given the authority to write immigration law and have to cooperate with Federal authorities, again, if they expect Federal largesse.

RELIGIOUS TITLE IX EXEMPTIONS

The very last thing I want to bring up and will submit some letters to the question is that there are Title IX exemptions from religious institutions I think before the Department, and I don't think action has been taken on these. And I will submit QFRs on this.

I would hope that the Department realizes that the freedom of religion is an important freedom. It is a First Amendment freedom, and that there are legitimate reasons to ask for exemptions from Federal regulations, including Title IX, and that the Department take action on those.

And with that, Mr. Chairman, I am actually going to yield back the last 20 seconds.

Mr. COLE. You are an example to the committee. I thank the gentleman. [Laughter.]

Next, on the basis of order of arrival, we will go to Mr. Pocan from Wisconsin. The gentleman is recognized.

Mr. POCAN. Great. Thank you, Mr. Chairman. Appreciate it.

FOR-PROFIT CHARTER ELIGIBILITY FOR VOUCHERS

And I thank you, Secretary. I have really been looking forward to today.

I come from Wisconsin, one of those States that, unfortunately, has had a failed experiment in taxpayer-funded voucher schemes and for-profit charters, and I know that recently you saw there were some researchers showing that in Indiana and Louisiana, Ohio, Washington, D.C., that students receiving vouchers saw their test scores drop.

I think you were asked recently about this, and I know you were on your way out and you didn't have a chance to answer. So I am glad that today we have got a chance to ask some of these questions.

But you know, my experience in the 14 years I was in the legislature in Wisconsin was during almost the entire growth period of this program. They turned down—kids with disabilities don't get into these programs, left to be in the public schools. They can turn down students who are gay or lesbian within these schools. My rural areas often don't have an alternative for people to go to. So they don't see that.

EFFECTIVENESS OF VOUCHERS IN WISCONSIN

But yet the one thing I would really disagree with you, in Wisconsin anyway, those public dollars do go to the private vouchers. So they are losing their money in rural schools to go to this experiment, which hasn't worked.

But let me just read you a couple things on the Wisconsin experience because, really, I know this inside and out. National Public Radio did a story on the Milwaukee voucher program. "Over the years, much of the research found test scores flat, lower in some cases, or slightly improved in others."

Milwaukee Journal Sentinel, "On average, students in Milwaukee's private school voucher program still performed lower than students in the city's traditional public school system."

Again, Milwaukee Journal, another article, Right Step, Inc.—I don't know if you are familiar with that school—a taxpayer-funded voucher school in Milwaukee. They are being sued by parents right now that the reports indicate that only 7 percent of their students tested at English language proficiency and zero percent in math.

So this is our public dollars going to these schools. I just would ask you, would you send your kids to a school where they have 93 percent of the students who aren't English proficient, and zero percent are math proficient?

Secretary DEVOS. Would I? Congressman, thank you for the question.

And I am really glad to hear you are from Wisconsin, and you have had some of the experiences in Wisconsin. I was just recalling the history of the program in Wisconsin—

Mr. POCAN. Since I only have 5 minutes, I appreciate that. But—

Secretary DEVOS. I know, but I want to remind you that Polly Williams, a Democrat city councilwoman, was the one who first introduced the Milwaukee program.

Mr. POCAN. And who now says it has not lived to its promise.

Secretary DEVOS. And who is no longer living.

Mr. POCAN. Right. Before she passed away said it does not live up to its promise. You are familiar with that, right?

Secretary DEVOS. But 321 students originally, and now 28,000 students in the City of Milwaukee.

Mr. POCAN. She said it didn't live up to the promise of what the creation was. But the question is would you send your children to a school with 93 percent not proficient in English—

Secretary DEVOS. Today, 28,000—28,000 students in the City of Milwaukee are being sent there by their parents.

Mr. POCAN. Okay. Well, I guess you are not going to answer that question either. So let me, if I can then, Madam Secretary, if I can take my time back, if you are not going to answer the question, let me ask a different question that you might be willing to answer.

So the last expansion in Wisconsin of this program, 75 percent of the kids—the parents who got this money, their kids already attended the school, and two-thirds of the money that went in the tax vouchers to the folks who received this were making more than \$100,000.

So, largely, this is tax policy. This isn't education policy. This is making sure people who are already attending these schools. Do you think that your Federal program will support this sort of thing? So it is not to encourage new outlets in education. It is simply to give money to people who already attend those schools.

Secretary DEVOS. Well, I really applaud Milwaukee for empowering parents to make the decisions that they think are right for

their students and their children. And I go back to what I said earlier about the fact that I think we need to shift our conversation—

Mr. POCAN. So will the Federal program—I guess, maybe I am sorry if I wasn't clear. Under what you are doing, there are 20 programs zeroed out, from arts to foreign language, mental health, Special Olympics. They are zeroed out under the budget proposal. But you have got new dollars for this failed experiment that I can tell you after 14 years in the legislature, we have had these dismal results.

My question is, will the path of the new dollars you are putting in for the Federal Government go down the failed path? In Wisconsin, it is going to people who already attend the schools. So there is nothing new about education. This is tax policy. It should be before the Ways and Means Committee.

Is that the intention of the new program expansion that you have?

Secretary DEVOS. I know the 28,000 students that are attending schools by the choice of their parents in Milwaukee, that is a success for those students because their parents have decided—

Mr. POCAN. So are you going to hold any accountability—

Secretary DEVOS. Their parents have decided that is the right place for their children.

Mr. POCAN. For example—Madam Secretary, seriously, you are not answering the question. So let me try one more. I have got 40 seconds. Maybe my trifecta—

Mr. COLE. I would remind the gentleman, please give her an opportunity to answer the question.

Mr. POCAN. But she is answering a different question than I am asking, and I guess at some point, the 5 minutes—

Mr. COLE. Please allow her to finish her answer.

ACCOUNTABILITY STANDARDS FOR VOUCHER SCHOOLS

Mr. POCAN. Sure. So will you have any accountability standards for these schools? So when we first started the program in Wisconsin, money went to someone who started a school who said he could read a book by putting his hand on it. And people bought Cadillacs with the dollars they got in the voucher program.

Are you going to have accountability standards in the programs that you are offering new dollars to at the Federal level?

Secretary DEVOS. Wisconsin and all of the States in the country are putting their ESSA plans together right now. And they are going to decide what kind of flexibility they are going to allow. They have more freedom than ever because of the ESSA legislation to be creative and innovative, and our conversation needs to shift from talking about schools and buildings and institutions to what is right for individual students.

Mr. POCAN. So I tried. I gave you 20 seconds. Will you have accountability standards was the question.

Secretary DEVOS. There are accountability standards. The States are required to have accountability standards.

Mr. POCAN. Are you going to with the Federal dollars was the question.

Secretary DEVOS. That is part of the ESSA legislation.

Mr. POCAN. Thank you, Mr. Chairman. I have got a second round. Thank you.

Mr. COLE. Absolutely. We now go to, I think, a Member that is probably not a stranger to you, Madam Secretary, Mr. Moolenaar from Michigan.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

SEXUAL ASSAULT ON CAMPUS

And Secretary DeVos, thank you for being here with us today, and I also want to thank you just for stepping up and being a leader for our kids in education in our country at this important time.

And from your message today, I think it is an important message of trusting parents, trusting our local and State educators, and really keeping the focus on kids and what is best for them. So I very much appreciate that message.

I wanted to bring up a specific topic to you that I had a recent listening session at Central Michigan University, and students in my district came forward with concerns regarding the rise of campus sexual assault across the Nation. And it has been recently reported that 1 in 5 women and over 10 percent of the student population will be a victim of sexual assault.

My understanding is you recently met with the First Lady of Michigan, who has recently unveiled a program to combat this growing issue by creating a campus sexual assault workgroup called Let's End Campus Sexual Assault.

I guess what I am wondering is what—is there a role for the Federal Government in this, meeting this challenge? And I appreciate the fact that you are working with State officials in addressing this concern. And I promised the student who asked me this question that I would ask you directly in a hearing. So thank you for being here.

Secretary DEVOS. Thanks, Congressman. It is great to see you.

And let me just say I share the concern that you and many others have about the rise in this issue on campuses, as well as many other issues on campuses. But the Office for Civil Rights (OCR) at the Department of Education is very committed to investigating complaints that reach the Office for Civil Rights, and we are invested in fully funding OCR.

I think—I know that there are a number of viewpoints on how the rules surrounding this have been implemented, and we are looking at those very closely. I have been meeting with a number of stakeholders, including First Lady Snyder from Michigan, and we take this issue very seriously.

It is—it is certainly an issue for the Office for Civil Rights to be engaged with and for the Department of Education to grapple with. But we are not at a point where we can communicate any change in direction or any new information at this point.

Mr. MOOLENAAR. Okay. Well, thank you for that. And I would like to keep in contact with you on that, and I know—

Secretary DEVOS. I would welcome that.

Mr. MOOLENAAR [continuing]. That the students across the country, that is a concern.

ENCOURAGING CAREER AND TECHNICAL EDUCATION

Another area that is a concern, in fact, I have heard as recently as today from business leaders about the need for skilled labor and career and technical education as a huge priority and the opportunity for jobs in this area in the future. I know there are different ideas. The Federal Government has a role, and I appreciated your year-round Pell Grant statement.

Are there partnerships or things that we can be doing at the Federal level to encourage career and technical education, and what thoughts do you have on that?

Secretary DeVos. Well, this clearly is an area that is of great focus on behalf of the President and this administration. And I have had the privilege and opportunity to visit three different community colleges since I have been in this job and all of them taking a really unique approach to partnering with local businesses that have great needs for skilled workers in skilled trades and really very high-skilled, high-paying jobs.

I think that the way we can best support it is to, in a very targeted manner, focus the dollars to help support community colleges in this pursuit—community colleges and other institutions of higher learning. I think we have done our young people a disservice over the last few decades by suggesting that a four-year college or university is the only way you can really be a success in life and that we have to have a much broader conversation around multiple pathways and multiple options for higher education, including, you know, layered credentialing.

And some of these programs that are being implemented at the community college level that are really meeting immediate needs, students are getting the training and education that they need and into a very well-paying job, can go back again a year or two or three later and get additional credentialing.

We have many, many jobs going unfilled in this country today that could be filled and addressed if there is that partnership. Again, it comes down to really a local level partnership with businesses and their needs.

I saw an amazing program in Salt Lake City, one in the Orlando area, and another one in Miami, all meeting very different needs for very different directions. But many of them STEM focused, and that was a common theme. And so I think that another area that we can play a role is to really highlight some of the best practices and some of the successes that are happening.

Mr. MOOLENAAR. Thank you.

Mr. COLE. We next go to the gentlelady from Massachusetts.

Ms. CLARK. Thank you, Mr. Chairman.

LOAN FORGIVENESS FOR AMERICAN CAREER INSTITUTE STUDENTS

And thank you, Madam Secretary, for being with us today.

First, a quick question from home. We have 4,500 Massachusetts students who attended the now-defunct American Career Institute. On January 18th, your Department told them that their loans would be forgiven. It should be completed between 90 and 120 days.

We are past the 120 days. Parents, our Massachusetts attorney general, and students are not getting a response from your Department. Can you reaffirm that you are moving forward with this loan forgiveness?

Secretary DEVOS. Thanks, thank you, Congresswoman.

Indeed, those to whom we have made a commitment, we are going to make good on that commitment, and that is in process. With regard to that regulation, that is something that we are studying carefully and looking at, and we will have something further to say on that within the next few weeks.

STUDIES, EVIDENCE AGAINST VOUCHERS

Ms. CLARK. Great. And it would be very helpful if you would get back to our attorney general and give some reassurance to our students.

I want to go back to the discussion you were having with my colleague from Wisconsin. You were recently in Indiana, where you called opponents of school choice flat-earthers. And I assume that you mean by that a flat-earther is someone who doesn't look at evidence, doesn't look at data, isn't willing to embrace innovation, creativity, just keeps believing what they always believe.

But we have had some major studies in. As you are proposing a \$250 million increase in pilots that would include vouchers for private schools, the studies from Louisiana, from Indiana, from Ohio, all show that students who choose private schools in voucher programs have experienced "significant losses in achievement."

And the studies also show that if we want to achieve good outcomes for students, those come through nonprofit schools that are open to all and are accountable to State and/or Federal authorities.

ENSURING CIVIL RIGHTS OF STUDENTS WITH PRIVATE VOUCHERS

You have talked a lot about the flexibility of States as being pre-eminent. So I want to go back to Indiana, to Bloomington in particular, and look at the Lighthouse Christian Academy. The Lighthouse Christian Academy currently receives over \$665,000 in State vouchers for students to attend their school.

They are also clear in their handbook and their guidance that if you are from a family where there is homosexual or bisexual activity—their word, not mine—or practicing alternate gender identity, you may be denied admissions. If this school, which obviously is approved to discriminate against LGBT students in Indiana, if Indiana applies for this Federal funding, will you stand up that this school be open to all students?

Secretary DEVOS. Thank you, Congresswoman, for your question with regard broadly to school choice and—

Ms. CLARK. It is actually kind of narrow because I have 1 minute left.

Secretary DEVOS. And I would like to refer back to your question about the comment about those who are resistant to change—

Ms. CLARK. I am sure you would. I want to ask particularly, is there a line for you on State flexibility? You are the backstop for students and their right to access a quality education. Would you, in this case, say we are going to overrule, and you cannot discriminate—whether it be on sexual orientation, race, special needs—in

our voucher programs? Will that be a guarantee from you for our students?

Secretary DeVos. For States who have programs that allow for parents to make choices, they set up the rules around that. And that is—

Ms. CLARK. So that is a no. Do see any circumstance where the Federal Department of Education under your leadership would say that a school was not qualified? What if they said we are not accepting African-American students, but that was okay with the State, does the State trump? Do you see any situation where you would step in?

Secretary DeVos. Well, again, I think the Office for Civil Rights and our Title IX protections are broadly applicable across the board. But when it comes to parents making choices on behalf of their students—

Ms. CLARK. This isn't about parents making choices. This is about use of Federal dollars. Is there any situation, would you say to Indiana that school cannot discriminate against LGBT students if you want to receive Federal dollars, or would say the State has the flexibility in this situation, yes or no?

Secretary DeVos. I believe States continue to have flexibility—

Ms. CLARK. And so there is—

Secretary DeVos [continuing]. in putting together programs—

Ms. CLARK. So if I understand your testimony, I want to make sure I get this right. There is no situation of discrimination or exclusion that if a State approved it for its voucher program, that you would step in and say that is not how we are going to use our Federal dollars? There is no situation if the State approved it that you would put the State flexibility over our students. Is that your testimony?

Secretary DeVos. I think—I think a hypothetical in this case—

Ms. CLARK. It is not a hypothetical. This is a real school applying for—

Mr. COLE. The gentlelady's time has expired, but I am going to allow the Secretary to answer.

Secretary DeVos. I go back to the bottom line is we believe that parents are the best equipped to make choices for their children's schooling and education decisions. And too many children today are trapped in schools that don't work for them. We have to do something different.

We have to do something different than continuing a top-down, one size fits all approach. And that is the focus, and States and local communities are best equipped to make these decisions and framework on behalf of their children.

Ms. CLARK. I am shocked that you cannot come up with one example of discrimination that you would stand up for students.

[Gavel sounding.]

Mr. COLE. You are not required to answer. We will go now to the gentleman from Idaho, Mr. Simpson.

CONGRESSIONAL INTENT AND TRIO FUNDS

Mr. SIMPSON. Thank you, Mr. Chairman. I am sorry I had to step out and finish a hearing over on the other side. But we have got hearings going on all over the place here.

You mentioned—I am a big supporter of TRIO just like you are in your comments, your answer I think to Senator Collins during your confirmation. As the Chairman is and I think most members of this program are.

And as you have said, you dropped the McNair and EOC programs because you thought they were outside of the Congressional intent of what we had planned for TRIO. If we fund those programs, would they then be within Congressional intent?

Secretary DEVOS. If that is how you defined it, I guess they would be. I am giving you the rationale for what we have proposed in the budget, and we believe those programs fall outside of the scope. And again, we have made some tough choices and decisions with presenting our appeal for the budget.

Mr. SIMPSON. And I understand that, and we will have those discussions, and there are always differences between what any administration proposes and what Congress wants to do. Those are fairly, I think, well-supported programs within Congress, and you will probably see funding in there.

2017 UPWARD BOUND APPLICATION PROBLEMS

In the fiscal year 2017 omnibus appropriations legislation, the subcommittee included a directive that encouraged you to use your discretion as the Secretary to review and score more than 77 applications to the Upward Bound program that were rejected for minor formatting issues like failure to double space and typographical errors in the budget narrative.

Would you please update the subcommittee on your Department's actions in response to that directive and also please outline what steps the Department will take to provide the opportunity for the rejected grant applications to be considered for funding.

Secretary DEVOS. Thanks for that question, Congressman.

As you know, this grant application process was under the purview of the previous administration. The process was opened and closed prior to my coming into the job.

And because it was when we found out about the issue with regard to formatting errors, it was after the competition had closed, and we looked at all viable legal remedies to try to address it and did not find any. Since then you have seen fit to appropriate \$50 million. And going back and looking at it again, we believe that that has materially changed our available options, and so we are going to use those funds, the \$50 million, to reconsider those applications that were considered not viable because of the formatting errors.

And so that is going to be our remedy, but let me just say that this issue apparently has been going on through four different Secretaries unaddressed. The moment I found out about it, I issued a Department-wide policy indicating that we are not going to reject applications for any competitive bid process based on formatting, that this is a bureaucratic requirement that we should be rid of now, and we are.

So anything going forward from here will not be held to those same formatting requirements. But with regard to this issue, which if you had any idea how much time it has chewed up internally for us, you would be amazed.

But we are—we have, because of that material change with the new appropriation, have found a way to be able to address that particular issue.

PROPOSED CUT TO IMPACT AID

Mr. SIMPSON. Thank you. I appreciate that.

Your budget also puts \$1.2 billion in for Federal Impact Aid, which is a \$67 million cut below Impact Aid payments currently for Federal property and States in States like Idaho and, in fact, States across the country that have Federal facilities that impact school districts. What is your justification for the cuts in the Impact Aid Program?

Secretary DEVOS. So the portion of the Impact Aid Program that we have proposed to eliminate is one that is not tied to any students at all, and so there are no students being supported in that particular Federal land area. And since those locales have had about 40 years to consider this, we thought it might be appropriate that they could have figured it out by now.

Mr. SIMPSON. Okay. I appreciate that answer. That will be interesting to look at.

Anyway, thanks for being here. I appreciate your testimony and look forward to working with you.

Secretary DEVOS. Thanks, Congressman.

Mr. SIMPSON. Thank you, Mr. Chairman.

Mr. COLE. I thank the gentleman.

We now move to my good friend from California, Ms. Lee.

Ms. LEE. Thank you, Mr. Chairman.

FEDERAL CIVIL RIGHTS ENFORCEMENT

Before I begin, I would like to introduce Latrenda Leslie, who is our foster youth shadow from Oakland, California. Latrenda, her oldest daughter will be

starting—

[Applause.]

Ms. LEE. She will be starting kindergarten this fall. And so as we deliberate today, let us keep in mind the young families who will be affected by our decisions. And I am really—Madam Secretary, good to see you—kind of hurt, quite frankly, that she heard your response to Congresswoman Clark's question with regard to discrimination against students.

It has been the Federal Government that allowed me to go to school, okay? And so when you say that it is up to the parents and local communities, even if young people are being discriminated against, that it is the parents and schools, and to take the Federal Government's responsibility out of that is just appalling and sad.

I see in your budget it reflects exactly what you said. You are cutting \$1.7 million from the Office for Civil Rights. To me, it is outrageous.

And again, I have to go back to your statement when you said that HBCUs, historically black colleges and universities are real pioneers when it comes to school choice, which completely ignores the fact that for many black students, HBCUs were their only choice.

Secretary DEVOS. I know that.

Ms. LEE. For too long, black students weren't allowed to enroll in predominantly white institutions, even at public schools in their own States. I could not go to public school, Madam Secretary. And so for you to sit here and say, as our Secretary, that it is okay if parents and local communities can discriminate, it is very sad, shocking, and disappointing.

PROPOSED ZEROING OUT OF HBCU MASTER'S PROGRAM

Now I see in your budget you say that HBCUs, the President said HBCUs are critical for black students. But I don't think you really mean that because you don't increase the funding for HBCUs, and you actually zero out the Strengthening Master's Degree Programs at HBCUs that we funded in fiscal 2017, which is extremely important for HBCUs.

And so I am wondering why are you doing that? What is that about, and why would you do that? As well as—and I just have to say cut so many programs, 24 programs that minority students and low-income students rely on. Twenty-first Century Community Learning Centers, that is after school programs for low-income students.

You are cutting, you are zeroing out, American history and civic academics. You are leveling out Preschool Development Grants. I mean not leveling. You are cutting them. You are eliminating them.

You are eliminating Special Olympics, \$12.6 million. You are just wiping out Special Olympics for disabled students. For the life of me, I got to understand what your thinking is about this budget and low-income students, vulnerable students, minority students, students who really deserve a shot at a good, quality public education.

Secretary DEVOS. Thank you, Congresswoman. A lot of questions or a lot of issues there.

Ms. LEE. Well, they are all wrapped around this budget and a reflection of what you see being our values.

Secretary DEVOS. Okay. Let me just start by saying I want to be very clear. I am not in any way suggesting that students should not be protected and not be in a safe and secure and nurturing learning environment. They all should have that opportunity, and I have continued to talk about that need for all students to have a safe and secure and nurturing learning environment.

Ms. LEE. That is not the issue. It is—

Secretary DEVOS. And the Department—the Department is going to continue and will continue to investigate any complaints or any issues surrounding, you know, allegations of discrimination. We have no proposal to change any of that.

So as we talk about States assuming more authority and flexibility in their—in their, you know, how they implement their programs for their students, nothing about that changes our desire to ensure that students have a safe and secure and nurturing learning environment.

With respect—

Ms. LEE. Madam Secretary? Referring to—

Secretary DEVOS. With respect to your question around HBCUs—

Ms. LEE [continuing]. Congresswoman Clark's, well, can you answer her question real—very quickly?

COMMITMENT TO HISTORICALLY BLACK INSTITUTIONS

Secretary DEVOS. Well, I would rather talk about the HBCUs and how our commitment, our continued commitment to HBCUs by continuing to fully fund at previous levels and—

Ms. LEE. I don't think that is what the HBCUs have requested. In fact, they need to see a small increase in their funding to make sure that black students have those educational opportunities, and then the cut in the Strengthening Master's Program at HBCUs is just wiping out. I mean, you are eliminating that for the most part with HBCUs. So you are really—it is eliminated.

Comment pertains to rows 1766–1822: Technically, the Strengthening Master's Degree Programs at HBCUs is not a "new program" as it was first funded in FY2009 for 6 years through FY2014. Funding was not requested in FY2015 or FY2016. In addition, the President's 2017 budget did not request funding for this program; however, Congress appropriated \$7.5 million in the 2017 appropriations bill after decisions had already been finalized for the President's 2018 budget request to Congress. So, in essence, the Department didn't consider the program in our 2018 budget because we didn't request funding for it in our 2017 President's budget.

Secretary DEVOS. It is—yes, okay. It is a new program that hasn't been part of this budget. So it is not eliminated because it hasn't been funded yet.

Ms. LEE. Wait just a minute. We did fund that at \$7.5 million, the Strengthening Master's Degree Program, and you are eliminating that.

Secretary DEVOS. We are working from the budget numbers that were available to us prior to your omnibus in April. That was just a few weeks ago.

Ms. LEE. So you are not eliminating it, or you are eliminating it?

Secretary DEVOS. No.

Ms. LEE. You are not?

Secretary DEVOS. The figures in the budget that we are working from were all put together prior to the omnibus legislature.

Ms. LEE. Okay. So you are going to restore the \$7.5 million in the strengthening master's degree program?

Secretary DEVOS. Well, I think that is going to be up to Congress to decide how to handle that anomaly.

Ms. LEE. So you are cutting it?

Mr. COLE. Well, to be fair, let the chair interject here. And with all due respect, the gentlelady's time is up, but I will certainly allow her to respond. I pointed this out at the beginning. This is simply a case where Congress said we were pretty late getting our omnibus done. That is on our fault.

And frankly, they had gone ahead and developed their budget. So they didn't have the guidance there. So we will have to revisit that ourselves, and I suspect the gentlelady probably would be pretty pleased with the decision that gets made, depending on the allocation.

But again, in fairness to the Secretary, they didn't have that information, and they did not know Congress had authorized that

program at the time they were putting together their budget. So it puts her in a difficult spot here, and nobody's fault, but it is just we have sort of overlapping documents here, and it creates some discrepancies on occasion.

Ms. LEE. I thank the chair, but I expect to see the \$7.5 million. [Laughter.]

Mr. COLE. I have a great deal of respect for my good friend from California, and I always listen to the point she makes. And a lot of these decisions will depend on what our allocation is, which we don't know. But I think the gentlelady knows we have worked together on a variety of these issues before, and—

Ms. LEE. And I appreciate that.

Mr. COLE [continuing]. Look forward to continuing that.

Ms. LEE. And I hope we can restore some of these programs—

Mr. COLE. Absolutely. With that, we will go to Mr. Womack, distinguished vice chairman of the committee.

Mr. WOMACK. Thank you, Mr. Chairman, and a great discussion.

Madam Secretary, welcome. And it hasn't been said since I have been here, but probably deserves to be said. We are beginning to see the early stages of a much-needed robust discussion about how we begin the process of getting our Federal budget under control. And the inescapable fact that many of the programs that we are talking about here are on the discretionary side of the budget, and it is being squeezed by runaway entitlement programs and the inability to address those, which becomes a very difficult political problem for the Congress, I understand that. But it is the truth.

And I am sad that we haven't taken up that particular discussion, but we will save that for another day.

PRE-COLLEGIATE CAREER AND TECHNICAL EDUCATION

Pretty good discussion with my friend from Michigan on career and technical education, and that is where I want to focus my question with you. The response that you gave Mr. Moolenaar was geared toward what we should be doing with our community colleges. But you had just made a statement that I completely agree with about—about what we have suggested to previous generations about a pathway to success, that that pathway has to be through a college degree.

I am of the strong opinion, based on my travels in my district and in my conversations with my job creators, that a lot of the really good opportunities out there exist today for young people who could leave high school, maybe not even without attending, darkening the doors of a college environment, and go right to work with proper training and proper skills and proper certifications, right to work with really good-paying jobs, a fulfilling opportunity at a great career in emerging technologies.

And so I believe in my heart that a lot of this training should be happening long before the decision is made to go or not to go to college. I have in my mind that that is probably somewhere in that late junior high stage, based on aptitude.

But, so I am going to ask you, where is that time in a young person's educational life, given the tremendous demand for jobs today, skills today that a lot of our graduates do not possess? Is this something that we should be doing in our high school curriculums?

Secretary DeVos. Thank you, Congressman.

The whole area of career and career preparedness and understanding the wide range of options that one has is, I think, an area that definitely needs a lot more discussion and a lot more energy around it. You know, today a lot of the funding for things that support these efforts are kind of bifurcated. Many of them, you know, in the Labor Committee or the Labor Department, and some in the Department of Education.

But the notion that there are many, many different opportunities for students beyond high school is not really addressed at an early enough age. And I think I agree with you that a couple of the places that I visited that have really great dual enrollment programs have started to address this, but I think there is an opportunity to have young people exposed to some of these opportunities much earlier. And apprenticeships and internships, we should be talking about how to encourage and support the growth of these in a major way.

I had opportunity to visit a really unique high school yesterday, one of the Cristo Rey schools. I don't know if you have heard about this, but these are Catholic high schools that, as a way to help support and fund the operations of the school, the students actually go to work in a business one day a week and, through doing so, gain a whole lot of personal experience and confidence, but also help to support their education. And they come out of high school, really, with a much broader understanding of the professional world, the work world, and options and opportunities they have.

Those kinds of unique and innovative approaches to exposing young people to a wide range of possibilities early on are things we should be encouraging. And I go back to this notion that, again, States and local communities are best equipped to try these things. They are the best laboratories of democracy, and we should be highlighting those that are working well and encouraging others to emulate them.

Mr. WOMACK. Yes, we may choose to agree or disagree on certain matters regarding budgets. But on that particular subject, we are in total agreement.

And I yield back my time.

Mr. COLE. I thank the gentleman, and just for informational purposes for my friend and the Secretary, we would love to have you visit Oklahoma, where we actually do have a great interlocking career tech and high school system where young people literally in late junior high, early high school go back and forth and get exposed to technical kinds of career that may be more appropriate for them.

But Ohio has a similar system, and I think we are two unique systems in the country. And it is well worth coming to see if you ever have an opportunity. We would invite you both.

Now with that, I want to go to my good friend from Tennessee, who has had to shuffle back and forth and do a lot of hearing. Mr. Fleischmann, you are up next.

Mr. FLEISCHMANN. Thank you, Mr. Chairman.

And Madam Secretary, it is a privilege to have you here before us today. I represent the people of the great Third District of Tennessee. That is Chattanooga and Oak Ridge. And as the chairman

alluded to, I was over at the Energy and Water Subcommittee this morning, so was a bit delayed.

First of all, I would like to mention how impressed I was with the emphasis that you placed on school choice. I think it is absolutely imperative that we give parents the options they need to ensure their children are properly prepared for the future. So I thank you for that position.

I was also especially impressed with the building evidence around innovation section of the budget. I think we really need investment in research activities that will allow school districts to identify what works and what doesn't.

COMPUTER SCIENCE CUTS UNDER TITLE IV

On an area of concern, as you may know, I am an advocate and I view myself as a champion for computer science education, computer science literacy, and I think there is tremendous bipartisan support for this endeavor. I was a little concerned about the Department's proposed cuts to Title IV, Part A grants authorized under ESSA.

In last year's appropriations bill, we worked hard to ensure that States would be able to use some of this money for computer science education. There are a half million computing jobs currently unfulfilled in the United States. However, our country only graduated and sent into the workforce 42,969 computer science specialists last year.

It is estimated that between 2016 and 2020, it is projected that there will be 960,000 job openings in computer science. If current graduation patterns continue, only 344,000 graduates will fill them.

So my question is, do you agree with me and colleagues from both sides of the aisle that we need partnerships with the private sector, which is looking to hire Americans for computer science jobs, and schools from kindergarten through high school to help ensure students from all walks of life are prepared for the computer science jobs that need to be filled now and in the future? And if so, how can we work to ensure that we prepare students for these jobs?

Thank you.

Secretary DeVos. Thank you, Congressman.

I definitely share your interest in ensuring that students have exposure to STEM subjects and, in fact, have opportunity to pursue really robust programs in that area. I would just as an anecdote refer to the high school that my husband started, a charter high school focused on aviation that has a very distinct STEM focus and has been really doing an amazing job of attracting kids that would have not been likely to be a part of a high school like that.

But with regard to specifics in the budget, this budget, again, was developed before the continuing resolution was addressed. But we do have a \$20 million experimental grant in for STEM competition, and I think that is a good place and, you know, good role for the Department. I think an important place for the focus to be placed around STEM is really, again, at the State level because they are putting the ESSA plans together. They have the opportunity to really customize it for the students in their States and their local communities.

And I had an interesting conversation I think it was last week with a number of superintendents from one from a rural district, one from a very large urban area, another from kind of a medium-sized city, and then the other one was actually a statewide superintendent, how they have implemented coding programs in their districts. And I believe the organization that they have partnered with on that has now entered 20 percent of the school districts in the country.

I think we need to continue to encourage that. I hesitate to say we should mandate it from the Federal level, but we should try to actually encourage and support those activities as States are putting their plans together.

Mr. FLEISCHMANN. Madam Secretary, I thank you, and I agree with you. I have engaged in some of those coding opportunities in the schools, particularly in some of our inner-city schools in Chattanooga, which have been traditionally underserved, and it was inspiring to go there and see high school students all the way down to the second graders engaging in coding. And I just look forward to working with you on this computer science literacy and with my colleagues on both sides of the aisle as we reach out to all American students in this regard.

Secretary DEVOS. Likewise. Thanks.

Mr. FLEISCHMANN. Thank you.

Mr. COLE. I thank the gentleman. We will now move to my good friend from Alabama, Mrs. Roby.

Mrs. ROBY. Thank you, Chairman.

And thank you, Madam Secretary, for being with us today. It is good to see you again. I am really looking forward to working with you and your Department through the oversight of this committee.

And let me say thank you for your service to our country. I want to convey my appreciation on behalf of all of the students and parents and educators in the State of Alabama.

STATE AUTONOMY AND FEDERAL OVERREACH

It was about a year ago when your predecessor was here and sitting right where you are now, and we had a good exchange about the role of the Federal Government in decisions concerning standards and curriculum for the classroom. So let me back up for a minute and just give you some background on my involvement in this issue.

Back in 2013, I introduced a bill called the Defending State Authority Over Education Act that prohibited the Federal Government from making special funding grants and coveted regulation waivers contingent upon whether a State is using certain curriculum or assessment policies. For 3 years we worked to get this language included in the comprehensive rewrite of No Child Left Behind, which is now the law E-S-S-A, ESSA.

Thankfully, we finally succeeded, and our strong State authority language was included in the Every Student Succeeds Act. So back to my exchange with your predecessor, which was taking place during the very critical implementation process of ESSA. What I was trying to get a straight answer on then was whether the officials within the Department of Education would simply ignore the law

and continue their old habit of exercising undue and inappropriate influence over State education decisions.

You have to remember that that kind of thing was commonplace under the previous administration, and I believe that the former Secretary King and I got to a good place. But I think we can get to an even better one today. So let me ask you, Madam Secretary, number one, do you acknowledge that the law now expressly forbids the coercion of States to adopt certain education standards and curriculum, including Common Core?

Secretary DEVOS. Absolutely.

Mrs. ROBY. And will the Department follow the letter and spirit of the law?

Secretary DEVOS. Absolutely, it will.

Mrs. ROBY. I appreciate that answer, and so to be clear, you can definitely count on me among those who believe that my State of Alabama and all States should, indeed, set high standards that challenge students and build critical thinking skills. I am glad that our State has made an effort to raise its standard in recent years when we lagged behind for so long.

And I certainly welcome collaboration with other States to share best practices. However, the intrusion of the Federal Government into that process directly or indirectly is inappropriate, and it invariably comes with a political agenda from Washington. This has bred a lot of confusion and distrust. And in many States, it has contributed to a volatile policy environment.

And so I appreciate your commitment and your forthrightness on this issue, and any other comments that you want to make about this I am welcome to hear.

Secretary DEVOS. Well, thank you, Congresswoman.

We share that concern, and you have my commitment that the Department is going to implement and follow the law that you have set out through ESSA. I would, frankly, love to see a competition on the part of all the States to outdo one another on how high they set their standards and how high they shoot. We should be shooting for excellence across the board, but in no way should it be a top-down, one size fits all solution from the Federal Government.

And my hope is that with the States' flexibility in opportunities here that they do, indeed, shoot high and that they are very ready to point out to others when they are not, you know, living up to the task of preparing all of our students for a great future.

Mrs. ROBY. Thank you so much for your commitment.

Mr. Chairman, I yield back.

Mr. COLE. I thank the gentlelady, another model of turning back time. I appreciate it.

I know the Secretary has a hard stop at 1:00 p.m. So we are not going to be able to do a second round. I regret that. But we had both the ranking member and the full chairman here, and I think we all stretched our time a little bit beyond 5 minutes anyway.

But I do want to allow my good friend the ranking member to make any comment or closing statement or question she cares to, and then I will do the same.

RANKING MEMBER CLOSING STATEMENT

Ms. DELAUR. Thank you very much, Mr. Chairman. And again, thank you, Madam Secretary.

Let me just try to correct the record in some instances here with my time. I think it is wonderful that we talk about career and technical education. You may have seen the Pew Research Center and Markle Foundation's "The State of American Jobs," which talked about 70 percent of American adults do not have a 4-year degree.

And while we can talk about it and give a lot of lip service to it, the fact of the matter is, and this was not a continuing resolution issue, there was a decision made for this budget to cut the career and technical education program by 15 percent, \$168 million. This is not—and you can't talk out of both sides of your mouth. You are either going to put the money where we believe we are going to make the best possible bang for the buck, or we should just be silent about it. Don't talk about it and do something about it.

Let me talk about vouchers for a moment. Gold standard, Institute of Education Sciences, gold standard evaluation of Washington, D.C., the only federally funded voucher program, found that vouchers negatively impacted student achievement. D.C. students using vouchers performed significantly worse on math in the first year they used the voucher. In the early grades, they performed worse in both math and reading. Similar results from Louisiana, Ohio, and Indiana, as my colleagues have pointed out.

Madam Secretary, you continue to say that Title I has not been cut. Title I has been cut by \$578 million. The fact of the matter is, is that with all due respect, on May 5th, we signed an omnibus bill. I don't want any process piece here, and that affects what my colleague Ms. Lee talked about, these are cuts to programs.

So the fact is that the budget proposes cuts that, if enacted, would impose real harm on our country's students. And I have to make the point again with regard to vouchers and children who are disabled or disabilities. You referenced the McKay Scholarship Program, and I will tell you that in that program, with information that I have, and we looked into it, no due process rights under IDEA. They give up due process rights granted by the individuals if you accept a Federal voucher.

No accountability for the participating schools. They do not have to be accredited. They do not have to provide any evidence of the quality of their programs. No evidence of student success. Because students do not take standardized tests in private schools, it is impossible to hold private schools accountable or compare their performance with public schools. Key NAEP scores have declined or flat between 2009 and 2015.

Now I make those corrections because we can't—if we are going to have a robust conversation about education, then let us put the facts on the table and go from there. This is a budget, and I characterized it, Mr. Chairman, in the Ag Appropriations Committee this morning, it is cruel. It is inhumane, and it is heartless. A \$9.2 billion cut to education.

And fact of the matter is when my colleague talked about there is 10 percent, there is less money going to high-poverty areas. The

teachers are more likely to be novices in these places. Those underserved areas are going to be hurt.

None of us in here are going to be hurt. We are going to be fine. Our kids and our grandkids are going to be okay. But millions of kids around this country are going to suffer what has been done with a \$9.2 billion cut to our education programs, which are supposed to serve our youngsters, make sure they have a good future and a bright future.

And I am going to fight this budget, Mr. Chairman, with every fiber of my body because it is wrong to do this to our kids.

Mr. COLE. I have no doubt. [Laughter.]

CHAIRMAN CLOSING STATEMENT

Mr. COLE. Madam Secretary, I just want to thank you very much for being here today. I want to thank you for your testimony, for your professionalism.

I particularly love the emphasis on choice and, frankly, trying to give as many options to young people as we possibly can, and you certainly laid that out robustly in your budget. I know you have had to make some tough decisions. We actually have three Cabinet-level jurisdictions here, and we are given an allocation, and we end up having to make a lot of tough decisions, too.

So we certainly have a great deal of sympathy for that, and I want to assure you, you see this is a committee that is a pretty spirited committee. And we appreciate you engaging with us today. We look forward for other opportunities to do that, and I know every member of this committee, on a bipartisan basis, if they can assist you in any way, want to do that. We want to see you succeed because we think your success represents the success of America's students.

We know you care about that deeply. You have demonstrated that over a lifetime. We know the President cares about that, and we look forward to working with you in that common endeavor as we go forward.

Secretary DeVos. Thank you, Mr. Chairman. Thanks for the opportunity.

Mr. COLE. Thank you very much, Madam Secretary.

Secretary DeVos. Thank you to the ranking member.

FOCUS, Title I Portability, and EIR Demonstration

Mr. Cole: Your budget proposes that \$1 billion in title I funding be used to "follow the student" to the public school of his or her choosing. In addition, your proposal includes \$250 million for a nationwide pilot program to enable scholarships for students to attend the public or private school of their choosing.

Can you tell us more about how these programs would work? Who would be eligible to receive the awards? What would be the criteria for students and families? How much would each scholarship be estimated to be? How will you evaluate program success?

Ms. DeVos: The Administration's Furthering Options for Children to Unlock Success (FOCUS) grants proposal under Title I Grants to Local Educational Authorities (LEAs) would support LEAs in establishing or expanding student-centered systems that: (1) differentiate funding based on student characteristics, providing disadvantaged students more funding on a per-pupil basis than other students; (2) offer a range of viable school options and enable the Federal, State, and local funds a student generates to follow him or her to a public school of choice; (3) make school performance and funding data easily accessible to parents; and (4) empower school leaders to use funds flexibly to address student and community needs. LEAs (including consortia of LEAs) that commit to developing and implementing these funding and enrollment systems would be eligible for grants, which the Department would administer under the Flexibility for Equitable Per-Pupil Funding (Flexibility) authority in Title I, Part E of the Elementary and Secondary Education Act (ESEA).

Under the Administration's proposal, the Department would establish minimum requirements for open enrollment systems aimed at maximizing opportunities for all students, particularly those from low-income families, to select, attend, and succeed in a high-quality public school. Such requirements could include making school information available to parents in a clear and timely manner, demonstrating a capacity to enroll students in their preferred schools, supporting school integration efforts, arranging or paying for transportation to schools of choice, and giving priority to students from low-income families or students in schools identified for improvement under Title I. LEAs that meet these requirements and the requirements under Title I, Part E would receive grants covering the period of their initial flexibility agreements (up to 3 years) and would use grant funds for activities related to developing, implementing, and sustaining their funding and enrollment systems.

Consistent with requirements in Title I, Part E, the Department would use funds pooled for evaluation under section 8601 of the ESEA to evaluate FOCUS grant implementation, including its impact on the equitable distribution of funding, the demographic distribution of students, the availability of public school choice options, and student achievement and other academic outcomes, such as high school graduation rates.

The request for \$250 million under the Education Innovation and Research (EIR) program would be used to replicate successful private school choice programs and build

evidence around what works. The Department has not yet determined the full range of requirements for the proposed competition, but is considering requirements in areas such as public transparency around private school choice options, facilitating the rigorous evaluations that are an essential part of the EIR program (for example, by requiring assessments of student achievement), and strategies to support effective school choice options to serve students with disabilities and rural areas. As for the amounts of the scholarships, we expect they will be similar to the amounts of those under the DC Opportunity Scholarships program, in the range of \$8,000-\$12,000, depending on students' grade level.

SEOG Elimination and Work Study Cut Rationale

Mr. Cole: Your budget proposes to eliminate the S-E-O-G program and make big changes to the way the federal work study program operates. I know many colleges depend upon these programs in developing their student aid packages, and I'm sure we will be hearing from them in the coming days.

Can you explain your rationale for the changes you propose to the campus based financial aid programs? How would your proposal impact access to college, college completion rates, and post-college debt?

Ms. DeVos: The Supplemental Educational Opportunity Grants (SEOG) program is proposed for elimination because it is not well-targeted and it is largely duplicative of the Pell Grant program. The SEOG program does not serve needy students effectively since aid is allocated to institutions primarily based on previous participation in the program. The FY 2018 Budget Request proposes to reform student eligibility in the Federal Work Study (FWS) program to ensure funds go to the undergraduate students who would benefit the most. It should be noted that, according to the College Board's 2016 Trends in Student Aid, SEOG and FWS together comprised only 0.7 percent of total Federal, State, and institutional student aid during the 2014/15 award year. Considering the restoration of year-round Pell, coupled with more well-targeted Work Study aid and our proposal to reform income-driven repayment plans, I expect our proposal to have a positive impact on student outcomes and student loan debt management. Of course, much work remains to be done, which is why I look forward to working with Congress to consider all policy options available to help improve higher education access, accountability, and affordability as part of the Higher Education Act reauthorization process.

21st Century Community Learning Centers Elimination

Mr. Cole: Your budget proposes to eliminate the 21st Century After School Program, funded at \$1.1 billion currently. This program is pretty popular, and I think most of us agree that kids should have a safe place to go between the hours of 3 and 6 pm, so this seems like a good idea.

Can you explain why you are proposing to terminate this program?

Ms. DeVos: This Administration is committed to investing limited Federal education dollars in programs that have a strong record of improving student outcomes. While there is research indicating the effectiveness of afterschool programs in general, performance data demonstrates the specific afterschool programs funded by the 21st Century Community Learning Centers (21st CCLC) are, overall, not helping students meet challenging academic goals. For example, on average from 2013 to 2015, less than 20 percent of program participants improved from not proficient to proficient on State assessments in reading and mathematics. Additionally, student improvement in academic grades was limited, with States reporting higher math and English grades for less than half of regular program participants. Moreover, fewer than half of students served attend the program enough to be counted as "regular program participants," with States reporting that 752,000 out of 1.8 million participants attended 21st CCLC programs for 30 days or more during the 2014-2015 school year. These performance data generally confirm the findings of the last rigorous national evaluation of the program, conducted in 2005, which also found the program had limited academic impact and low student attendance rates.

These data strongly suggest that the 21st CCLC is not generating the benefits commensurate with an annual investment of more than \$1 billion in limited Federal education funds. Moreover, the provision of before- and after-school academic enrichment opportunities may be better supported with other Federal, State, local or private funds including the \$15 billion Title I Grants to Local Educational Authorities program.

SSEA and Lack of Funding in 2018 President's Request

Mr. Cole: As you know, the recently reauthorized Every Student Succeeds Act consolidated and eliminated several smaller categorical programs in favor of a large block grant, the Student Support and Academic Enrichment Grant program. The idea behind it is that school districts know their needs best, and that instead of spending time chasing after this or that little program, hiring people to write grant applications and comply with different requirements, it would be better to give schools flexible funding to meet their needs. Funds could be used for technology and computer investments, for anti-bullying and counseling initiatives, for physical education programs to combat childhood obesity, or any number of other activities at local discretion.

I'll confess I was a bit surprised to see this program terminated in your budget. We funded it at \$400 million, which I was disappointed was lower than the House bill's original proposal of \$1 billion. Nevertheless, I think the philosophy behind the program is the right one, and I hope we could see the levels increased in the future.

Why do you propose to terminate the program?

Ms. DeVos: Even at the FY 2018 authorized level of \$1.6 billion, the Title IV-A Student Support and Academic Enrichment Grants program would deliver formula-based grants that for the majority of Local Educational Authorities (LEAs) are too small to have a meaningful impact. For this reason, Title IV-A was a lower priority in an FY 2018 President's Budget request that aimed to increase support for national security and public

safety without adding to the Federal budget deficit. In addition, most of the activities authorized under Title IV-A may be supported through much larger and similarly flexible programs like the \$15 billion Title I Grants to LEAs program.

Reasons for CTAE Reduction and Anticipated Outcomes

Mr. Cole: My home state of Oklahoma, along with the State of Ohio, is one of the Nation's leaders in career and technical education. We recognize that not every student is cut out for or wants to pursue a four year college degree, but every student needs to be prepared for lifelong learning and some sort of training past the high school level. Career and technical education opens the door for so many students to find their passion, and to connect with a good paying job in a growing industry that will set them up for success.

Why does your budget propose to cut the career and technical education program, how would these cuts be implemented, and what do you expect the program impact to be?

Ms. DeVos: The FY 2018 President's Budget request would continue to provide significant Federal resources to support State and local Career and Technical Education (CTE) programs while also maintaining the fiscal discipline necessary to support the President's goal of increasing support for national security and public safety without adding to the Federal budget deficit. We also note that the forthcoming reauthorization of the Perkins Act will provide an opportunity to reconsider ways to streamline, improve, and strengthen the Federal investment in high-quality CTE programs. The proposed reduction would simply reduce the amount of funding distributed through the statutory funding formula, and the Department believes the impact would be minimal both because it would be shared across States and because Federal CTE funding constitutes a small percentage of the overall funding for CTE programs across the nation.

Reasons for Adult Education Reduction and Anticipated Outcomes

Mr. Cole: Similarly, there is high demand for adult education courses around the country. Whether it be new immigrants who want to learn English and assimilate into American culture or older drop outs who realize they made a mistake and now want to get their GED, adult education programs provide a second chance for older students. I've heard a lot of success stories from the program.

Why does your budget propose to cut them?

Ms. DeVos: The proposed cut reflects the tough decisions needed to achieve the President's goal of increasing support for national security and public safety without adding to the Federal budget deficit. The FY 2018 President's Budget request would continue to provide significant grant funding to support adult education programs that help adults without a high school diploma or the equivalent to become literate and obtain the knowledge and skills necessary for postsecondary education, employment, and economic self-sufficiency.

How Department Plans to Spend 2017 Indian Education Increase

Mr. Cole: You know that Indian education programs are near and dear to my heart. You may not have been expecting the large increase they received when you put together your budget proposal, but we did provide the program with a \$21 million increase in fiscal year 2017. I would like to know how your Department plans to spend that additional money, and how you will ensure it will make a real difference in the educational outcomes of our Native students.

Ms. DeVos: Thank you for your continued support of Indian education programs. We appreciate your leadership on this important issue. The Department plans to use \$15 million of the increase for new grants for Native Youth Community Projects (NYCP) grants and nearly \$4 million for new Professional Development grants. These funds will support NYCP grantees addressing the most pressing local challenges and opportunities facing Native students. The new Professional Development grants will support teacher and administrator training necessary to address the shortfall of qualified teachers in Indian Country. The increase in National Activities funding will be used to support additional, larger Native language immersion grants and technical assistance for the new Native language grantees.

Rejected Upward Bound Applications

Mr. Simpson: Secretary DeVos, thank you for your response to my question regarding the reconsideration of certain TRIO Upward Bound applications that were rejected based on minor formatting errors. The intent of the language that this committee included in the Fiscal Year 2017 Consolidated Appropriations Act regarding submission of corrected Upward Bound applications was to allow the Department to have broad discretion over the types of minor issues that warrant flexibility in reconsideration. Does the Department plan to include in the pool of reconsidered applications those that contained unintentional minor technical errors, such as a typo in the requested funding level, which had previously disqualified the applicant but have since been corrected?

Ms. DeVos: I believe that the Department should focus its efforts on helping children be successful. The outright rejection of a handful of Upward Bound applications for bureaucratic formatting issues, rather than the contents of the applications themselves put process before kids. We opted to review these applications because we believe a fair assessment of the application includes a review of the contents of the application itself. The increase in funding for TRIO programs allowed us to review these applications without denying grants to other applicants that had properly applied for funding.

The explanatory statement accompanying the Consolidated Appropriations Act 2017 was clear that Congress was only encouraging the Department to provide flexibility to applicants whose applications were rejected based on minor formatting issues. The explanatory statement did not address applications rejected for any other reason. In the instances you identify, the Department noted inconsistencies in the budgets proposed by the applicants and the maximum award size for those entities. Unlike minor formatting

issues, the size of an applicant's requested award goes directly to the nature and quality of the application itself and is central to the Department's review. I appreciate the fact that these issues may have been inadvertent, but the sheer volume of applications we receive each year make it impractical for the Department to fully review and assess every instance in which a proposed budget exceeded the maximum award size and make a determination regarding whether the excessive request was intentional or the result of an error. Doing so would require vastly more Department time and resources and would delay the review and award process, creating challenges for the effective implementation of projects nationwide. The Department has to proceed under the assumption that every applicant intended for the content of their application to appear as it does and evaluate the quality of the application on that basis.

Cuts to Career and Technical Education Programs

Ms. Roby: The proposed budget contains steep cuts to career and technical education programs in our nation's high schools and community colleges. Such a cut is especially troubling when the House Education and Workforce Committee just last week passed a Bi-Partisan bill to reauthorize these programs to help them better meet the needs of employers of a skilled workforce, as well as, the needs of students and workers training for these available jobs. How do you defend cutting a proven, successful, and locally-driven program that helps create jobs and promote economic growth in communities across the country?

Ms. DeVos: While the Administration does support the role Career and Technical Education (CTE) programs play in helping students attain the technical skills they need to get jobs that pay good wages, a decrease was necessary to align with overall Budget priorities and maintain the fiscal discipline necessary to support the President's goal of increasing support for national security and public safety without adding to the Federal budget deficit. We believe that, despite the cut, the FY 2018 President's Budget request would continue to provide significant flexible formula grant funds that support State and local efforts to implement high-quality CTE programs. We also note that the forthcoming reauthorization of the Perkins Act will provide an opportunity to reconsider ways to streamline, improve, and strengthen the Federal investment in high-quality CTE programs.

Title IV Rural Technology Funds Elimination

Ms. Roby: Secretary DeVos, I was pleased to hear during your Senate confirmation hearing that you support distance learning options for students in rural areas. I believe this came in response to a question from Senator Enzi on how you plan to engage with rural and frontier states.

As you know, the state of Alabama also has a lot of students living in rural areas. That being the case, I am concerned that the Education Department is proposing to zero out funding for Title IV, Student Support and Academic Enrichment grants, which is specifically intended to provide "students in rural, remote, and underserved areas with the

resources to benefit from high-quality digital learning opportunities." Can you help me understand how technology for rural schools will be funded with Title IV funds being completely eliminated?

Ms. DeVos: The poorly structured Title IV-A program, which delivers formula-based grants that for a majority of Local Educational Authorities (LEAs) including small, rural LEAs are too small to have a meaningful impact, was a lower priority in an FY 2018 President's Budget request that aimed to increase support for national security and public safety without adding to the Federal budget deficit. However, the FY 2018 President's Budget request for education maintains strong support for key Elementary and Secondary Education Act (ESEA) formula grant programs that serve vulnerable students and communities and can be used to improve and expand the use of educational technology, including Title I Grants to LEAs and the Rural Education Achievement Program.

Supporting Effective Instruction Elimination

Ms. Roby: The Supporting Effective Instruction State Grants program, also known as Title IIA, supports professional learning that improves both the content knowledge and practice tailored to meet the needs of teachers and leaders across academic and other learning areas and enable them to target inventions to meet individual student learning needs. Also, many states are finalizing their ESSA plans this summer and have proposed to use that funding to support educator training and professional development, including the Secretary's home State of Michigan. Can you explain the rationale for the program's elimination? And how will the Department aid states in specifically supporting school leaders?

Ms. DeVos: The Supporting Effective Instruction (SEI) State Grants program duplicates activities that may be supported with other Federal, State, and local funds; has not demonstrated success in contributing to improved teacher quality or student outcomes; and makes formula-based allocations to Local Educational Authorities (LEAs) that often are too small to have a meaningful impact on student outcomes. While the SEI State Grants program authorizes a wide range of activities intended to improve the quality of the educator workforce, in school year 2015-2016, 52 percent of funds were used for professional development and 25 percent were used for class-size reduction. An LEA that identifies either activity as a key strategy for responding to a comprehensive needs assessment may use Title I, Part A funds for the same purpose. Title I funds also may be used to recruit and retain effective teachers. Under the Every Student Succeeds Act (ESSA), States have great latitude in how to use other funding sources and can devote them to the kinds of activities supported under Title II-A, if those are their priorities. In addition, the first competition under ESSA for the Supporting Effective Educator Development (SEED) program, which is being held in 2017, included an absolute priority for supporting effective principals or other school leaders. Applicants selecting this priority, if awarded grants, will use funds to support projects designed to improve principal or other school leader effectiveness and increase the number of highly effective principals and leaders in schools with high concentrations of high-need students.

IRS Data Retrieval Tool Security Breach

Ms. Roby: There have been a number of recent developments related to the Department of Education's Free Application for Financial Aid (FAFSA) data breach with the IRS's data retrieval tool (DRT), which resulted in \$30 million being stolen from the federal government and millions of students delayed in getting their student aid. I am concerned that the Department is not doing enough to make sure Title IV dollars are being given to students who need it, rather than fraudsters looking to steal from the Government. In fact, in 2013, the Department of Education Office of Inspector General issued a report finding that Title IV fraud had increased 82 percent between 2009 and 2012. The Office of Inspector General concluded that while \$187 million was probable loss over that time period, up to \$874 million also could have been lost. While the DRT vulnerability exposed the Title IV system to fraud at the starting point of the process when a student completes a FAFSA, it is also important to address the fraud issues throughout the Title IV system, including at the student's point of enrollment and when Title IV funds are disbursed.

Ms. DeVos: Federal Student Aid (FSA) is the largest source of Federal student aid for postsecondary education in the United States. In Fiscal Year 2016, FSA delivered nearly \$125 billion in aid to approximately 12 million students attending more than 6,000 postsecondary education institutions. FSA must balance the need to make the Federal student aid delivery process simple and efficient for students and their families with the need to protect taxpayer dollars. This balance has led FSA to create a highly-automated and integrated aid delivery process that includes schools, Federal loan servicers, and others designed to assist FSA in identifying and stopping fraud when it occurs.

Consideration of fraud risk is a key component of the Department's and FSA's efforts to develop draft risk profiles as required by the 2016 update to OMB Circular A-123. FSA considers the risk of fraud when performing its risk assessments to identify and prioritize business processes to annually assess for effectiveness, when designing control activities for these processes, and in root cause analyses.

FSA has developed robust internal controls to prevent, detect, and, where appropriate, recover improper payments, including those related to fraud. In FY 2016, FSA documented and assessed 328 controls to detect and prevent improper payments and found that 99.7 percent (327 out of 328) of the controls tested were designed effectively, and 96.6 percent (172 out of 178) were operating effectively. Examples of some of FSA's improper payment controls include:

- Under normal circumstances, promoting use of the IRS DRT, which allows eligible FAFSA filers (approximately 10 million each year) to electronically transfer IRS tax return information;
- Requiring school verification of applicant data on the FAFSA form, and updating that selection criteria annually;
- Conducting annual program risk assessments and reviews of program participants, including schools, lenders, guaranty agencies, and contractors;

- Comparing data on the FAFSA form to the Social Security Administration's Death Master File to ensure that an identity thief is not attempting to use the process to steal Federal funds;
- Using the Federal excluded parties list database to ensure that schools and school officials that participate in the Federal student aid process were not previously barred from receiving Federal funds;
- Using Unusual Enrollment History flags to identify persons who are receiving aid at multiple schools over a short period of time;
- Conducting annual training for more than 6,000 postsecondary institutions on how to properly administering federal student aid and manage Federal funds; and
- Analyzing nearly 30,000 referrals from the OIG about potential student-level fraud, and driving each referral to a final, conclusive action.

Additionally, FSA has identified corrective actions to address the root causes of improper payments. These corrective actions include, but are not limited to

- Promoting the use of the IRS DRT (scheduled to return for the 2018–19 FAFSA form on October 1, 2017), which enables FAFSA filers and, as needed, parents of filers, to transfer certain tax return information from an IRS website directly to the online FAFSA form. Although FSA encourages use of the IRS DRT, in order to require use of the DRT for all eligible applicants, Congress would need to change the law pertaining to consent to sharing taxpayer information;
- Continuing to use data-based statistical analysis to enhance verification selection of the FAFSA filers with the highest statistical probability of error and the impact of such error on award amounts. Enhancement to verification procedures is a continuous process that is reviewed annually;
- Beginning on October 1, 2016, for the 2017–18 award year, FAFSA filers completed their FAFSA form using "prior-prior" year tax return information. For the 2017–18 award year, students and families provided tax return information from calendar year 2015 (not from calendar year 2016). This is in contrast with the "prior year" process previously employed, where many filers submitted their FAFSA forms before their tax returns were completed. The "prior year" process resulted in the need for some filers to estimate tax return information that, subsequently, would need to be corrected once the tax return was filed; or worse, was never corrected. The FAFSA form changes enacted for Award Year 2017–18 reduced the proportion of filers who had to use estimated tax information.;
- Coordinating with our contracted loan servicers to develop and implement corrective action plans to address consolidation errors, such as funds returned due to duplicate funding or multiple Loan Verification Certificates, inclusion of student loans that the borrower desired to exclude or were determined to be ineligible, and payoffs sent to the wrong address; and
- Coordinating with our contracted loan servicers to develop and implement corrective action plans to address refund errors, such as refunds made to ineligible lenders and borrowers, made for ineligible purposes, made in the incorrect amount, and/or sent to the incorrect payee.

FSA is continuously working to identify new controls to combat improper payments. In addition, existing controls—such as the regression analyses used to choose applicants for school verification—are continuously updated to improve our ability to detect and prevent improper payments.

Despite our vigilance and our continuous efforts to reduce improper payments, including those related to fraud, and to protect taxpayer dollars, it would be irresponsible for us to leave you with the impression that a zero-percent improper payment rate is feasible. In its 2016 Global Fraud Study, the Association of Certified Fraud Examiners found that its members who participated in the survey estimated that the typical organization loses five percent of revenues in a given year as a result of fraud. The 2013 OIG Management Information Report (MIR) titled "Student Aid Fraud Ring Assessment" (XI8M0001) issued 1/17/2013 found that, for the period 2009 to 2012, total estimated fraud was \$187 million or 0.037 percent of the \$510 billion in outlays.

Broader Title IV Fraud and Attempts to Address

Ms. Roby: What is the Department of Education's long term plan to ensure that all Federal Student Aid disbursed goes to actual students who need the money to access and complete college and not fraud rings? Will this plan address, without delay, Title IV fraud at all points of vulnerability, not just at the FAFSA DRT breach, but also at the points of awarding federal aid, enrollment, and disbursement? If so, where is it included in the Department's budget request?

Ms. DeVos: The Department is committed to ensuring the integrity of the student aid delivery system through multiple safeguards, including hundreds of controls to combat improper payments including fraud, and we continue to identify necessary corrective actions and new controls that could further reduce improper payments.

Consideration of fraud risk is a key component of the Department's and FSA's efforts to develop draft risk profiles as required by the 2016 update to OMB Circular A-123. FSA considers the risk of fraud when performing its risk assessments to identify and prioritize business processes to annually assess for effectiveness, when designing control activities for these processes, and in root cause analyses.

Fraud Reduction Measures and Response to OIG Findings

Ms. Roby: The Department of Education has proposed cuts to federal student aid programs, but has the Department looked at how to save the program money by addressing fraudulent activity? What steps has the Department taken since the OIG issued the 2014 report to address fraudulent activity and protect the mission of the federal student aid program?

Ms. DeVos: The Department continually evaluates fraud risk in the design, implementation, and assessment of internal control. In response to the Office of the Inspector General (OIG) OIG Management Information Report (MIR) titled "Student Aid Fraud Ring Assessment" (XI8M0001) issued 1/17/2013 and the preceding OIG Investigation Program Advisory Report (IPAR), "Distance Education Fraud Rings" (L42L0001) issued 09/26/2011, the Department established a Distance Education Fraud Ring Task Force to develop and implement corrective actions to address the OIG's recommendations. These corrective actions included but were not limited to new requirements for verification and enhancements to many of the Department's internal controls. Working with the OIG, the Department established a process to receive from the OIG referrals of suspected fraud identified from analytics or hotline operations. The Department has established processes for the analysis and disposition of all referrals, including recovery of any improper payments. Analysis of referrals to include identification of fraud risk indicators and anomalous activity informs management's assessment of internal control and leads to improvements and corrective action.

Impact Aid and Department Measures to Support Military Children

Ms. Roby: As you know, Impact Aid provides a tax-replacement for school districts in areas impacted by a federal presence, such as military installations. Over 85-percent of military-connected students are educated in public schools, as such Impact Aid is a critical funding stream to ensure schools can meet the unique challenges these students face related to mobility and deployment. We just celebrated 'the month of the military child' in April. How will you ensure the federal government does its part to support the education of military kids and the schools that serve them?

Ms. DeVos: The FY 2018 President's Budget request recognizes the longstanding Federal responsibility for school districts serving military-connected students by providing \$1.2 billion for Impact Aid Basic Support Payments and Payments for Children with Disabilities. The Department also is launching a major upgrade of the Impact Aid payment system in FY 2017 to ensure that the Department's Impact Aid office will be able to continue to process applicant data efficiently and make payments in a timely manner so that Impact Aid districts can meet the educational needs of military-connected students.

Impact Aid and IT Improvements

Ms. Roby: The IT that supports the Impact Aid program office is decades old and is badly in need of an update. This is an urgent priority to ensure that school districts receive their payments without issue and that school administrators can easily access their payment vouchers which enable them to transmit information securely, and ensures the Impact Aid office which processes over \$1 billion in direct grants to 1,200-plus school districts can operate efficiently and effectively. How are you prioritizing this much-needed investment?

Ms. DeVos: The Department recognizes that the current Impact Aid IT system is in need of a major upgrade to ensure that the Impact Aid office will be able to continue to process applicant data and make payments in a timely manner. As part of the President's

FY 2017 Budget request, the Department requested an increase for the Program Administration budget to fund this critical IT investment. While Congress did not appropriate the additional funding, the Department has secured over 80 percent of the funding needed for FY 2017 projected costs and will continue to prioritize this investment subject to Congressional appropriation levels in FY 2018 and beyond.

Student Suicide Countermeasures and SROs

Ms. Herrera Beutler: In 2014, suicide was the second leading cause of death among young people ages 13 to 19 years. In Washington state, the latest Health Youth Survey found that the percentage of students who experience high anxiety, and who consider or attempt suicide, is on the rise. According to the study, the number of 8th and 10th grade students who have thought about suicide, has increased by at least 6 percentage points in the last decade. Youth suicide is a problem in areas of my district and I have made a commitment to do everything I can to help our school districts address this challenging problem.

Part 1: My question for you, Madam Secretary, is what do you see as the Department's role in combatting youth suicide and how does the Department of Education plan on partnering with local school districts, as well as other agencies, to be able to effectively and swiftly address the mental health crisis of our nation's youth.

Part 2: Further, in many cases, School Resource Officers play a vital role in this effort. School Resource Officers engage with students on a daily basis and provide a wide range of important services to our nation's youth, including identifying depression and suicidal behavior among school children. These officers also serve as educators, emergency managers and informal counselors, and work in coordination with schools and school districts to identify and assist children at-risk of depression and suicide.

For the last few years, the COPS Hiring Program has given additional consideration to SRO grant applications when making awards. I appreciate the role School Resource Officers play in our schools and communities and support the COPS program's efforts to incentivize hiring of SROs. It really makes a difference.

Do you agree the practice of School-Based Policing through School Resource Officers is an effective strategy to promote safety in our nation's schools, protect students from crime and bullying while also aiding in the coordinated effort to identify depression and suicidal behavior? And if so, do you think the Department of Justice should continue to promote the hiring of School Resource Officers within the COPS hiring program?

Ms. DeVos: Suicide is a major public health issue that affects people of all ages, backgrounds, and racial and ethnic groups throughout the country. When a student commits

suicide, it is not only a tragedy for his or her family, but it can also significantly affect other students and disrupt school learning environments. While the causes of youth suicide are complex and determined by multiple factors, the goals of suicide prevention are simple: reduce factors that increase the risk of suicide and increase factors that promote resilience and encourage an effective community response to the risk. Schools can play an important role in reaching these goals. The Department provides a wide range of technical assistance resources on suicide prevention through its Office of Safe and Healthy Students, including information on the risk factors and warning signs for suicide, how to screen for and intervene with students at risk of suicide, and how to respond to a suicide death. Our Project SERV (School Emergency Response to Violence) program has provided grants for counseling and mental health services to a number of school districts that have experienced multiple suicides.

School-based law enforcement officers can be an important part of a comprehensive school safety plan. School Resource Officers (SROs) often play three roles in our schools: law enforcer, informal counselor, and educator. In their capacity as counselors and educators, SROs can, and should, support positive school climate goals by developing positive relationships with students and staff, and helping to promote a safe, inclusive, and positive learning environment. Schools should ensure that school-based law enforcement officers receive rigorous training before the officers begin working on the school campus as well as continuing throughout their work at the school. One key distinction is that SROs are primarily responsible for addressing major threats to safety or serious criminal conduct—it is up to school administrators and staff to maintain order and handle routine disciplinary matters so as to avoid inappropriate or unnecessary student involvement in the juvenile justice system. I defer to the Department of Justice, which administers the COPS program, on whether the program be used to promote the hiring of SROs.

Chronic Absenteeism and Department Countermeasures

Ms. Herrera Beutler: According to a 2014 Department of Education report, over 6 million students were chronically absent, or missed 10% or more days of school, and my state of Washington has the highest rate of chronic absenteeism by school district in the nation. Unfortunately the research shows, that a student who is chronically absent is 7 times more likely to drop out of school than their peers who are not. Two weeks ago, I held a roundtable with the Superintendents in my district to discuss this very issue, and they each emphasized that this problem is incredibly multifaceted and varies from district to district. I recently introduced the Chronic Absenteeism Reduction Act with Congressman Tim Ryan that would allow school districts the flexibility to implement strategies that would combat chronic absenteeism within their districts. My question for you is how does the Department of Education plan on empowering local school districts to address this issue effectively?

Ms. DeVos: We agree that flexibility to use Federal funds to meet locally determined needs, including efforts to reduce chronic absenteeism, is a key strategy for empowering State and local educators to improve academic and other education-related outcomes for all students. Such flexibility is the centerpiece of the Every Student Succeeds

Act (ESSA), and we are committed to maximizing local flexibility to innovate as we move forward with ESSA implementation. In addition, ESSA includes two key provisions that will help promote more effective efforts to address chronic absenteeism. First, data on chronic absenteeism must be included in the State report cards required by section 1111(h)(1) of the Elementary and Secondary Education Act (ESEA), as amended by the ESSA. Second, the State-developed accountability systems required under the ESSA must include one or more indicators of school quality or student success, which may include measures related to chronic absenteeism. Finally, because of this new emphasis on chronic absenteeism in the ESSA, we anticipate expanding technical assistance and related support to States and school districts on this issue, including, for example, support provided through the Department's network of Comprehensive Centers.

College Funding Simplification

Ms. Herrera Beutler: You stated that “the Budget simplifies funding for college, while continuing to help make a college education more affordable.” How exactly do you intend to do that?

Ms. DeVos: The President’s Budget Request proposes to simplify student loan programs and student loan repayment by replacing five different income-driven repayment plans with a single plan aimed at prioritizing effective loan repayment for undergraduate borrowers. The Administration believes that this repayment plan, with payments capped at 12.5 percent of a borrower’s discretionary income, and forgiveness provided after either 15 or 30 years of loan payments (depending on whether the borrower has any graduate borrowing), provides an effective backstop to facilitate student loan repayment for all borrowers. The President’s Budget Request also supports the restoration of Year-Round Pell Grants, which will help make college more affordable for our neediest students.

Public Service Loan Forgiveness

Ms. Herrera Beutler: I see that your budget eliminates the Public Service Loan Forgiveness Program. In my district we have a significant number of public servants who benefit from this program. These individuals serve in non-profits, schools, soup kitchens, community gardens, and contribute to building up our communities where it is needed most. How do you intend to incentivize individuals to serve in these sectors when their salaries cannot sustain their school debt?

Ms. DeVos: I do not believe it is the Department of Education’s role to incentivize individuals to serve in specific sectors of the economy. However, as mentioned in the response to Part 1 of your question, the Administration believes that its proposed income-driven repayment plan will provide an effective backstop to facilitate student loan repayment for all borrowers, including those in the public sector.

Private Schools and IDEA/Students with Disabilities

Ms. Herrera Beutler: There is growing concern among families with children with disabilities in regards to the school choice program. Currently, not all Private Schools are required or equipped to care for students with disabilities. If a child with disabilities is attending a low performing school but the closest alternative option does not legally need to care for these students, what choice do they have?

Ms. DeVos: Every year across this country, far too many families, including families of children with disabilities, are faced with the challenges of a geographically assigned school that does not or cannot meet their student's needs. For decades, we have taken a one-size-fits-all approach to dealing with these schools, favoring heavy-handed top-down Federal regulations over community-based solutions. The simple fact is that every child is unique and has her own set of needs, and not every school is prepared to meet all of those needs. Children and their families need the ability to find educational options that work for them, and we need to recognize that the Federal government requiring someone to do something doesn't mean they will be good at it. We have required public schools to provide for the needs of all students with disabilities for more than forty years, and yet far too many students don't experience success in the traditional school system. One of the strengths of any school choice model is providing true educational options to families, including the choice of providers who have greater flexibility than their existing school. We should strive to ensure that every student in this nation has access to a great education, regardless of the type of school they attend.

Paperwork Reduction and Streamlining Efforts to Aid LEAs

Ms. Herrera Beutler: Schools in my district have expressed concern about the excessive amounts of burdensome paperwork they are required to fill out. For schools in my district, only 2.5% of their total revenues are federal funds, yet the time associated is greatly higher. How does the Department intend to streamline these processes and work with local schools around the country in order to ensure these educators are spending more time providing our students with a quality education and not on burdensome paperwork?

Ms. DeVos: We strongly agree that excessive paperwork and other administrative requirements not only cost time and money but reduce local flexibility to innovate on behalf of students and families. This is why one of President Trump's first actions when he took office was to delay implementation of the burdensome new Elementary and Secondary Education Act (ESEA) regulations promulgated by the Obama administration. He then fully supported and signed into law the action by Congress to overturn those regulations under the Congressional Review Act. He also has made further regulatory reform a core initiative of his administration, including at the Department of Education, where we are currently engaged in a rigorous review of all of our regulations for the purpose of eliminating regulatory burden and overreach and ensuring that we regulate in the future only when absolutely necessary.

School Lunches

Ms. Herrera Beutler: The burden of food service regulations is causing schools to spend a significant amount on food programs. When schools lose their grandfathered cooks under old regulations, they are then forced to look for companies to supply the food program, and sometimes staffing, due to the high number of regulations. This is costly, and for some schools in rural areas being able to have a company willing to come in is difficult at best. For the 16/17 school year, Morton School District, which is located in my district, is having a company ship food to their schools from Salem, OR in order to meet these regulatory requirements. This is a 308 mile roundtrip. The well-intended food service guidelines result in less efficiency and extraordinary time spent on compliance. Less compliance regulations and some flexibility for rural areas/small school districts would enable these districts to better meet the needs of students more efficiently.

Ms. DeVos: The Department suggests directing this inquiry to the Food and Nutrition Service at the U.S. Department of Agriculture, which oversees school food service.

AbilityOne Jobs and Michigan Vocational Rehabilitation

Mr. Moolenaar: I am concerned that jobs for people with disabilities are being threatened by Obama-era regulatory/sub-regulatory guidance and on inconsistent implementation of portions of the Workforce Innovation and Opportunity Act (WIOA). I understand that in recent weeks, eighteen (18) state Vocational Rehabilitation (VR) agencies, including in my state of Michigan have stopped making placements to non-profit agencies for AbilityOne Program jobs. The guidance they are referencing is a Department of Education's FAQ entitled, Integrated Location Criteria of the Definition of "Competitive Integrated Employment." As you may be aware, many AbilityOne jobs, such as those 2,000 individuals employed on AbilityOne contracts in Michigan, are in integrated settings and pay well above minimum wage. In many communities, AbilityOne jobs are among the best jobs available, which is especially important given the fact that 80% of people with disabilities do not have jobs. These jobs take place on military installations, at GSA buildings, and at many Federal agencies where daily interaction with the public and other government employees is a daily occurrence. In addition, these jobs pay an average hourly rate of \$12.68 in Michigan. State VR agencies have been making placements to AbilityOne jobs through nonprofits for many years. Not only have thousands of individuals with disabilities found meaningful employment, they have also reduced their reliance on public assistance programs while becoming proud tax payers. I am writing to ask if you would be willing to consider this situation at your earliest convenience with the goal of encouraging state VR agencies to continue placements to AbilityOne affiliated agencies when requirement for placements are met, just as they have in the past.

Ms. DeVos: State Vocational Rehabilitation (VR) agencies are in the best position to determine whether a training or employment location satisfies the integrated location criteria of the regulatory definition of "competitive integrated employment." The Department has provided technical assistance to the State VR agencies, both in the preamble to the August 2016 final regulations, (81 FR 55629), as well as in sub-regulatory guidance (such as the FAQs you referenced), that VR agencies must conduct a case-by-

case analysis of each employment setting within a community rehabilitation program (CRP) to determine if it satisfies the criteria. Training or employment locations should not be automatically disqualified without a factual analysis.

The Integrated location criteria of the regulatory definition of "competitive integrated employment" are that the employment is: 1) typically found in the community; and 2) where the employee with a disability interacts, for the purpose of performing the duties of the position, with other employees within the particular work unit and the entire work site, and, as appropriate to the work performed, other persons (e.g., customers and vendors) who are not individuals with disabilities (not including supervisory personnel or individuals who are providing services to such employee) to the same extent that employees who are not individuals with disabilities and who are in comparable positions interact with these persons (34 CFR 361.5(c)(9)(ii)). With respect to the provision of services, integrated setting is defined as a setting typically found in the community in which applicants or eligible individuals interact with nondisabled individuals other than nondisabled individuals who are providing services to those applicants or eligible individuals (34 CFR 361.5(c)(32)(i)).

The use of the phrase "work unit" in the regulatory definition of "competitive integrated employment" properly focuses the consideration of the interaction of the individual with the disability with employees without disabilities on the particular job and the environment in which the work is performed. As used in the definition, "work unit" may refer to all employees in a particular job category or to a group of employees working together to accomplish tasks, depending on the employer's organizational structure. The level of integration experienced by all individuals with disabilities employed by a CRP is not the same throughout the CRP and is dependent on the circumstances of the particular job within each work unit of the organization. Therefore, some employment opportunities offered by a CRP may be considered to be in "integrated locations," and thus satisfy the definition of "competitive integrated employment," while others may not.

State VR agencies may continue to make job placements with AbilityOne-affiliated agencies if all criteria of the definition of "competitive integrated employment," including those for an integrated location, are met. As previously stated, each State VR agency must make the case-by-case analysis on the facts of each job position, and a determination made if a placement to AbilityOne meets all of the requirements of the definition of "competitive integrated employment." Through guidance on competitive integrated employment (<https://rsa.ed.gov/display.cfm?pageid=570>), the Department has been clear, that State VR agencies must determine case-by-case, based on the facts presented, whether an employment setting meets both criteria for an integrated location, and they are encouraged to visit employment sites and gather the facts necessary for these determinations. Therefore, the State VR agency is responsible for determining whether the jobs performed by individuals with disabilities employed by CRPs satisfy the definition of "competitive integrated employment" when individuals seek the VR agency's assistance in obtaining these positions.

The Department continues to work with State VR agencies by reviewing policies and procedures, and providing technical assistance to State VR agencies to ensure that they are conducting a case-by-case analysis of employment settings within CRPs and referring individuals with disabilities who choose to pursue non-integrated employment. In regards to Michigan Rehabilitation Services (MRS), the Department has conducted teleconferences with the State staff. MRS is in the process of conducting an analysis of the employment opportunities offered by the Michigan CRPs.

ESSA State Plan and Approach to Modifications

Ms. DeLauro: Implementation of the Every Student Succeeds Act (ESSA) is one of the most important functions the Department of Education will be undertaking this year. ESSA requires the performance of each group of historically underserved students to be included in State accountability systems rather than simply aggregating students together to ensure these students receive the support they need to excel. Another key equity protection included in ESSA is its requirement for States to identify and support schools with "consistently underperforming" groups of historically underserved students. ESSA also requires States to include the four-year graduation rate in their accountability systems because the ultimate goal of the K-12 education system is for students to graduate from high school prepared for postsecondary education and the workforce.

In the event that some States are not complying with the letter and spirit of the law, please provide specific ways in which you will require States to make modifications to their plans to bring them into compliance before approving them.

Ms. DeVos: The Department is committed to reviewing and approving Elementary and Secondary Education Act (ESEA) consolidated State plans consistent with the requirements of the ESEA, as amended by the Every Student Succeeds Act (ESSA), including input from expert peer reviewers. The Department is providing written feedback on each State plan, including a list of items that require additional information or revision in order to meet the requirements for approval. We also are providing the peer review notes, which may differ from the Department's feedback. Department staff are available to provide technical assistance in working through any outstanding items.

ESSA State Plan Peer Reviewers

Ms. DeLauro: ESSA requires that the Department of Education administer a peer review of State plans to implement this law. In 2016, the Department requested applications of peer review candidates and noted that the training of peer reviewers would begin in March of 2017 and that the peer reviews would occur in two windows, according to the application submission deadlines for ESSA State plans. Peer review is to assess the extent to which State plans sufficiently address applicable laws and regulations. However, now that the ESSA regulations for State plans, accountability and reporting have been repealed, several questions come to mind:

In your letter to State school officers, you mention working with them and State governors to "prioritize State flexibility." Can you describe what this collaboration will look like and what elements will be prioritized for State flexibility?

Will you publish the names of peer reviewers, those that applied and those that were selected?

Can you describe the process you will use to assess peer reviewer candidates for conflicts of interest and how you ensure that selected peer reviewers have no such conflicts? Will you publish the peer review notes, including their recommendations to States? By what date will you publish this information?

Ms. DeVos: As is always the case, the Department will provide technical assistance and support to help States develop strong plans for the implementation of the Elementary and Secondary Education Act (ESEA). We will also carry out our responsibilities to ensure each State is meeting all requirements in the ESEA.

The Department will provide a list of the approved peer reviewers after the conclusion of the process to peer review each State's plan.

Following long-standing practice to vet any person who serves as a peer reviewer in any capacity, the Department's Office of Government Ethics will review each candidate with respect to the peer's review of any State plan to ensure there is no conflict of interest.

Yes, the full peer notes will be published at the same time as the interim letter is sent to the State. As of July 13, 2017, interim letters and peer notes for Connecticut, Delaware, Louisiana, Massachusetts, Nevada, New Jersey, New Mexico, Oregon, and Tennessee are available on the Department's website.

Title I and FOCUS Authority

Ms. DeLauro: The President's budget includes a \$1 billion proposal within Title I for a new competitive grant authority. This grant authority was not included in the bipartisan ESSA by Congress, and similar proposals were specifically struck down during Congressional debates. Please explain how this proposal is aligned with ESSA. What authority does the Department have to create this new program?

Ms. DeVos: The Title I Furthering Options for Children to Unlock Success proposal, or FOCUS, is not a competitive grant program but is based on, and aligned with, the Flexibility for Equitable Per-Pupil Funding demonstration authority in section 1501 of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA). The Administration's intention is to approve participation by all applicants that meet the requirements of the FOCUS proposal and to fund as many approved applicants as possible; it may be possible for some applicants to implement FOCUS plans without additional funds. We further note that enhancing or expanding open enrollment systems is consistent with Congress's recognition, in the school improvement

provisions of section 1111(d) of the ESEA, as amended by the ESSA, that public school choice options are an appropriate strategy for improving the educational opportunities available to students enrolled in schools identified for comprehensive support and improvement. The Department is seeking authority through appropriations language to combine the weighted student funding flexibility under section 1501 with open enrollment systems. The Administration believes that the combination of these two reforms holds significant promise for increasing access to a high quality education for the disadvantaged students served both by Title I and the ESEA more broadly.

Common Core and FOCUS Incentivization

Ms. DeLauro: Although you were a supporter of Common Core, you and others in the Trump Administration decried the Obama Administration for using federal dollars to incentive adoption of Common Core standards, claiming that in doing so, President Obama made Common Core "federal standards." If the FOCUS and EIR grants are competitive, how is what you are proposing to do incentivizing States and LEAs to adopt your preferred policy priorities justified in light of these previous criticisms? Can you provide an explanation for how this "policy incentivization" or "competition" is substantively different from that of just a few years ago?

Ms. DeVos: Every administration expresses its priorities through its annual budget request, and virtually every administration's budget request includes either proposed modifications of existing programs as is the case for the President's 2018 request for the Department of Education or entirely new programs. We are committed to adhering to the numerous and very specific prohibitions on the Department's authority in the Elementary and Secondary Education Act (ESEA) as amended by the Every Student Succeeds Act (ESSA), and are confident that our Furthering Options for Children to Unlock Success (FOCUS) and Education Innovation and Research (EIR) proposals are not inconsistent with any of those prohibitions because they would not affect the approval of any State's ESEA consolidated State plan or a potential waiver request, and they would not mandate, direct, or control the specific instructional content, academic standards and assessments, curricula, or program of instruction of any State, school district, or school.

Title I-A Cut and "Fully Funded"

Ms. DeLauro: The President's budget proposes a \$578 billion cut to Title I-A for programs that support services for disadvantaged students. This cut exacerbates the already inequitable distribution in funding for high poverty school districts.

During the hearing, you expressed that Title I funding will be "consistent" and "fully funded." Can you explain what you mean by consistent and fully funded? How are the proposed cuts aligned with your belief that Title I-A funding should be consistent?

Ms. DeVos: The FY 2018 President's Budget request proposed level funding for the Title I Grants to Local Educational Authorities (LEAs) program based on the FY 2017 annualized Continuing Resolution that was in effect at the time the President's Budget was

developed. Consequently, the Administration's budget policy for Title I calls for level funding, and we look forward to working with Congress to accomplish that goal while supporting other priorities in the FY 2018 President's Budget request.

Title I-A Flexibility and Applicability When Cutting Broad Base Funds

Ms. DeLauro: Throughout your testimony, you pointed to the new flexibility in Title I-A, and pointed out that funds can be used for many of the programs you cut or eliminate. With a significant reduction in Title I-A funds, how will States have the funds to utilize the flexibility and meet the statutory requirements?

Ms. DeVos: As previously noted, we did not propose a significant reduction in Title I funding based on Congressional appropriations action at the time the FY 2018 President's Budget request was developed. However, we also believe that a key theory of action behind the Every Student Succeeds Act (ESSA) is that greater flexibility for States and school districts will allow local leaders to determine the most efficient and effective use of all education funds, and not just the less than 8 percent of K-12 spending that comes from the Federal government. With fewer Federal strings attached as a result of the ESSA, we believe States and school districts will be able to invest all of their resources more effectively and more productively, based on their own determination of needs and priorities rather than directives from Washington.

Funding Distribution by Socioeconomics

Ms. DeLauro: In your exchange with Rep. Roybal-Allard, she asked if you believe that high-poverty school districts should get more resources than low-poverty schools. In your response, you stated that "Yes, I think the reality is that they do receive higher levels of funding." As Rep. Roybal-Allard pointed out later in the exchange, high-poverty schools in fact do not receive higher funding than low-poverty schools. Do you still believe high-poverty schools receive greater funding than low-poverty schools? If yes, please provide specific examples. As you later stated during the exchange, you believe high-poverty schools should receive more federal resources than low-poverty schools. What steps will you take to ensure students in high-poverty schools receive the funding resources needed to provide a high-quality, equitable education? How are these steps aligned with the current proposed budget?

Ms. DeVos: I was merely making the point that under Federal education programs like Title I, statutory formula provisions generally ensure that high-poverty districts receive more funding than low-poverty districts. Moreover, the FY 2018 President's Budget request includes a key initiative the \$1 billion Title I Furthering Options for Children to Unlock Success proposal, or FOCUS that would encourage school districts, consistent with the Flexibility for Equitably Per Pupil Funding demonstration authority in Part E of Title I, to direct a greater share of Federal, State, and local resources to the high-poverty schools that tend to enroll higher percentages of educationally disadvantaged students. In addition, the FY 2018 President's Budget request generally maintains strong support for the flexible Federal formula grant programs that States and school districts rely on to meet the

academic and non-academic needs of their most vulnerable students, including students from low-income families, students with disabilities, and English learners.

Title I, FOCUS Funds Source and Public Schools

Ms. DeLauro: During your exchanges with subcommittee members, you frequently stated that the Administration is not shifting money away from public schools for school choice initiatives. However, you propose a large cut to (or to eliminate) Title I-A, Title II-A, IDEA, career and technical education, and many programs that specifically support public school students who face challenges in accessing an equitable, high-quality education. Please provide an explanation of how funds are not being shifted away from public schools and where the Administration found the extra \$1 billion in funds for the choice initiative.

Ms. DeVos: The \$1 billion Title I Furthering Options for Children to Unlock Success (FOCUS) initiative included in the FY 2018 President's Budget request would support expanded public school choice in participating Title I districts, and thus would not shift Federal education funds away from public schools. Moreover, we believe the FOCUS program would improve access to an equitable, high-quality education for public school students in participating districts.

Supplement and Supplant Title I Funds

Ms. DeLauro: As you know, Congress passed ESSA with bipartisan support. It is important that it is funded to ensure that all students have "significant opportunity to receive a fair, equitable, and high-quality education, and to close educational achievement gaps." Title I funds under ESSA, which are given to local educational agencies, must supplement and not supplant state and local funds. This provision was added to the then Elementary and Secondary Education Act of 1965 after the NAACP Legal Defense and Educational Fund released a report in 1969 detailing the extreme misuse of Title I funds in states across the country. For example, in Mississippi, several school districts used federal funds almost exclusively to build and equip cafeterias and libraries, to hire teachers, and to provide instructional materials and books to Black students - resources available to schools serving white students through state and local funds. Such misuse continues to this day. Recent research from the Department of Education shows that, on average, "Title I schools are shortchanged by about \$440,000 per year, and the federal funds spent in these schools are often, in effect, being used to make up some or all of that shortfall, instead of providing the additional resources needed in high poverty schools." How will you ensure that States and districts use Title I funds to supplement and not supplant state and local funds as required by ESSA?

Ms. DeVos: We are committed to enforcing all statutory provisions of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA) including the Title I supplement not supplant provision.

Rationale for Teacher Training Fund Cuts

Ms. DeLauro: In response to questions for the record from your confirmation hearing to Ranking Member Murray, you stated that you "support great schools - in all forms - and great teachers and school leaders who dedicate their lives to help students achieve and succeed" (p. 12-13, question 5). Why then have you proposed to eliminate nearly \$2.1 billion in funding to help recruit, develop, and retain "great teachers and school leaders"?

Ms. DeVos: The FY 2018 President's Budget request does not include funding for the Supporting Effective Instruction (SEI) State grants because the program duplicates activities that may be supported with other Federal, State, and local funds; has not demonstrated success in contributing to improved teacher quality or student outcomes; and makes formula-based allocations to Local Educational Authorities (LEAs) that often are too small to have a meaningful impact on student outcomes. For example, school districts may use allocations under the much larger \$15.5 billion Title I Grants to LEAs program to recruit and train great teachers and school leaders.

State/Local Efforts to Address Teaching Needs

Ms. DeLauro: Have you started to "work with States, universities, colleges of education and other stakeholders to ensure we have a strong pipeline of well-prepared and effective teachers"? This work will be of incredible significance considering your proposed cuts to Title II.

Ms. DeVos: Yes. For example, we requested continued support for our Supporting Effective Educator Development (SEED) program, which beginning in 2017 can support grants to universities as well as to national nonprofit organizations. Grantees will receive funding to provide evidence-based professional development and provide teachers and school leaders with evidence-based enhancement activities, including activities that lead to advanced credentials. We believe that this program is an effective vehicle for supporting evidence-based educator preparation and development efforts that can serve as models for similar efforts across the country.

Cut to Teacher Training Funds and Ongoing Recruitment and Retention Concerns

Ms. DeLauro: At the hearing, you pointed to Title I generally as a funding stream that schools could use to achieve the goals of Title II-A. However, how do you propose schools and districts support, recruit, and retain teachers while also carrying out the activities required under Title I when the budget proposes cuts at \$578 million from existing Title I funding streams?

Ms. DeVos: The Administration's request for Title I Grants to Local Educational Authorities (LEAs) maintained level funding for the existing funding streams at the 2017 annualized Continuing Resolution level, which, given the absence of a final appropriation for 2017, was the basis for the FY 2018 President's Budget request. We look forward to working with Congress on continuing to maintain strong support for Title I.

Department Aid to States in Lieu of Full Title II-A Funding

Ms. DeLauro: Title II-A supports professional learning that improves both the content knowledge and practice tailored to meet the needs of teachers and leaders across academic and other learning areas and enables them to target interventions to meet individual student learning needs. Also, many States are finalizing their ESSA plans this summer and have proposed to use that funding to support educator training and professional development, including in your home state of Michigan. How would the Department aid States in specifically supporting school leaders without this funding?

Ms. DeVos: The Department supports a number of programs to help States and school districts recruit, prepare, and support effective teachers and school leaders. For example, the Teacher and School Leader Incentive Grant program, for which the FY 2018 President's Budget request includes nearly \$200 million, helps school districts expand human capital management systems and performance-based compensation systems that help attract and retain effective teachers, principals, and other school leaders. The FY 2018 President's Budget request also would provide \$42 million for the Supporting Effective Educator Development program, which provides grants to nonprofit organizations and institutions of higher education to provide evidence-based professional development to teachers, principals, and other school leaders. The \$15.5 billion Title I Grants to Local Educational Authorities (LEAs) program also is a key source of Federal support for locally directed efforts to recruit and train effective teachers and school leaders. And the Department provides a wide range of technical assistance designed to build State and local capacity to improve teaching and learning, including the Center on Great Teachers and Leaders funded through the Comprehensive Centers program.

Striving Readers Literacy Report Status

Ms. DeLauro: In Fiscal Year 2015, the Secretary was directed to utilize a 5 percent set-aside from the Striving Readers Comprehensive Literacy (SRCL) program to implement a national evaluation of the program. Specifically, the Secretary was directed to produce a report on effective policies to strengthen student literacy used by states participating in the SRCL program. What is the status of this report and when will the results be available publicly?

Ms. DeVos: We did not implement a national evaluation in FY 2015 because that was the final year of the FY 2011 cohort of six States implementing Striving Readers projects. However, in 2017, we plan to make 510 new, fully funded awards using the FY 2016 and FY 2017 appropriations, and the Department's Institute of Education Sciences currently is engaged in the design of a national evaluation of these new projects.

Improving Literacy While Eliminating Funding and Teacher Training

Ms. DeLauro: Only 36 percent of fourth-graders, 34 percent of eighth-grade students, and 37 percent of twelfth-grade students performed at or above the proficient level in the 2015 Reading assessment of the National Assessment of Educational Progress

(NAEP) the Nation's Report Card. Yet, the budget request eliminates funding for professional development, the Literacy Education for All, Results for a Nation (LEARN) program, and the Innovative Approaches to Literacy program. Therefore, how does the Department Education plan to promote effective literacy instruction if all literacy programs and professional development funds for States are eliminated?

Ms. DeVos: We believe that the already robust evidence base for effective literacy instruction, combined with more than \$15 billion in annual Title I funding that may be used to pay for the implementation of evidence-based literacy instruction, provides substantial support for States and school districts that choose to prioritize literacy instruction as part of their efforts to improve student outcomes. Moreover, the Department will be using an estimated \$380 million in combined FY 2016 and 2017 appropriations to fully fund a new cohort of 5-10 Striving Readers (the nearly identical predecessor to LEARN) grantees in an FY 2017 competition, providing ample opportunity for additional States to build evidence on effective literacy instruction and related practices that may be supported with Federal, State, and local education funds in future years.

Support for Evidence-Backed School Leadership Efforts despite Reducing Funding

Ms. DeLauro: More than a decade of research shows that well-prepared, well-supported principals have a huge influence on teacher practice and student success. In fact, a landmark study found that there were virtually no documented instances of troubled schools being turned around without intervention by a strong school leader. The School Leader Recruitment and Support Program, which received bipartisan support during the passage of ESSA, is the only federal program focused specifically on investing in evidence-based strategies to strengthen school leadership in high-need schools. How does the budget proposal support locally driven strategies that are backed by evidence, such as those supported by the SLRSP program, which is proposed for elimination?

Ms. DeVos: The School Leader Recruitment and Support Program, which was funded at \$14.5 million in 2017, is a small discretionary grant program that supports only 18 grantees and has minimal national impact. While school leadership is important, other Federal funds are available to support improved leadership in high-need schools. In particular, both regular Title I Grants to Local Educational Authorities (LEAs) and Title I funds reserved for school improvement, which are available to more than 14,000 school districts and 55,000 public elementary and secondary schools, may be used to recruit, prepare, support, and retain effective principals and other school leaders in Title I participating schools. Moreover, districts are required by the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA), to include evidence-based strategies, which could include evidence-based plans to strengthen school leadership, in their comprehensive support and improvement plans.

Department Efforts to Recruit Diverse Teaching Force

Ms. DeLauro: In July 2016, the Department's report entitled "The State of Racial Diversity in the Educator Workforce" found an alarming lack of diversity in the K-12

teaching workforce. What value do you see in increasing the diversity of the K-12 teaching workforce as the number of minority students continues to grow? How does the Department's budget create better pathways for teachers of color and help districts attract and retain teachers of color, especially to high-need urban and rural school districts? How is the Department working to lessen the cost of becoming a teacher to help recruit a diverse teaching workforce?

Ms. DeVos: States and school districts bear primary responsibility, and most of the costs, for recruiting and training effective teachers and school leaders, and thus have primary responsibility for increasing the diversity of the K-12 teaching workforce. At the same time, the Department administers key programs that both directly help States and districts achieve this goal and provide models that may adopted more broadly. For example, the 2017 competition for the Teacher and School Leader Incentive Grant (TSLIG) program includes a competitive preference priority for applicants who design projects to attract, support, and retain a diverse and effective workforce. In addition, the FY 2018 President's Budget request would continue to support the Supporting Effective Educator Development (SEED) program, which provides grants for a variety of projects to improve the teacher and school leader workforce, including grants that create alternate pathways to the teaching profession. Our 2017 competition for SEED awards under ESSA included a competitive preference priority on promoting diversity in the educator workforce. Applicants responding to this priority must design and implement projects to improve the recruitment, support, and retention of educators from diverse backgrounds. The FY 2018 President's budget also maintains strong support for the postsecondary student aid programs that all students, including minority students who will become teachers, rely on to help pay college costs.

How to Coordinate with Other Federal Agencies to Promote STEM

Ms. DeLauro: In order to maximize the effectiveness of federal funding for STEM, there needs to be close coordination with other agencies of the federal government that play a role in expanding these opportunities for students. How would you prioritize coordinating the Department's activities with other agencies, particularly the National Science Foundation, Department of Defense and Department of Commerce?

Ms. DeVos: We agree that improving Science, Technology, Engineering and Math (STEM) education should be an ongoing Federal priority, and anticipate developing a comprehensive, government-wide STEM strategy as part of the FY 2019 President's Budget request scheduled for release in early 2018.

Department Immigration Resource Provision

Ms. DeLauro: What is the Department doing to provide schools and districts with resources to address immigrant students and families?

Ms. DeVos: The Department provides formula grants under both Title I and Title III of the Elementary and Secondary Education Act (ESEA) that school districts may use

to meet various needs of immigrant students. In particular, Title I funds may be used as part of schoolwide projects to meet both academic and non-academic needs of immigrants students and families. Title III funds are focused on English language acquisition, and include competitive grants that support professional development designed to improve instruction for English learners.

DHS and DOJ Cooperation

Ms. DeLauro: Is the Department working with the Department of Homeland Security and the Department of Justice to ensure that sensitive locations, including schools, are not targets for immigration activities? What assurances can you give families that parents and students can come and go from school without the fear of being detained by immigration officers?

Ms. DeVos: The Department of Education supports efforts by the Departments of Homeland Security and Justice to enforce our nation's immigration laws, but does not play a role in those efforts.

ED's Role in School Climate for Immigrants

Ms. DeLauro: In response to these deep concerns amongst families about safely bringing their children to school, many schools across the country - both K-12 and postsecondary schools - have passed "sanctuary," "safe zone," or "welcoming" resolutions. Are you supportive of these efforts? Can you provide further clarification on the role of the Department in promoting school climates that are safe and free from federal immigration interventions?

Ms. DeVos: The Department supports meaningful and effective enforcement of the nation's immigration laws, but does not play a role in enforcement activities.

EIR, Vouchers despite Rejection in ESSA

Ms. DeLauro: The budget proposes \$270 million for EIR, a program authorized in ESSA, to "test and build evidence for effectiveness of private school choice." Vouchers were debated and rejected during the passage of ESSA, yet your budget specifically requests funds for vouchers through EIR. Please provide a justification of how funding vouchers through this program is aligned with Congressional intent in the law.

Ms. DeVos: We believe that both the proposed demonstration of private school choice programs and the accompanying appropriations language are entirely consistent with the Education Innovation and Research (EIR) program, which is explicitly intended to support the development and implementation of innovative projects that hold promise for improving student achievement or attainment for high-need students.

Official IDEA Due Process Outreach Efforts

Ms. DeLauro: We know that some schools that accept vouchers require families to relinquish their due process rights and guarantees under IDEA. And it appears that your voucher proposal would not require private schools to enforce IDEA at all, even though its taxpayer funded. Obviously, this has significant ramifications for children with disabilities and their families.

You have made the argument that we need to move away from a "one size fits all" education model. Since becoming Secretary, what official outreach have you conducted with students with disabilities to discuss this proposal? Can you explain how they and their parents and teachers played a role in putting it together? How do they feel about students giving up their rights?

Ms. DeVos: The development of the FY 2018 President's Budget occurred on a dramatically accelerated timeline compared to the typical process, leaving us with limited opportunities for the types of extended outreach efforts I would have liked. However, the Department is always open and willing to discuss the concerns of students with disabilities and their families regarding any of our policy proposals. They are a particularly important and vulnerable population, and we think deeply about any potential effects of our proposals on these students. That being said, I think it is important to note that the status of children with disabilities parentally placed in private schools, including those using vouchers, is clear under the Individuals With Disabilities Education Act (IDEA), and our proposal does not change the rights of these students in any way. Should a State, as a matter of State law, require that private schools guarantee due process rights to students with disabilities participating in a voucher program, or provide those students with special education and related services, as public agencies are required to do under the IDEA, they are free to do so. However, the IDEA is clear about the responsibilities of private schools and public agencies, and the Department is not seeking to change any of the rights afforded to students with disabilities and their families.

Private School Enrollment Guarantees for Vouchers

Ms. DeLauro: In voucher programs, private schools have maintained their right to deny admission to students, including students with disabilities. Private schools have also claimed they cannot provide the services and supports needed for students with disabilities.

Should schools accepting vouchers guarantee enrollment of students with disabilities and should those schools provide the services outlined in their IEP?

Ms. DeVos: All children, including children with disabilities, should have access to the very best education that we can offer. For some students, that is in a classroom in their geographically assigned school. For others, it may be in a charter school, a magnet program, or a private school. I believe that parents and children should have access to the full range of educational options to find the setting best designed to help them reach their potential. However, the Individuals with Disabilities Education Act (IDEA) is clear that not all of these educational environments are subject to the same requirements under the law. Requiring private schools to implement individualized education programs (IEPs) for

children with disabilities placed by their parents in such settings would be contrary to the framework of IDEA, and the proposals in the FY 2018 President's Budget do not contemplate any changes to that statute.

IDEA Compliance Expected of Private Schools

Ms. DeLauro: Several members of the subcommittee asked about the due process rights for students with disabilities under your voucher proposal. When questioned about the rights of students with disabilities in schools, you consistently point to State flexibility. Ultimately, IDEA is a federal law and States do not have the choice whether or not to implement it

Will the Department require private schools in any federal voucher proposal to implement the federal law – IDEA – to provide an education to students with disabilities?

Ms. DeVos: The Department is committed to ensuring that the Individuals with Disabilities Education Act (IDEA) is fully and appropriately implemented under any Federal voucher program. Under the terms of that law, private schools are not required to guarantee a free appropriate public education or provide special education and related services to parentally placed children with disabilities. To require private schools to do so as a matter of Federal policy would be contrary to the statute, and this Department does not plan to engage in any activities or institute any requirements that contravene a law passed by Congress. Should a State, as a matter of State law, choose to extend protections similar to those provided under the IDEA to students with disabilities enrolled in public schools, they are free to do so, but we do not believe the Department currently has the authority to do so under the clear terms of the IDEA.

Protecting Parent Rights

Ms. DeLauro: During the hearing, you pointed to it being a parent's choice to sign away their rights in Florida. Schools receiving federal dollars do not get to pick and choose with components of IDEA are implemented. What steps would you take to ensure parents do not sign away their rights under any federal voucher proposal?

Ms. DeVos: You are correct that States and Local Educational Authorities (LEAs) receiving funds under the Individuals with Disabilities Education Act (IDEA) are required to meet the terms of that statute. However, the requirements of the IDEA do not extend to all entities receiving any Federal funding, and the IDEA is clear about the rights and responsibilities of public agencies and private schools regarding services for children with disabilities who are parentally placed in private schools. As such, it is critically important that parents and families understand the implications of any decision regarding educational choice, and the Department annually provides more than \$27 million to nearly one hundred grantees nationwide dedicated to ensuring that parents understand their rights under the IDEA. These parent training and information centers will serve a critical role in any rollout of a Federal voucher program to ensure that the needs of students with disabilities are met,

and parents fully understand any decisions they make regarding the educational future of their children.

Florida McKay: Why an Example?

Ms. DeLauro: Throughout your exchanges with members of the subcommittee and when discussing vouchers for students with disabilities, you point to the Florida McKay program as a model. Unfortunately, there has been significant waste, fraud, and abuse of public dollars going into this program. Further, students with disabilities are often in segregated schools and the quality of education is unknown without proper oversight. Please explain why this program is a model and upholds the tenets of IDEA.

Ms. DeVos: Waste, fraud, and abuse are unacceptable in any program, particularly one that allocates the tax dollars of hard-working Americans. I believe deeply in helping all children, including children with disabilities, meet their full potential; and we need to ask ourselves whether our current system does that for all children. Far too many children in this country are held back by our focus on buildings and systems, not children. The McKay program provides options for parents, understanding that our job should be to help kids succeed, not to maintain the status quo when it's not working. I can assure you that, should Congress adopt the Administration's voucher proposal, I will do everything in my power to ensure that not a single taxpayer dollar is lost to waste, fraud, or abuse. We owe it to our children to make our investments work for them, and every dollar wasted is one that doesn't help a child become the very best version of herself possible.

Maintaining Voucher Advocacy despite IES Evidence against Effectiveness

Ms. DeLauro: The proposed budget justifies drastic cuts for various education programs because they are "duplicative, ineffective, or more appropriately supported through State, local, or private funding sources." The Institute of Education Sciences' gold standard evaluation of the only federally funded voucher program found that vouchers negatively impacted student achievement. This report comes on the heels of recent studies in Louisiana, Ohio and Indiana that arrived at similar conclusions. Why are you proposing to spend taxpayer dollars on programs that have been shown to be ineffective or have a harmful impact on student achievement?

Ms. DeVos: We believe that recently released studies of various private school voucher programs, most of which examined student progress after only one or two years, are not conclusive and, in fact, demonstrate a need for further evaluation of the long-term impact of vouchers on student outcomes, including such outcomes as high school graduation and enrollment and success in postsecondary education. Consequently, we think it makes sense to propose a modest expansion of Federal support for private school voucher programs. We note that the \$250 million increase proposed for the Education Innovation and Research (EIR) voucher competition in the FY 2018 President's Budget request is less than 1/2 of one percent of the Department's total discretionary request.

Justifying Cutting Title IV-A

Ms. DeLauro: Congress created a block grant program in ESSA to give districts local control and wide discretion to prioritize investments in a well-rounded curriculum that we know is critical to student learning and development, supporting safe and healthy students, and supporting effective uses of technology. Your budget's proposed elimination of Title IV-A funding would reduce schools' abilities to provide critical college and career preparation classes as well as activities that promote positive school climates, including school-based mental health services. How can you justify eliminating funding that helps ensure students have access to a quality and equitable education?

Ms. DeVos: The Title IV-A Student Support and Academic Enrichment Grants program delivers formula-based grants that for the majority of Local Educational Authorities (LEAs) are too small to have a meaningful impact. For this reason, Title IV-A was a lower priority in an FY 2018 President's Budget request that aimed to increase support for national security and public safety without adding to the Federal budget deficit. In addition, most of the activities authorized under Title IV-A may be supported through much larger and similarly flexible programs like the \$15.5 billion Title I Grants to LEAs program.

15% CTE Cut and National Security

Ms. DeLauro: Recently, the House Education and Workforce Committee marked up the reauthorization of the Carl D. Perkins Career and Technical Education Act (CTE). It cleared the committee with unanimous approval. You and the President both have publicly stated that you would like to emphasize workforce training and pushed back on the idea that a four-year college degree should be a requirement for every student. Programs funded through the CTE Act are integral to aligning education with workforce training and empowering students to achieve meaningful postsecondary credentials and degrees beyond just the four year bachelor's degree through strengthening the pipeline from high school to career.

Your budget proposes to cut CTE state grants by 15 percent in order to increase funding for national security. How would having a less educated citizenry make our nation more secure? As Congress considers a bipartisan and comprehensive reauthorization of CTE that makes needed improvements to the program, is a proposed 15 percent reduction in funding indicative of your commitment to implement program improvements and support high quality CTE?

Ms. DeVos: While the Administration does support the role Career and Technical Education (CTE) programs play in helping students attain the technical skills they need to get jobs that pay good wages, a decrease was necessary to align with overall Budget priorities and maintain the fiscal discipline necessary to support the President's goal of increasing support for national security and public safety without adding to the Federal budget deficit. The FY 2018 President's Budget request would continue to provide significant flexible formula grant funds that support State and local efforts to implement high-quality CTE programs. Federal CTE funding constitutes a small percentage of the overall funding for CTE programs across the nation, and we expect that support for high-

quality CTE programs from other sources would continue, despite the proposed reduction in Federal funds.

STEM Contest on top of CTE Cuts: Rationale

Ms. DeLauro: The budget request includes a \$20 million proposal for CTE National Programs to hold a competition related to STEM fields. Why does the Administration propose a small competitive grant program as well as a 15 percent reduction to the state formula program?

Ms. DeVos: The Career and Technical Education (CTE) Science, Technology, Engineering and Math (STEM) proposal in the FY 2018 President's Budget request reflects the Administration's commitment, even in a time of fiscal constraint, to support innovative instruction and training in an area of critical importance to our technology-based economy. The regular CTE formula grants program generally does not provide sufficient funding to support innovative, potentially ground-breaking demonstration projects and also doesn't require the kind of coordination across secondary and postsecondary CTE programs that can both improve outcomes for students and maximize the Federal CTE investment.

How Budget Does (or Doesn't) Move to Full IDEA Funding

Ms. DeLauro: Chairman Cole highlighted the recent Supreme Court ruling on the Endrew case in which the unanimous Court opinion stated the obligation of schools to provide a meaningful educational benefit for students with disabilities. He described that this will likely require school districts to provide more services and there will be budget ramifications. In your response, you described your budget as anticipating fully funding IDEA. The President's budget proposes a \$113 million cut from IDEA Part B. Can you explain how this budget moves towards fully funding IDEA?

Ms. DeVos: Thank you for the opportunity to clarify this issue, as I know it is of paramount concern to millions of parents, students, and teachers across this country. As you know, the timing of this year's budget request and appropriations process was unique. The President's FY 2018 Budget request was developed in advance of final passage of a FY 2017 appropriation. As a result, the request may seem to propose a reduction for a particular program when the policy was, in fact, level funding. In a budget environment where we were forced to make exceptionally difficult decisions, not a single program funded under Individuals with Disabilities Education Act (IDEA) was proposed for reductions. We recognize that full funding for IDEA is a heavy lift, and we hope that Congress will show the same commitment to maintaining historically high funding levels for IDEA as has the Administration.

Steps Planned to Ensure Equitable Education for IDEA Students

Ms. DeLauro: During this exchange with Chairman Cole, you also describe the federal government's role in the education of students with disabilities as being important. What steps will you take to ensure all schools receiving federal dollars are implementing

IDEA and providing a meaningful educational benefit that enables students with disabilities to obtain an equitable education?

Ms. DeVos: As you know, all States and public agencies receiving funds under the Individuals with Disabilities Education Act (IDEA) are required to fully implement the law, including ensuring access to a free appropriate public education for all children with disabilities in the least restrictive environment. The Department is committed to helping States and Local Educational Authorities (LEAs) meet these requirements through targeted monitoring and technical assistance, and the targeted use of competitive grant funds. Several years ago, the Department shifted its approach to State monitoring under IDEA to the Results Driven Accountability (RDA) framework. Under RDA, the Department focuses its provision of technical assistance (and its monitoring efforts), on State identified measurable results helping States achieve their own goals, identified through a rigorous process of self-examination work that is supported by a \$43 million investment in a technical assistance center. The Department also makes available a wide array of technical assistance documents and tools designed to help States align with evidence-based practices proven to improve results for students with disabilities. The Department's competitive grant portfolio is also designed to help States meet the needs of students with disabilities and implement best practices, including:

- a \$21 million investment in supporting States seeking to align their special education teacher certification and licensure standards to align with evidence-based practices;
- a \$50 million per year investment in helping to train the next generation of special education teachers and related services providers, prepared to meet the needs of children with low-incidence disabilities;
- a \$17.5 million investment in helping States and local educational agencies implement positive behavioral interventions and supports to reduce suspensions and expulsions, particularly for students with disabilities;
- a \$10 million investment in providing technical assistance to States and local educational agencies on best practices related to the inclusion of children with disabilities in the general education environment to the maximum extent possible; and
- a \$3.5 million investment in model demonstration projects to build the knowledge base around what works for students with disabilities.

Elimination of Special Olympics

Ms. DeLauro: The President's budget proposes eliminating funding to the Special Olympics for education activities. First established in the 1960s, the Special Olympics program has grown to provide support individuals with intellectual disabilities in "discover[ing] new strengths and abilities, skills and success." In particular, the Unified Schools program helps to promote inclusive opportunities for students with disabilities. Ultimately, Special Olympics is a critical component of helping students with disabilities receive an inclusive education and enabling them to grow and reach the objectives of

IDEA. Please provide a thorough justification for the elimination of the program beyond the information provided in the budget justification.

Ms. DeVos: While the Administration agrees that the Special Olympics education programs, including the Unified Schools program, support worthwhile activities that benefit individuals with disabilities, the Administration believes that these programs are more appropriately supported with philanthropic funds, and does not believe additional funding is necessary for the successful operation of Special Olympics. Special Olympics is a well-established non-profit organization with a broad network of program volunteers and supporters. Special Olympics has been successful in raising financial support through such vehicles as direct mail contributions, individual and corporate contributions and sponsorships, investments, non-Federal grants, royalty income, and accreditation fees. In fiscal year 2015, Special Olympics boasted 856,729 donors/members, with over \$101 million of revenue raised from donors, and an additional \$5 million of revenue collected through other non-Federal sources. With a board of directors that includes businessmen, attorneys, Olympic medalists, former professional athletes, recording artists, and other well-known public figures, Special Olympics is well positioned to generate additional support for program activities through non-Federal sources.

Supported Employment State Grants

Ms. DeLauro: The budget proposes to eliminate Supported Employment State Grants, a program that provides services to individuals with disabilities who need more extensive services than what is provided through the Vocational Rehabilitation State Grant program. Supported Employment State Grant program was recently reauthorized in the bipartisan Workforce Innovation and Opportunity Act (WIOA). As the budget justification notes, WIOA made significant changes to the provision of supported employment services, including the provision of services to youth with the most significant disabilities. What stakeholders with extensive knowledge of these programs were consulted when making this decision?

Ms. DeVos: I recognize the importance of assisting our most vulnerable youth, particularly youth with the most significant disabilities, as they transition from school to work, including providing opportunities that will lead them on the pathway to employment in competitive integrated employment or supported employment. I also recognize the value of supported employment services in assisting those individuals with the most significant disabilities who might not otherwise be able to obtain and maintain competitive employment in an integrated setting. However, I do not believe that a separate supplemental grant program is necessary for the provision of supported employment services when the provision of such services is already authorized and largely payed for with Vocational Rehabilitation (VR) State Grant funds. In fact, proposals to eliminate or consolidate the Supported Employment (SE) State Grants funds have been included in 10 annual Budget Requests to Congress over the last 15 years; and we are well aware of the benefits and challenges of our proposal, including the challenges that have arisen in implementing amendments to the SE State Grants program made by the Workforce Innovation and Opportunity Act (WIOA).

The SE State Grants program does not provide more extensive services than what is provided through the VR State Grants program. VR State agencies provide supported employment services to assist eligible individuals with the most significant disabilities who have been determined through the VR program to need intensive services and ongoing supports to achieve a supported employment outcome. Supported employment services are provided by the VR agency, for a period of not more than 24 months (unless under special circumstances the eligible individual and the rehabilitation counselor jointly agree to extend the time to achieve the employment outcome identified in the individualized plan for employment), with VR funds, or in conjunction with the supplemental funds provided under the SE State Grants.

For example, in FY 2015, State agencies spent a total of \$210.2 million to provide purchased services for individuals with a goal of supported employment, 87 percent (\$183 million) of which were from Title I VR funds. The cost of purchased services is in addition to the costs of services provided directly by VR agency staff under the VR State Grants program. In addition, amendments to the Rehabilitation Act of 1973 (Rehabilitation Act) made by WIOA changed the maximum amount of administrative costs permitted under the SE State Grants program from 5 percent to 2.5 percent. Because the cost of administering the SE State Grants program exceeds the current 2.5 percent limit (and the prior 5 percent limit), VR State Grant funds have and are currently being used to pay the majority of the administrative costs for the SE State Grants program. For example, VR State agencies typically charge all indirect costs incurred under the SE program to the VR award.

Administrative burden, including reporting and accountability, continues to be a challenge for the Department and States. Due to the supplemental nature of these grants, States have difficulties in accounting for the use of SE funds at an individual level, and thus we do not have reliable data on the number of individuals that benefit specifically from these supplemental funds. Ensuring that States meet the new program and administrative requirements for the SE State Grants program that were added by the WIOA amendments to the Rehabilitation Act has significantly increased burden. Given the relative high level of administrative burden at both the Federal and State levels, the overall benefit of these additional resources is significantly reduced.

While amendments to the SE State Grants program seek to leverage non-Federal resources to generate additional funds for expanded services (i.e., extended services) to youth, the 10 percent match that States must provide for half their SE grant allotment is not likely to have an appreciable impact in generating resources to cover the cost of extended services given the relatively small size of most SE State Grant program awards. Half of the States still receive the minimum allotment of \$300,000. With a few exceptions among the minimum allotment States, a State's SE allotment only provides a one percent increase in funds relative to their VR allotment.

I believe that we need to find more efficient and effective ways of providing resources to States without increasing the burden of carrying out largely duplicative programs. We are happy to work with Congress to ensure that the needs of youth with the

most significant disabilities who require supported employment services continue to be addressed under the VR State Grants program.

Review of Data Collection and Best Practices

Ms. DeLauro: The President's budget proposes a \$158 million increase to the Charter School Program. Strong accountability and oversight are critical to ensuring non-profit, high-quality charter schools provide public education options to students. Based on your proposed increase in Charter funding, it is critical that we understand your approach to charter school management. Have you reviewed data collection efforts and determined what is necessary for effective charter school management as you committed to do in responding to a question for the record from Ranking Member Murray in your confirmation hearing?

Ms. DeVos: The Department continuously works to improve management and oversight for all of the programs it administers, including the Charter Schools Program. For example, in the area of data collection, beginning with the 2016-2017 school year, we will be collecting new charter school data elements from State educational agencies as part of EDFacts. These new data elements include information on charter management organizations (CMOs) and education management organizations (EMOs) that will improve transparency and help the Department, States, and other oversight entities provide stronger accountability for Federal charter school funds.

OIG CMO Review

Ms. DeLauro: Similarly, in the past you committed to reviewing the Office of the Inspector General's report on Charter Management Organizations (CMOs) and Education Management Organizations (EMOs) released on September 29, 2016. Have you reviewed this report, and if so, which of OIG's recommendations will you follow that are outlined in this report? Are there efforts beyond the recommendations in the report you are considering in order to strengthen the oversight and accountability for charter schools?

Ms. DeVos: The Department has reviewed the OIG report and has taken initial steps in response to each of the recommendations in the report. In addition, as previously noted in regard to expanded data collection on Charter Management Organizations (CMOs) and Education Management Organizations (EMOs) through EDFacts, the Department has undertaken and will continue to take additional actions to strengthen its oversight of the Charter School Program. At the same time, our authority is limited primarily to oversight of direct grantees, and we do not have the resources to monitor directly the more than 6,400 charter schools currently operating across the nation.

Ways to Modify Mismanagement Moving Forward

Ms. DeLauro: What steps have been taken thus far to address the identified mismanagement of funds moving forward, and how will the Department increase oversight in order to guarantee effective use of the funds in order to best serve students?

Ms. DeVos: As part of the corrective action plan that was developed in response to the recommendations of the Office of Inspector General (OIG) audit report and approved by OIG, the Department has formed an internal oversight working group comprised primarily of staff from the Office of the Deputy Secretary (including the Risk Management Service), the Office of Elementary and Secondary Education, the Office of Special Education and Rehabilitative Services, and the Office of Innovation and Improvement (OII), which as of June 2017 has conducted three quarterly meetings. In addition, OII has discussed the topic of the audit report with Charter Schools Program (CSP) grantees during its 2016 and 2017 grantee project directors conferences. The Department also will: (1) issue guidance on charter school management and oversight practices no later than December 2017; (2) modify program monitoring protocols under the CSP, Title I of the Elementary and Secondary Education Act (ESEA), and Individuals With Disabilities Education Act (IDEA), to ensure appropriate oversight of charter schools that are affiliated with Charter Management Organizations (CMOs); and (3) update the Compliance Supplement to include appropriate procedures for reviewing charter school relationships with CMOs.

Rationale for \$1.2 Billion Cut to After School Programs

Ms. DeLauro: The 21st Century Community Learning Centers program provides opportunities for low-income students to participate in afterschool programs. These programs provide academic enrichment activities, services to reinforce and complement the regular academic program, and literacy programs. It was established by Congress to award grants to rural and urban public schools, or consortia of such schools, to enable them to plan, implement, or expand projects that benefit the educational, health, social services, cultural and recreational needs of the community. Based on data reviewed by the Afterschool Alliance, close to 1 in 3 students improved their math and language arts grade, 7 in 10 improved their homework completion and class participation, and 2 in 3 improved their classroom behavior. Please explain why you decided to eliminate the nearly \$1.2 billion in funding for these critical programs that help low-income students in light of this evidence that the program works?

Ms. DeVos: While there is research indicating the effectiveness of afterschool programs in general, performance data demonstrates the specific afterschool programs funded by the 21st Century Community Learning Centers (21st CCLC) are, overall, not helping students meet challenging academic goals. For example, on average from 2013 to 2015, less than 20 percent of program participants improved from not proficient to proficient on State assessments in reading and mathematics. Additionally, student improvement in academic grades was limited, with States reporting higher math and English grades for less than half of regular program participants. Moreover, fewer than half of students served attend the program enough to be counted as "regular program participants," with States reporting that 752,000 out of 1.8 million participants attended 21st CCLC programs for 30 days or more during the 2014-2015 school year. These performance data generally confirm the findings of the last rigorous national evaluation of the program, conducted in 2005, which also found the program had limited academic impact and low student attendance rates. These data strongly suggest that the 21st CCLC

is not generating the benefits commensurate with an annual investment of more than \$1 billion in limited Federal education funds.

OCR, Discrimination and Federal Funding

Ms. DeLauro: If a school is known to discriminate against an ethnic, religious, or racial minority, to discriminate against students based upon their disability status, or to discriminate against students for their sexual orientation or gender identity, should that institution be allowed to receive federal funds?

Ms. DeVos: Congress has charged the Department with enforcing laws that prohibit discrimination in federally assisted programs and activities on the basis of race, color, or national origin (Title VI), sex (Title IX), or disability (Section 504). Every recipient of federal financial assistance, as a condition of receiving federal financial assistance from the Department, is required to execute an assurance that it will comply with the requirements of these laws. Under my leadership, the Office for Civil Rights will vigorously enforce these laws.

Status of Discriminatory P-12 Institutions

Ms. DeLauro: What is the present scope of the problem at K-12 schools nationwide that are known to discriminate against ethnic, religious, or racial minorities, students with disabilities, and LGBTQ students? How many such campuses presently exist? Do any presently receive federal funding?

Ms. DeVos: The Department's Office for Civil Rights (OCR) enforces laws that prohibit discrimination in federally assisted programs and activities on the basis of race, color, or national origin (Title VI), sex (Title IX), or disability (Section 504). Every recipient of federal financial assistance, as a condition of receiving federal financial assistance from the Department, is required to execute an assurance that it will comply with the requirements of these laws. OCR conducts complaint investigations, OCR-initiated compliance reviews, and directed investigations of particular recipients of federal financial assistance to determine if they are in compliance with the laws OCR enforces. An OCR determination that a particular recipient has violated one (or more) of the laws that OCR enforces is based on the facts found in that investigation. In other words, OCR does not "know" that a particular recipient has discriminated unless OCR has found a violation based on specific facts found.

If OCR finds a violation, as required by the civil rights statutes, OCR's first obligation is to attempt to effect compliance by voluntary means. In such a case, OCR will seek an agreement with the recipient, which, if fully implemented, will result in the recipient remediating the violation. OCR monitors the recipient's compliance with the agreement for the duration of the agreement. If a recipient enters into such an agreement and satisfies all requirements of the agreement, it may continue to receive federal financial assistance from the Department. If OCR is unable to obtain compliance by voluntary means in a particular

case, then OCR will act to achieve compliance by means of the actions authorized by the civil rights statutes. This includes termination of (or refusal to grant or to continue) federal financial assistance to the recipient as to whom there has been notice of an opportunity for an administrative hearing and following an express finding on the record that the recipient failed to comply. The statutes also provide that compliance may be obtained by other means authorized by law so that OCR may also refer cases in which voluntary compliance cannot be negotiated to the Department of Justice for judicial enforcement.

Thus, in any case in which OCR found that a recipient violated one of the laws OCR enforces, OCR either obtains voluntary compliance, which as explained above, does not affect the recipient's receipt of federal financial assistance so long as the recipient complies with its agreement to remediate the violation, or OCR, if unable to achieve voluntary compliance, takes action to enforce the law, which, as explained above, may result in termination of federal financial assistance to the recipient following an opportunity for an administrative hearing. In other words, if OCR has made a finding that a recipient has violated one of the civil rights laws for which OCR is responsible, that violation is addressed in accordance with the means required by these statutes.

In addition, in cases in which a recipient expresses interest in resolving issues and allegations before the conclusion of an OCR investigation and OCR determines that it is appropriate to do so in that case, OCR and the recipient may enter into a voluntary agreement, prior to a finding of a violation, whereby the recipient agrees to resolve the issue and allegations in compliance with the applicable law.

OCR issues annual reports about its compliance activities. The following is a link to OCR's most recent annual report: <https://www2.ed.gov/about/reports/annual/ocr/report-to-president-and-secretary-of-education-2016.pdf>.

For more information, the following is a link to a page that links to earlier annual reports: <https://www2.ed.gov/about/offices/list/ocr/congress.html>.

OCR Staff Reductions

Ms. DeLauro: As Secretary, you have a responsibility to ensure every American child has the opportunity to learn in an environment where they feel safe, welcome, and supported. I am disappointed that your budget proposes to cut the Office for Civil Rights by dozens of staff members. What message does this cut send to the students who turn to OCR when their rights have been denied?

Ms. DeVos: The Office for Civil Rights (OCR) will continue to fulfill its mission of vigorous civil rights enforcement. The requested funds would ensure essential program support to resolve complaints of discrimination filed by the public and to ensure that

institutions receiving Federal financial assistance are in compliance with the civil rights laws enforced by OCR. OCR is working to ensure that OCR remains fully capable of accomplishing its core mission to prevent and remedy discrimination by efficiently investigating incoming complaints and utilizing OCR's discretion to initiate compliance reviews and directed investigations to address systemic violations of civil rights.

OCR and Candice Jackson Qualifications

Ms. DeLauro: The new acting head of OCR Candice Jackson who is not subject to Senate confirmation has a limited background in civil rights law and once complained that she experienced discrimination because she is white. She has written favorably about and helped edit a book by an economist who called the Civil Rights Act of 1964 "monstrous." What specific qualifications make Jackson equipped to oversee the Office for Civil Rights?

Ms. DeVos: As a rape survivor and a gay woman, Ms. Jackson understands the importance of pursuing vigorous enforcement of the nation's civil rights laws. She is a civil rights lawyer with extensive experience representing victims of sexual harassment and assault as well as persons accused of such violations. Her legal experience lends itself to developing policies designed to ensure that all claims of campus sexual harassment and violence are thoroughly and fairly investigated and resolved. Under Ms. Jackson's leadership, the Office for Civil Rights (OCR) has already made progress improving the efficiency and effectiveness of OCR's civil rights investigations, dedicating its resources equally to all forms of discrimination complaints.

OCR Enforcement

Ms. DeLauro: In response to a question for the record for your confirmation hearing from Ranking Member Murray, you stated that "the Office for Civil Rights would have [your] strong support in carrying out its statutory obligations to enforce the civil rights law under its jurisdiction" (p. 14, question 10) Does that include Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the base of race, color, or national origin for any federally funded program or activity?

If so, why did you refuse to commit to barring states from using federal funds to discriminate against a Black student during the hearing?

Ms. DeVos: Congress has charged the Department to enforce Title VI, which prohibits discrimination in federally assisted programs and activities on the basis of race, color, or national origin. Every recipient of federal financial assistance, as a condition of receiving federal financial assistance from the Department, is required to execute an assurance that it will comply with the requirements of Title VI. Under my leadership, the Office for Civil Rights will vigorously enforce this law.

Parental Rights and State Law vs Federal and Authority

Ms. DeLauro: Please explain your answer during the exchange with Rep. Clark in which you said the following: "I believe states continue to have flexibility. [] I go back to the bottom line is we believe that parents are the best equipped to make choices for their children's schooling and education decisions and too many children today are trapped in schools that don't work for them. [] States and local communities are best equipped to make these decisions." Are you suggesting parent choice and State law supersede civil rights laws?

Ms. DeVos: The Department is responsible for enforcing laws that prohibit discrimination in federally assisted programs and activities on the basis of race, color, or national origin (Title VI), sex (Title IX), or disability (Section 504). Recipients of federal financial assistance, as a condition of receiving federal financial assistance from the Department, are required to execute assurances that they will comply with the requirements of these laws. Under my leadership, the Office for Civil Rights will vigorously enforce its legal responsibilities regarding institutions that receive federal financial assistance.

Efforts to Prevent LGBTQ Discrimination

Ms. DeLauro: To what extent are you committed to ensuring that federal funds are not used to fund schools, public or private, that discriminate against or exclude LGBTQ students, students of color, and students with disabilities?

Ms. DeVos: Congress has charged the Department with enforcing laws that prohibit discrimination in federally assisted programs and activities on the basis of race, color, or national origin (Title VI), sex (Title IX), or disability (Section 504). Every recipient of federal financial assistance, as a condition of receiving federal financial assistance from the Department, is required to execute an assurance that it will comply with the requirements of these laws. Under my leadership, the Office for Civil Rights will vigorously enforce these laws against institutions that receive federal financial assistance.

Efforts to Include Private Schools in Data Collection

Ms. DeLauro: The Office for Civil Rights is required to collect and monitor data from every district across the country regarding educational opportunities, discipline, and access. What steps would you take to make sure private schools receiving federal funds through vouchers, tax-credits, or education savings accounts are included in this data to ensure parents, students, policymakers, and other stakeholders have access to information critical to ensuring equitable opportunities?

Ms. DeVos: The Office for Civil Rights (OCR) is granted authority to collect data in a form and containing such information it determines as necessary to enable OCR to ascertain whether the recipient has complied or is complying with covered civil rights laws. Accordingly OCR administers, and is committed to funding the Civil Rights Data Collection (CRDC), which serves not only as an important enforcement tool, but also as a resource that allows the public to access and use the data for purposes such as making informed educational choices, learning about local civil rights coordinators, and for policy-

making purposes. More than 17,000 public school districts across the nation provide data which may be indicative of exclusionary discipline practices and other civil rights issues identified in this question. Currently, OCR requires data from school districts that place students in educational settings that are not operated by the students' home districts.

Additionally, the Department will continue to explore and evaluate options regarding what data to collect and how best to collect information from these students' home districts as well as schools that educate students with Federal funding through voucher programs so that families across the country can make meaningful and informed school choice decisions that account for the important civil rights issues identified herein.

Integration Programs and Reconsidering Funding

Ms. DeLauro: The Department's Opening Doors, Expanding Opportunity grant program was created to help "communities in preparing to implement innovative, effective, ambitious, comprehensive, and locally driven strategies to increase socioeconomic diversity in schools and LEAs as a means to improve the achievement of students in the lowest-performing schools."

I am disappointed that you ended this program before grants were announced. A Department spokesperson said that the \$12 million grant program was discontinued after you became Secretary because it would not be a wise use of tax dollars, in part because the money was to be used for planning, not implementation.

However, Opening Doors, Expanding Opportunity funds were designed to also support pre-implementation activities, including piloting integration strategies in select schools. In light of this information, are you willing to reconsider your decision to discontinue the program? If not, why not?

Ms. DeVos: We believe that discontinuing the Opening Doors, Expanding Opportunities competition was the correct decision, and we have redirected the planned funding to supplemental School Improvement Grant awards, as promised when we canceled the competition.

Department Role in Upholding Spirit of *Brown v. Board of Education*

Ms. DeLauro: What do you see as the Department's responsibility in ensuring that all students have access to high-quality, integrated public schools (i.e., the promise of *Brown v. Board of Education*)?

Ms. DeVos: Ensuring access to a high-quality education for all students is an essential part of the Department's mission, and the FY 2018 President's Budget request demonstrates a strong commitment to that goal. In particular, we believe that expanding public and private school choice options is an effective strategy for empowering students and families to obtain a high-quality education, and the FY 2018 President's Budget request invests \$1.4 billion in three initiatives to expand school choice: \$1 billion for the Title I

Furthering Options for Children to Unlock Success, or FOCUS; \$250 million for a private school voucher competition under the Education Innovation and Research program; and a \$167.5 million or 50 percent increase for the Charter Schools Program.

Federal Role in School Integration

Ms. DeLauro: To what extent do you support initiatives to integrate schools and reduce racial segregation in schools? How?

Ms. DeVos: We believe that expanding public and private school choice, particularly for students from low-income families in high-poverty schools, is one of the most promising strategies for reducing racial and economic segregation in our school system. As previously noted, the FY 2018 President's Budget request includes \$1.4 billion in new funding to expand school choice.

Opening Doors, Expanding Opportunities Elimination Effect

Ms. DeLauro: Twenty-six districts indicated interest in applying for the Opening Doors, Expanding Opportunities grant program. What impact do you think eliminating the Opening Doors, Expanding Opportunities grant program will have on these districts' efforts to reduce racial segregation in schools, which is the promise of *Brown v. Board*?

Ms. DeVos: Given the small amount of funding involved and the limitation on activities to planning and pre-implementation of proposed plans, we believe that most applicants will be able to continue their work without Federal funding.

Impact Aid Federally Connected Fund Elimination

Ms. DeLauro: Your budget proposes to eliminate Impact Aid Federal Properties. At the hearing, you said: "The portion of the Impact Aid program that we've proposed to eliminate is one that is not tied to any students at all so there are no students being supported in that particular federal land area. Since those locals have had about 40 years to consider this we thought it might be appropriate that they could've figured it out by now." However, there are federally connected students in these schools (even if the formula is based on the valuation of the Federal Property rather than the students), including military connected students. The federal government continues to acquire property and several new school districts have become eligible within the last several years. The notion that school districts should have adjusted to the loss of local tax revenue is unfounded, given that schools rely on tax revenue annually to run their school systems. In some of these communities, the federal government is the largest landowner. As long as the federal government owns property in these communities, the federal government should meet its obligation to schools, students, and taxpayers in those communities through Impact Aid. Why do you propose to eliminate funding that supports federally connected students?

Ms. DeVos: The policy of the Administration is to use available Impact Aid funds to help pay for the education of federally connected children, including children of

members of the uniformed services, children of Federal employees who both live and work on Federal property, children of foreign military officers, children living on Indian lands, and children residing in federally assisted low-rent housing projects. We are committed to providing impact aid support for federally connected children, and our 2018 request maintains that commitment. Our budget request includes only a targeted cut to Impact Aid Payments for Federal Property. Payments for Federal Property are made to districts without regard to the presence of federally connected children. These payments do not necessarily provide for the educational needs of these children. While it is true that districts that receive funding under the Impact Aid Payments for Federal Property program do serve federally connected students, the calculation of these payments to districts has no relationship with the numbers of federally connected students impacted by the federal presence, unlike the Basic Supports Payment and Payments for Children with Disabilities program.

When the Payments for Federal property authority was first established in 1950, its purpose was to provide assistance to Local Educational Authorities (LEAs) in which the Federal Government had imposed a substantial and continuing burden by acquiring a considerable portion of real property in the LEA. The law applied only to property acquired since 1938 because, in general, LEAs had been able to adjust to acquisitions that occurred before that time. Over 64 percent of districts that currently receive Payments for Federal Property first applied before 1970. We believe that the majority of LEAs receiving assistance under this program have now had sufficient time to adjust to the removal of the property from their tax rolls.

Unique Challenges for Native Students

Ms. DeLauro: Native Alaskans did not receive the right to education within their communities until 1975 and the more than 23 percent of the students in the state are Native. Native Hawaiian education was not recognized until 1988 and more than 32 percent of Hawaiian students are Native Hawaiian. Identity and culture have been shown to be critically important to Native student success.

Do you believe that Indian, Native Hawaiian, and Native Alaskan students face unique challenges in attaining a high-quality education? Please explain your view of why these challenges exist. Why have you proposed eliminating the Alaska Native and Native Hawaiian education programs and reducing funding for Indian Education by more than \$21 million?

Ms. DeVos: In the context of the limited Federal role in education, we believe that providing a high-quality education for Native Alaskan and Native Hawaiian students is primarily the responsibility of the States of Alaska and Hawaii and their respective school districts. Moreover, the restoration of State and local control over the use of Elementary and Secondary Education Act (ESEA) funds under the Every Student Succeeds Act will empower local leaders to use other, larger sources of Federal education funds, such as the \$15.5 billion Title I Grants to Local Educational Authorities (LEAs) program, to better meet local needs, including the academic and non-academic needs of Alaska Native and Native Hawaiian students, rather than Federal mandates. Consequently, the FY 2018

President's Budget request proposes to eliminate funding for the Alaska Native Education and Native Hawaiian Education programs because they largely duplicate services that may be funded through other Federal education programs as well as State, local, and private funds. Please note that the FY 2018 President's Budget request provided level funding for Indian education programs based on the FY 2017 annualized Continuing Resolution that was in effect at the time the President's Budget was developed.

Effect of Cuts on HBCU Funding and Affordability

Ms. DeLauro: While the President's budget maintains funding for the Title III, Part B Strengthening HBCUs Program, HBCUs and their students rely on many more higher education and financial aid programs that are cut in this budget. For example in 2015-16, HBCUs disbursed over \$600 million in subsidized student loans to over 150,000 students. These students would face considerably higher college costs under the President's budget proposal to phase out subsidized loans. Has the Department performed an analysis of the effect of cuts to loan subsidies, SEOG, federal work study, and TRIO to the HBCU sector specifically? What would be the change in fiscal outlook at these schools as a result of these proposed cuts?

Ms. DeVos: The Budget provides \$492 million for programs that provide direct support to Historically Black Colleges and Universities (HBCUs), as well as other Minority-Serving Institutions (MSIs), and Hispanic-Serving Institutions through the Higher Education Act Titles III and V programs. Titles III and V funding are important vehicles for helping close gaps among racial and socioeconomic groups in college enrollment and degree attainment by improving these institutions' academic programs, institutional capacity and student support services. Within this amount, the Administration's budget proposes \$244.2 million to support HBCUs and \$63.2 million to support Historically Black Graduate Institutions, representing more than 62 percent of the funds set aside for MSIs.

Interpreting Donald Trump's Signing Statements Regarding HBCUs

Ms. DeLauro: President Trump's signing statement that accompanied the FY 2017 omnibus implies that HBCU Capital Financing funding is unconstitutional and that HBCUs discriminate against non-African Americans. HBCUs are designated as such based on mission, accreditation status and the year the institution was established. Our analysis shows that funding for HBCUs has never before been mentioned in a signing statement, let alone has its constitutionality been challenged.

Why did the signing statement mention HBCUs? There are numerous other programs at the Department that provide funding based on HBCU-status. Why were those programs not named?

Ms. DeVos: The President's statement was not intended to signal any change in policy regarding Historically Black Colleges and Universities (HBCUs), and the President also publicly re-affirmed this Administration's ongoing commitment to and "strong

support" for HBCUs. The President's comment was solely intended to reinforce the fact that the Administration expects to operate all programs in accordance with the requirements of the Constitution, which is already being done for the HBCU programs. A similar sentiment has been conveyed by every President going back to President Reagan, but previous Presidents have generally not called out specific programs.

SEOG Elimination and Helping Poor Students

Ms. DeLauro: Your budget eliminates all funding for the Supplemental Educational Opportunity Grant, or SEOG, which would take \$733 million away from 1.6 million students. Your administration has suggested this program isn't well targeted to needy students, even though 80 percent of dollars go to students whose families earn less than \$30,000 or who are independent and very likely to be low income. What flaws did you identify in the SEOG program? If the program is imperfect, why not reform it instead of yanking away this crucial resource? What exactly are you doing to help make college more affordable to the students with the fewest financial resources? Why is the \$733 million cut from SEOG not being added to the Pell program?

Ms. DeVos: The Supplemental Educational Opportunity Grants (SEOG) program is proposed for elimination because it is not well targeted and it is largely duplicative of the Pell Grant program. The SEOG program does not serve needy students effectively since aid is allocated to institutions primarily based on previous participation in the program. Funds are being added to the Pell program through the restoration of year-round Pell, which should help needy students complete college faster and with less debt. Of course, much work remains to be done, which is why I look forward to working with Congress to consider all policy options available to help improve higher education access, accountability, and affordability as part of the Higher Education Act reauthorization process.

De Facto Pell Reduction: Justification

Ms. DeLauro: Your budget proposal cuts \$4 billion from Pell Grant funding and allows the annual inflation adjustment to the maximum grant to expire, meaning in real terms all 7.5 million Pell recipients would have their grants cut next year. Do you support the continued expansion of Pell to help low-income students afford the cost of college? How can you justify taking funds from the Pell Grant program and letting inflation reduce the value of the grants? Why is the inflation adjustment not included in the budget proposal?

Ms. DeVos: This Administration is committed to supporting and sustaining the Pell Grant program, which is crucial to so many students. The Budget reflects that by fully funding the program at the maximum award calculated by statute, \$5,920 for the 2018-19 award year. The proposed \$3.9 billion cancellation of unobligated funds would not affect students or decrease awards. We expect the Pell Grant program to remain fiscally sound for the foreseeable future.

Pell Guidance: Expected Release Date

Ms. DeLauro: I am proud that my colleagues and I were able to reinstate Year Round Pell grants in the FY 2017 omnibus. The explanatory statement accompanying the omnibus directs the Department to release guidance by July 1, 2017. When will the Department release its guidance?

Ms. DeVos: The Department issued guidance to institutions through a Dear Colleague Letter on June 19th.

Impact of CCAMPIS funds elimination

Ms. DeLauro: Have you provided any technical assistance, or are you in the process of providing any technical assistance, to institutions on best and efficient practices in addressing college students' child care needs? Given that you have acknowledged the need for addressing college students' child care needs, why have you proposed to completely eliminate funding for CCAMPIS? What do you anticipate the impact of eliminating funding for CCAMPIS will be?

Ms. DeVos: While the Administration agrees that the Child Care Access Means Parents in School (CCAMPIS) program supports worthwhile activities that benefit low-income parents in postsecondary education through campus-based child care services, there is limited evidence of the effectiveness of this program. We believe the minimum grant requirement of \$10,000 spreads dollars too thin across too many program objectives to have much of an impact. In addition, eliminating this program is consistent with the Administration's intent to eliminate programs that are more appropriately supported with State, local, or private funds. The President FY 2018 Budget request maintains funding for existing programs within the Department of Health and Human Services Administration that provide services that assist low-income parents with child care needs.

Disparate Discipline Practices

Ms. DeLauro: Have you reviewed, as you said you would in response to questions for the record for your confirmation hearing, documents related to reduce exclusionary disciplinary practices, which have a disproportionate impact on minority students, students with disabilities, and LGBTQ students?

Ms. DeVos: We are reviewing Office for Civil Rights regulations and guidance addressing this issue. The Department is firmly committed to ensuring vigorous enforcement to prevent discrimination in school discipline, and to providing resources to states, localities, and schools to help them provide safe and supportive learning environments for students and teachers.

Title IX and State/Local Autonomy

Ms. DeLauro: Do you believe that states and localities may choose whether to comply with federal civil rights laws? Is it the view of the Department that states and localities may individually decide whether Title IX protects transgender students?

Ms. DeVos: All programs and activities that receive federal financial assistance (recipients) must comply with federal civil rights laws, including states and localities that receive such assistance. Under my leadership, the Department's Office for Civil Rights (OCR) will continue to vigorously enforce all of the federal civil rights that it is charged with enforcing, including Title IX. OCR has made clear that transgender students may be victims of sex discrimination under Title IX. Anyone, including a transgender student, who believes that a recipient has engaged in sex discrimination, may file a complaint with OCR.

Transgender Title IX Rescission

Ms. DeLauro: You recently stated that you "consider protecting all students, including LGBTQ students, not only a key priority for the Department, but for every school in America. We owe all students a commitment to ensure they have access to a learning environment that is free of discrimination, bullying and harassment." How are learning environments for transgender students made safer by the Administration's decision to rescind the guidance to schools regarding their obligations under Title IX?

Ms. DeVos: In the Dear Colleague Letter (DCL) rescinding the 2016 guidance, and in the statement I released at the time of that rescission in February, I clarified that the guidance was being rescinded first and foremost because it was procedurally improper, not having been issued after appropriate public notice and comment. I also emphasized that a one size fits all federal mandate for intimate facilities in schools was not an appropriate approach, when this issue can and should be left to states and local districts to find reasonable solutions that take into account the needs of all students. Finally, I emphasized that rescission of that guidance in no way diminishes the Department's commitment to protecting all students, regardless of gender conformity, from harassment and bullying and promoting education environments that support and meet the needs of all students.

The withdrawal of the 2016 guidance does not leave transgender without protections. The Office for Civil Rights (OCR) continues to rely on Title IX and its implementing regulations, as interpreted in decisions of federal courts and OCR guidance documents that remain in effect, in evaluating complaints of sex discrimination, whether or not the individual is transgender. OCR has made clear in internal guidance to its regional enforcement offices that even though the 2016 DCL on transgender students has been withdrawn, transgender students may still be the victims of sex discrimination under Title IX, and OCR investigators must take their complaints seriously.

Gainful Employment

Ms. DeLauro: At the subcommittee's Inspector General hearing earlier this year, the Department's IG agreed with me that quote - "the gainful employment rule is a good rule in terms of protecting kids and protecting taxpayers' dollars."

As I mentioned in my statement, CBO estimated that repealing the Gainful Employment rule would cost taxpayers \$1.3 billion over 10 years. I am alarmed that you issued a delay for two key deadlines as one of your first acts as Secretary.

Can you commit to no further delays? Will you implement the rule as written?

Ms. DeVos: On June 16, 2017, the Department published a notice in the Federal Register of its intent to establish two negotiated rulemaking committees, one of which will develop proposed regulations to revise the gainful employment regulations. Other than delays to the deadlines for alternative earnings appeals and disclosure requirements (specified in Federal Register notices published on March 6, 2017, and July 5, 2017), the gainful employment rule will remain in effect as implemented since July 1, 2015 while revisions to the rule are negotiated.

ITT Tech Borrower Defense

Ms. DeLauro: Your spokesperson says that you are "committed to protecting students who have been defrauded by schools."

1. How many borrower defense loan discharges have been approved under this Administration?
2. How many borrower defense applications are currently pending at the Department?
3. How many defrauded borrowers who were notified by the Department before January 20 that their loans would be discharged have not yet received their discharges?
4. By when will they get their discharges?
5. Why haven't the former students of American Career Institute, who were told their loans would be automatically discharged, had their loans discharged?
6. The Department announced in January that it had received over 2,500 borrower defense claims from former ITT students and was beginning to award the first discharges to affected students. How many ITT students have received discharges and refunds?

Ms. DeVos: 1. No claims have been approved since Jan. 20, 2017.

2. As of July 6, 2017, 65,169 claims were pending.
3. Approximately 1,992 borrowers who received notifications prior to Jan. 20, 2017, have not yet received a discharge.

4. The loans not yet discharged represent complex cases, including claims for non-direct loans. The Department is working to effectuate discharge of these loans as quickly as possible but at this time we do not have a specific timetable for their completion.

5. All loans for ACI claims have either been discharged or sent to the appropriate loan servicer for discharge.

6. No ITT discharges have been processed.

July 1 Borrower Defense Deadline

Ms. DeLauro: In an answer to a question for the record from Senator Murray during your confirmation process, you said defrauded students have a right to seek legal remedies in court. The borrower defense and college accountability regulations finalized in October ensure that federal student loan borrowers can seek justice in the courts, thereby also preventing colleges from evading accountability through forced arbitration, as Corinthian Colleges and ITT did and most large for-profit colleges continue to do. In March, the ED IG testified before this subcommittee that this regulation will also better protect taxpayers from sudden school closures. The regulation goes into effect on July 1. Do you commit to implementing this regulation by July 1?

Ms. DeVos: On June 16, 2017, the Department published a notice in the Federal Register of its intent to establish two negotiated rulemaking committees, one of which will develop proposed regulations to revise the borrower defense regulations. In addition, as indicated in the Notification of Partial Delay of Effective Dates (Section 705) notice published in the Federal Register on June 16, 2017, the Department has postponed the effective date of certain provisions of the final rule published November 1, 2016 pending judicial review. Affected provisions include the standard and process for adjudicating borrower defense claims, financial responsibility standards, loan repayment rate disclosures for proprietary schools, prohibitions against institutions including arbitration or class action waivers in their agreements with students, closed school and false certification discharges, and collection costs associated with loan rehabilitations. The specific regulatory sections for which the 705 Notice delayed the effective dates are:

- § 668.14(b)(30), (31), and (32) Program participation agreement.
- § 668.41(h) and (i) Reporting and disclosure of information.
- § 668.71(c) Scope and special definitions.
- § 668.90(a)(3) Initial and final decisions. § 668.93(h), (i), and (j) Limitation.
- § 668.171 General.
- § 668.175(c), (d), (f), and (h) Alternative standards and requirements.
- Part 668 subpart L, Appendix C.
- § 674.33(g)(3) and (g)(8) Repayment.
- § 682.202(b)(1) Permissible charges by lenders to borrowers.
- § 682.211(i)(7) Forbearance.
- § 682.402(d)(3), (d)(6)(ii)(B)(1) and (2), (d)(6)(ii)(F) introductory text, (d)(6)(ii)(F)(5), (d)(6)(ii)(G), (d)(6)(ii)(H) through (K), (d)(7)(ii) and (iii), (d)(8),

and (e)(6)(iii) Death, disability, closed school, false certification, unpaid refunds, and bankruptcy payments.

- § 682.405(b)(4)(ii) Loan rehabilitation agreement.
- § 682.410(b)(4) and (b)(6)(viii) Fiscal, administrative, and enforcement requirements.
- § 685.200(f)(3)(v) and (f)(4)(iii) Borrower eligibility.
- § 685.205(b)(6) Forbearance.
- § 685.206(c) Borrower responsibilities and defenses.
- § 685.212(k) Discharge of a loan obligation.
- § 685.214(e)(2), (f)(4) through (7) Closed school discharge.
- § 685.215(a)(1), (c)(1) through (c)(8), and (d) Discharge for false certification of student eligibility or unauthorized payment.
- § 685.222 Borrower defenses.
- Part 685 subpart B, Appendix A Examples of borrower relief.
- § 685.300(b)(11), (b)(12), and (d) through (i) Agreements between an eligible school and the Secretary for participation in the Direct Loan Program.
- § 685.308(a) Remedial actions.

Profiting on Loans

Ms. DeLauro: On the campaign trail, President Trump said it was unfair that the government profits from federal student loans and that he would put an end to it. Yet the student loan changes in the Administration's budget generate \$143 billion in additional revenues from student loans, meaning taken together the proposed student loan reforms will increase government profits and make loans more costly for students. How can you justify generating \$143 billion in additional revenues from student loans?

Ms. DeVos: We acknowledge that the need for fiscal discipline required some tough choices in the FY 2018 President's Budget request. Rising student debt is a complex issue and a serious challenge. The Administration is committed to ensuring that all students and their families have access to postsecondary education. It is important to remember that student loans offer generous benefits, including fixed interest rates far below what the market would offer to most students and repayment plans, particularly income-driven plans, to keep their loan payments manageable. Our proposed student loan reforms expedite student debt relief for the most vulnerable borrowers while eliminating inefficient subsidies such as Public Service Loan Forgiveness, which in particular has been linked with incentives for students to over-borrow. At the same time, the FY 2018 President's Budget request would simplify student loan repayment by consolidating five Income-Driven Repayment (IDR) plans into a single plan. This plan would set a borrower's monthly payment at 12.5 percent of discretionary income and shorten the maximum repayment period for borrowers with only undergraduate debt to 15 years (with any remaining balance being forgiven at that point).

Loan Policies Shifting \$20 Billion to Poor Families

Ms. DeLauro: In particular, the Administration's budget eliminates the subsidized student loan program for undergraduate students, a majority of whom are also Pell grant recipients. Department of Education data has shown that Pell recipients are much more likely to borrow than wealthier students and graduate with significantly higher debt balances. Eliminating subsidized loans would result in even higher debt burdens for low-income students. Do you realize that ending the subsidized loan program would shift more than \$20 billion in costs to students from families with the fewest family resources to repay their loans once they graduate?

Ms. DeVos: We acknowledge that the need for fiscal discipline required some tough choices in the FY 2018 President's Budget request. The primary benefit provided by Subsidized Stafford loans is to help student loan borrowers manage their debt once their loans enter repayment. They do this by subsidizing interest payments during certain periods, such as when the student is attending college. However, these benefits are not primarily driven by the student's ability to repay during repayment but rather at the time they took out their loan. The Administration's proposal to simplify student loan programs and student loan repayment by replacing five different income-driven repayment plans with a single plan provides an effective backstop to facilitate student loan repayment for all borrowers.

Income Driven Repayment

Ms. DeLauro: Under current income-driven repayment plans, students must pay 10 percent of their discretionary income, but under the proposed plan, they would pay 12.5 percent. Why increase the amount struggling borrowers owe? Do you really think it's reasonable to saddle graduate students with a 30-year repayment term? Would borrowers that are currently enrolled in an income-driven repayment plan continue to be able to use those plans?

Ms. DeVos: Given that the initial establishment of Income-Based Repayment set monthly loan repayment at 15 percent of a borrower's discretionary income with forgiveness after 25 years, I don't think that an income assessment of 12.5 percent with forgiveness after 30 years for students with graduate debt is disadvantageous. In addition, borrowers with lower incomes (who we assume would be at most risk to struggle making repayments) would see little difference between a 10 percent and 12.5 percent income assessment. For example, a single borrower with \$25,000 in adjusted gross income would see a difference of only about \$15 per month. One of the key aspects of the Administration's proposal is that those borrowers who typically struggle the most with repaying their loans are given the most expedited debt relief.

Institutional Status Conversion

Ms. DeLauro: Your budget proposes a 'streamlined pathway to debt relief for undergraduate borrowers.' To effectuate this concept, it is important that the Department focus on student debt attributable to propriety, for-profit educational institutions. These institutions, particularly those with poor performance histories, continue to draw

significantly more than their proportionate share of federal funds in the form of student loans and grants when compared to non-profit institutions.

I'm concerned that a company with a history of problematic actions is going to be sold to a small nonprofit with no track record of operating a higher education institution. Further, as the Department focuses on proprietary institutions in addressing student debt issues, it must be cognizant of the desire by some underperforming proprietary institutions (such as EDMC) to convert their current status to for-profit institutions in a manner that may significantly reduce appropriate regulatory oversight and may reduce funds available to legitimate non-profit schools and universities. What is the Department doing to ensure that inappropriate conversions from for-profit to non-profit status are not being used to avoid necessary and appropriate regulatory oversight?

Ms. DeVos: The Department's regulations identify certain ownership transactions that require the institution to apply for and obtain approval from the Department to continue participating in Title IV, Higher Education Act (HEA) programs. These include instances where an institution has a change in status as a for-profit, nonprofit, or public institution. With regard to conversions from for-profit to non-profit status, the Department's regulations impose several requirements for an institution to participate in Title IV as a nonprofit. To that end, the Department examines the owner's state authorization and IRS tax exemption status and also determines whether the owner of the institution seeking to convert to non-profit status would retain control and continue to receive the financial benefit from the institution's operation as a Title IV participating institution. The Department will continue to examine closely applications submitted by institutions seeking a change of ownership or control and a conversion from (or to) for-profit to (or from) non-profit status.

Selling Institutions and Special Conditions

Ms. DeLauro: Every past instance of a similar sale has resulted in the imposition of substantial additional conditions. Will you commit to placing the same requirements on this sale? A letter of credit equal to 25 percent or more of Title IV funds? The closure of low value programs, such as those that fail gainful employment? A truly independent monitor to keep track of recruitment, advertising, and admissions practices? Tuition reductions? Targets for improved completion and retention?

Ms. DeVos: The Department will examine closely applications submitted by institutions seeking to convert from for-profit to non-profit status in accordance with its regulations and will analyze the individual facts and circumstances of each sale.

Loan Servicing Policies

Ms. DeLauro: You wrote in the Wall Street Journal that you want to treat student loan borrowers as valued customers. It's extremely hard to square that laudable intention

with the details of the changes the Administration is making that roll back requirements that servicers make reasonable efforts to help borrowers.

Why did you end the requirement that servicers should offer special "high-touch" services to borrowers in need of extra assistance?

Why did you strike out the requirement that servicers should send notifications to borrowers who send their payments to the wrong location?

Why don't you want servicers to have to make contact with borrowers in income-driven repayment plans who have not submitted their required annual recertification?

Why don't you want materials to be available in Spanish?

Why did you withdraw a policy memo from the Obama administration that requires that a company's past performance be considered when deciding whether it deserves new business from Federal Student Aid?

Ms. DeVos: a) Why did you end the requirement that servicers should offer special "high-touch" services to borrowers in need of extra assistance?

In general, changes to the servicing requirements reflect an effort to balance improved service for borrowers with the cost of providing that service. Student loan servicing already costs nearly \$1 billion annually and under current requirements that amount will continue to grow steadily over the next decade as our borrower portfolio increases. As discussed in more detail below, we believe the specific requirements removed from the servicing solicitation would add considerable cost without ensuring a commensurate improvement in borrower outcomes. The Department also believes that other requirements that remain in the solicitation allow the Department to address the goals underlying the items that were dropped in a more efficient, cost-effective manner.

Regarding "high-touch" servicing, the specific requirements were removed to reduce the expected ongoing costs of executing those requirements indefinitely. An entire series of requirements remains in place that will allow FSA to execute outreach campaigns as desired and focus on keeping—and paying for—only those efforts that prove to be effective.

b) Why did you strike out the requirement that servicers should send notifications to borrowers who send their payments to the wrong location?

Under remaining requirements payments sent to the incorrect location will be routed to the proper location and applied with the effective date of when the payment was initially received. Borrowers will continue to receive notifications on where to send payments during any transfer or transition processes. Once the new contract is fully implemented, borrowers will only send payments to one location.

c) Why don't you want servicers to have to make contact with borrowers in income-driven repayment plans who have not submitted their required annual recertification?

Servicers will continue to contact borrowers under the income-driven plans. Under remaining requirements borrowers will be provided up to five notifications to recertify prior to being removed from an Income-Driven Repayment (IDR) plan, as well as at least two more if they fail to recertify and are removed. Other forms of outreach – phone, text, etc. – will be executed if they are determined to be needed and efficient. An entire series of requirements remains in place that will allow FSA to execute outreach campaigns.

In addition, under remaining requirements all customer service agents will receive training on how to assist borrowers and will be able to assist borrowers with questions about IDR. FSA will review and approve all training materials and monitor calls taken by the servicer. The contract will include financial disincentives that will apply when the servicer fails to meet explicit quality standards.

d) Why don't you want materials to be available in Spanish?

Spanish language materials on FSA sites have had minimal usage. Given the cost of building and maintaining a Spanish language version of the loan servicing website, we believe it would be more efficient and cost-effective to provide borrowers with the ability to call the call center and speak with a representative in Spanish.

e) Why did you withdraw a policy memo from the Obama administration that requires that a company's past performance be considered when deciding whether it deserves new business from Federal Student Aid?

Prospective servicers will be evaluated based on their capability to effectively service student loans, provide high-quality customer service, and keep borrowers in good repayment status, as demonstrated by its relevant past performance. A major element of effective servicing is compliance with all relevant legislative and regulatory guidance. Accordingly, all relevant past performance information, including enforcement actions, will be considered. In assessing these factors, FSA reserves the right to obtain past performance information other than that described in the solicitation and to consider such other past performance information in the evaluation and selection for award.

f) Servicers have been fined for impropriety in the past for their mishandling of borrower over- or underpayments. Why would you take away the requirement that directs a servicer to provide online options for their borrowers so the borrower may direct their payments in a way that would better benefit them?

Under remaining requirements borrowers will still be provided with information on the default payment application method both online and in billing statements. The borrower will continue to have the ability to provide instructions on how a payment is to be applied.

g) Typically, a company user tests their materials and products before sending them out to the public, but you removed the requirement directing a servicer to user test their materials annually. If your goal is to treat borrowers like customers why would you take away a requirement that is considered a good business practice across the board?

The communications, notices and training materials used by the servicer to interact with borrowers will all be reviewed and approved by FSA prior to implementation. In addition, the Department still has the option to conduct tests and obtain other customer input in cases where the Department believes it will provide useful information.

h) You put one servicer in charge of a trillion dollar system and eliminate customer service centers that could help funnel the volume, how can you ensure the new servicer has the capacity to deal with a huge and widely diverse student loan portfolio, and how would you oversee the contractors they will inevitably have to hire to handle customer service?

Servicers will be required to demonstrate that they have the capacity to manage the Department's portfolio as part of the proposal evaluation process. While the Department has eliminated unnecessarily prescriptive requirements regarding the use of additional customer service vendors, the Department continues to allow vendors to leverage subcontractors as part of their proposal.

Regarding oversight, the Department recognizes that continued monitoring of the servicer will be needed to ensure the servicer is providing quality servicing. The Department will approve all communications, training, and procedures the servicer is providing. In addition, the Department will execute quality monitoring of borrower communications and provide constant feedback to the servicer as needed to improve service. (This will actually be easier with a single vendor, as the Department will not need to divide limited oversight resources across nine servicers, the current number of servicers.) The contract will include financial disincentives that will apply when the servicer fails to meet explicit quality standards.

Using a single servicer will help to provide consistency for all borrowers while providing a more efficient use of taxpayer money. By requiring that the Department be able to obtain rights to the servicing solution, as well as independently reviewing instructions to operate the solution, we will be able to keep the option available of choosing a different vendor should the current vendor not perform at acceptable levels.

PSLF Elimination Reasons

Ms. DeLauro: Congress created the Public Service Loan Forgiveness (PSLF) program in a bipartisan manner under President George W. Bush. PSLF is intended to help students who want to work in government or non-profit fields and alleviate some of the pressure they may feel to pursue higher paying careers because of student loan debt.

In addition, 81 percent of Black graduates borrow money to complete college, and come out with more debt than their peers, burdening communities of color with debt. Loan repayment assistance programs are key for these communities to attain economic mobility.

Why is the program planned for elimination? Do you believe it a worthy goal to incentivize student borrowers to enter public service jobs? Why do you want to discourage individuals from serving their communities and their country through public service? Should only those who are fortunate enough not to have to take out loans to attend college be able to afford to work in the public sector? Do you believe it is important to have qualified nurses and teachers throughout the country? Do you think it will be important next year as well as this year? If so, why should this option not be available for public servants who begin their career next year when it is (and should be) available for public servants who've just started their career?

Ms. DeVos: The need for fiscal discipline required some tough choices in the FY 2018 President's Budget request, and the proposed elimination of Public Service Loan Forgiveness (PSLF) is a reflection of these tough choices. There is considerable concern over the projected cost of PSLF. We currently estimate it will cost \$27 billion over the next ten years. It is poorly targeted, disproportionately benefiting higher balance, higher income borrowers. It also creates perverse incentives for students to over-borrow on the assumption that their balances will eventually be forgiven. Some graduate schools, most prominently law schools, have used these perverse incentives as marketing tools, at the same time running the risk of expanding graduate programs with little to no regard to labor market demand.

The President's Budget Request proposes to simplify student loan programs and student loan repayment by replacing five different income-driven repayment plans with a single plan aimed at prioritizing effective loan repayment for undergraduate borrowers. The Administration believes that this repayment plan, with payments capped at 12.5 percent of a borrower's discretionary income, and forgiveness provided after either 15 or 30 years of loan payments (depending on whether the borrower has any graduate borrowing), provides an effective backstop to facilitate student loan repayment for all borrowers, including those who work in the public sector.

Protecting and Grandfathering PSLF Recipients

Ms. DeLauro: In a recent legal filing this spring, the Department of Education noted that letters sent out certifying people for this program may not be binding. I am very concerned about the individuals who are having the rug pulled out from under them those who had been told by the federal government that their employers qualified them for PSLF. Many of these borrowers have made major life decisions based on the promise of loan forgiveness and may be betrayed after they have lived up to their end of the agreement.

Will you allow these borrowers to be grandfathered-in for the time period for which they were approved? What are you doing to improve transparency and reduce confusion going forward?

Ms. DeVos: Under 455(m)(1) of the Higher Education Act of 1965, as amended (HEA), a borrower may qualify for forgiveness of a William D. Ford Direct Loan under the Public Service Loan Forgiveness (PSLF) Program if the borrower makes 120 qualifying monthly payments while employed full-time in an eligible public service job. To help borrowers determine if they are on the track for forgiveness, the Department created the Employment Certification for Public Service Loan Forgiveness (Employment Certification) form that borrowers can submit periodically while they are working toward meeting the PSLF eligibility requirements.

When a borrower submits an Employment Certification form, FedLoan Servicing makes a preliminary determination regarding the employer's status and the borrower's status for PSLF. In most cases, FedLoan Servicing can make an appropriate preliminary determination of eligibility based solely on information submitted by the borrower on the Employment Certification form. In a small percentage of cases, however, usually involving employers that are not government agencies or tax-exempt under Section 501(c)(3) of the Internal Revenue Code, FedLoan Servicing or the Department find that the initial determination was based on inaccurate information or was otherwise incorrect and has to be retracted.

To improve transparency and reduce confusion, the Department has 1) revised our website to be clearer about which organizations qualify for PSLF, 2) revised communications to be clearer about why an organization doesn't qualify for PSLF when that is the case, and 3) revised the PSLF forms that borrowers and employers complete to be clearer about the organizations that qualify for PSLF.

FSA IRS Tool Oversight

Ms. DeLauro: As you know, the IRS data retrieval tool was taken down, which has made it much more difficult for students to file a complete FAFSA. What are you going to do to ensure FSA is doing their oversight job, and how are you as Secretary going to hold them accountable? We hear a lot of complaints about how complicated the FAFSA is, and the data retrieval tool made the FAFSA a lot easier for families to complete that form and get the aid they need to go to college. My concern is that, after this issue with the DRT, the Department will no longer create tools that make aid more easily accessible. Going forward, how are you going to make sure the Department is protecting student data while also ensuring students have access to tools that make it easy for borrowers to apply for and receive federal aid?

Ms. DeVos: The Department remains committed to providing efficient, secure, customer-focused tools that will enable individuals to securely complete the FAFSA application. One such tool, the DRT, is the result of a collaborative effort between the IRS and FSA, intended to provide students, parents, and borrowers an easy and effective method to access required IRS tax information and transfer that data directly from the IRS into a FAFSA or an income-drive repayment (IDR) plan application. Following the DRT

data breach, the Department worked closely with the IRS to implement an encryption solution. The solution is in place for the IDR plan application, and will be in place for the 201819 FAFSA with its launch on October 1, 2017. The Department is focused on protecting student data while also ensuring that FAFSA applicants access to tools, information and resources that improve the application experience.

FSA Appointee Parameters

Ms. DeLauro: As you look to fill to fill the chief operating officer for the Office of Federal Student Aid, can you promise that:

Whomever selected will be completely independent of the federal student loan and debt collection industry and have no conflicts with these companies or the other financial entities that invest in them? You will rewrite the Federal Student Aid head's performance contract to make enforcing rules to protect students and taxpayers their primary objective for evaluating their performance?

Ms. DeVos: I was pleased to announce the appointment of Dr. Wayne Johnson on June 20, 2017. Dr. Johnson is a highly regarded leader with more than 30 years of experience in the financial services industry and holds a Ph.D. in higher education leadership. He will be a tremendous asset to the Department as we move forward with a focus on how best to serve students and protect taxpayers.

Secretary DeVos and Chief Operating Officer-designate Johnson will make it a top priority to protect students and tax payers. This will include reviewing, monitoring, and changing — when necessary — the processes and systems that support Title IV aid application and disbursement to assure that taxpayers' dollars are being appropriately deployed and students and families are protected from waste, fraud or abuse.

Ethics Waiver: Secretary

Ms. DeLauro: Have you requested and received a waiver for any policy decisions that impact entities with which you have holdings?

Ms. DeVos: The Secretary has not requested either a statutory (under 18 U.S.C. 208(b)(1)) or a regulatory (under 5 C.F.R. 2635.503(c)) waiver for any policy decision(s) related to her financial holdings. The Department is not aware of the Secretary requesting or receiving a waiver issued or approved under Executive Order 13770; waivers under Executive Order 13770 are issued by the White House and not the Ethics Division of Department's Office of the General Counsel.

Ethics Waiver: Department

Ms. DeLauro: Has anyone at the Department requested and received an ethics waiver?

Ms. DeVos: The Ethics Division of the Department's Office of the General Counsel has not issued either a statutory waiver under 18 U.S.C. 208(b)(1) or regulatory waiver under 5 C.F.R. 2635.503(c) to any political appointee of the Department. However, waivers concerning the Ethics Pledge in Executive Order 13774 are administered by the White House.

The Department can provide information on to statutory waivers under 18 U.S.C. § 208(b)(1); in order to do so, however, more information will be required, including but limited to the time period concerned and the category of employee (i.e., career versus political).

Teacher Shortage in Context of Title II-A Cuts

Ms. Roybal-Allard: The United States, particularly California, is amid a major teacher shortage. Last year, public school classrooms were short approximately 60,000 teachers, and the shortages are particularly difficult for schools and districts in high-poverty areas and in rural communities. These shortages oftentimes a result of high teacher turnover can significantly impact educational opportunities and the quality of education that students receive. Research conducted by New Leaders found that outstanding school principals can attract and retain great educators. Additional research found that teachers often identify a strong principal and supportive administration as more important than salary in their decision to stay at a school.

Secretary DeVos, how do you plan to tackle the teacher shortage issue with which so many of our local schools and districts are dealing?

Ms. DeVos: Three-quarters of Title II-A funds are used for professional development and class-size reduction, neither of which is key strategy for addressing teacher shortages. As previously noted, the FY 2018 President's Budget request would provide nearly \$200 million for the Teacher and School Leader Incentive Grants program, which is designed to build the evidence base on effective practices for attracting and retaining effective teachers that may be supported by other Federal, State, and local funds, including the \$15.5 billion Title I Grants to Local Educational Authorities (LEAs) program.

Budget Addressing Shortages in Context of II-A Cuts

Ms. Roybal-Allard: How does the proposed budget support efforts to address teacher shortages, especially in light of all the cuts made to education, especially Title II-A?

Ms. DeVos: Three-quarters of Title II-A funds are used for professional development and class-size reduction, neither of which is key strategy for addressing teacher shortages. As previously noted, the FY 2018 President's Budget request would provide nearly \$200 million for the Teacher and School Leader Incentive Grants program, which is designed to build the evidence base on effective practices for attracting and

retaining effective teachers that may be supported by other Federal, State, and local funds, including the \$15.5 billion Title I Grants to LEAs program.

Supporting Principals and Leaders

Ms. Roybal-Allard: How do you plan to support principals and other school leaders whose approach is critical to retaining great teachers and who are on the frontlines dealing with this crisis?

Ms. DeVos: We are committed to full and effective implementation of the Every Student Succeeds Act, which was expressly designed to provide State and local educators, including principals and teachers in the classroom, greater flexibility and freedom to use of all education funds, and not just the less than 8 percent of K-12 spending that comes from the Federal government, to improve school performance and student outcomes. We believe that freeing teachers to use their professional training and judgment to meet student needs, rather than following dictates from Washington, will encourage more teachers to remain in the profession.

Evidence for Effectiveness of Other/New Programs

Ms. Roybal-Allard: The proposed budget justifies drastic cuts for various education programs because they are "duplicative, ineffective, or more appropriately supported through State, local, or private funding sources." What is the evidence that other programs in the proposed budget are effective at increasing student achievement, such as the FOCUS grant program?

Ms. DeVos: Consistent with the principles of flexibility and local control that are the guideposts of the Elementary and Secondary Education Act (ESEA) as amended by the Every Student Succeeds Act (ESSA), the President's FY 2018 Budget request emphasizes strong support for flexible formula grant programs that help States and school districts meet the academic and non-academic needs of the vulnerable students who have been the focus of the ESEA for over half a century: students from low-income families, students with disabilities, English learners, and other disadvantaged students. Smaller, less flexible programs, as well as those not directly focused on improving academic outcomes for students, were a lower priority in the FY 2018 President's Budget request. At the same time, we believe school choice empowers students and parents to directly consider evidence of positive academic and non-academic outcomes in light of their specific educational needs. Consequently, expanding school choice through such initiatives as the proposed Title I Furthering Options for Children to Unlock Success (FOCUS) program is a critical accountability strategy for improving outcomes in our education system.

District Input and Financial Impact of Portability

Ms. Roybal-Allard: Through public statements and policy actions, this Administration has made clear that restoring local control is a major tenet of its approach to K-12 education. Yet your budget violates that premise. Instead, your request would

incentivize districts to adopt portability despite warnings from major school districts and nonpartisan stakeholders that portability would undermine local control in limiting districts from using the funds in ways they believe will be most effective.

According to the Los Angeles Unified School District, the second largest school district nationwide, portability will have catastrophic financial implications. School budgets must be set far in advance to allow for the extensive planning needed to hire teachers, arrange classes and plan for student resources and services. This will increase their administrative burden, possibly jeopardizing students' educational experience, with no evidence that it will add value for students.

Has your Department considered the financial implications that portability will have on districts, and has the Department considered how it would mitigate the disruption a portability structure would impose for public school districts, if enacted? Were major school districts consulted in your development of this proposal?

Ms. DeVos: The Title I Furthering Options for Children to Unlock Success (FOCUS) initiative proposed in the FY 2018 President's Budget request is significantly different from the "Title I portability" proposal debated during the development of the Every Student Succeeds Act (ESSA). For example, the Title I FOCUS program would not affect regular Title I allocations to local school districts. And rather than simply provide States with an optional mechanism for reallocating Title I funds, the FOCUS proposal builds on the Flexibility for Equitable Per-Pupil Funding demonstration authority in Part E of Title I of the Elementary and Secondary Education Act (ESEA), as amended by the ESSA, by allowing participating districts to develop comprehensive weighted student funding systems explicitly designed to increase funding for high-poverty schools and other schools serving high percentages of disadvantaged students. Finally, one authorized use of the proposed \$1 billion in funding for the FOCUS initiative would be to provide transition payments to schools that may experience declining enrollments, thus cushioning the financial impact of the open enrollment systems that would be implemented by participating districts.

Evidence for FOCUS Grants

Ms. Roybal-Allard: Your budget justifies drastic cuts for various education programs because they are "duplicate, ineffective, or more appropriately supported through State, local, or private funding sources." What evidence did your Department review that suggested that the FOCUS grant program would effectively increase student achievement?

Ms. DeVos: Our Furthering Options for Children to Unlock Success (FOCUS) proposal is based in part on the growing body of evidence demonstrating that charter schools, which are public schools of choice, have been effective in improving student outcomes and providing options for students and parents seeking access to a high-quality education. We believe that that combination of greater choice for students and parents and greater flexibility over school-level resources provided by weighted student funding

systems holds similar promise for improving student achievement and other academic and non-academic outcomes. But we note that Title I, Part E the underlying authority for Title I FOCUS is a demonstration program that includes a rigorous evaluation requirement, so FOCUS also is about building evidence on what works to strengthen local public education systems.

IDEA and FOCUS

Ms. Roybal-Allard: Last year, the federal government provided only 16% of the average per pupil expenditure of the Individuals with Disabilities Education Act. This amount is far below the 40% threshold Congress committed to help fund the I-D-E-A and has strained school districts' ability to fully provide for I-D-E-A students. The FY18 Department of Education budget request would provide an even smaller percentage of Congress's spending obligation for children with disabilities by cutting Part B State Grants by \$113 million and \$24 million overall from 2016.

In a January 2017 letter to Senator Isaacson, you stated you would pursue "broader educational options" for students with disabilities. Will these "broader educational options" include a voucher program funded through the that will take additional dollars away from the already-constrained special education funding in I-D-E-A? If so, how much more of scarce I-D-E-A funding do you intend to take for your voucher proposal?

Ms. DeVos: Thank you for the opportunity to clarify this issue, as I know it is of paramount concern to millions of parents, students, and teachers across this country. As you know, the timing of this year's budget request and appropriations process was unique. The President's FY 2018 Budget request was developed in advance of the final passage of a FY 2017 appropriation. As a result, the request may seem to propose a reduction for a particular program when the policy was, in fact, level funding. This is the case for the Special Education Grants to States program. No program funded under the Individuals with Disabilities Education Act (IDEA) is reduced nor is any IDEA funding being used to finance the school choice proposals in this Budget.

Michigan Local Turnaround and Lessons

Ms. Roybal-Allard: You have previously stated that "federal law must be followed where federal dollars are in play." However, you previously backed the Education Achievement Authority school turnaround effort in Detroit, Michigan. As you know, the E-A-A has been subject to formal complaints for violating federal special education law through decertifying nearly 800 students from special education status and removing services from individualized education programs.

What lessons did you learn through your experience with the E-A-A, and how would you use your Department's budget to ensure that any school receiving public dollars-whether district, charter, or private- does not engage in abusive and fraudulent treatment of students with disabilities, especially in light of your proposal to reduce federal special education resources?

Ms. DeVos: For anyone who has spent time working in or studying the Detroit Public Schools, it is clear that far too many its schools are not meeting the needs of their students. These children were stuck in schools that were themselves stuck in a cycle of failure. I believed that the Educational Achievement Authority (EAA) held promise for making sweeping changes to schools that were not adequately serving children they were supposed to serve. Unfortunately, the EAA did not bring the dramatic positive changes we all hoped that it would and, in some cases, exacerbated existing problems. Change is never easy, and a one-size-fits-all approach rarely works.

Regarding children with disabilities, the Individuals with Disabilities Education Act (IDEA) is clear about their rights and any attempt by public agencies to subvert their responsibilities under the law or violate the rights of children with disabilities is unacceptable. The Department regularly conducts oversight activities of its grantees under IDEA to ensure that they are meeting their general supervision obligations, including fully investigating, adjudicating, and resolving instances in which children with disabilities have not been provided the full dispute resolution protections afforded them under the law. I can assure you that the Department will continue its efforts to ensure that States and Local Educational Agencies meet their responsibilities under the IDEA.

Signing IDEA Rights Away for Vouchers

Ms. Roybal-Allard: Will you prohibit schools receiving federal monies from requiring students to sign their I-D-E-A rights away?

Ms. DeVos: The Individuals with Disabilities Education Act (IDEA) is very clear about the responsibilities that public agencies, including Local Educational Authorities (LEAs), have regarding support for children with disabilities, whether they attend a public or a private school and the Department does not intend to allow any entity to engage in activities that are expressly forbidden by the IDEA. However, it is important that we clarify the rights and protections that IDEA affords.

Children with disabilities enrolled in public schools, including public schools of choice, such as magnet schools and charter schools, are entitled to a free appropriate public education (FAPE) in the least restrictive environment and are afforded all of IDEA's rights and protections, including dispute resolution protections such as due process. Children with disabilities who are placed by their parents in private schools (parentally placed children with disabilities), including those using vouchers, are not guaranteed FAPE under the IDEA. Instead, LEAs are required to set aside a portion of their funding each year to provide equitable services to these children in consultation with representatives of the private school and the parents of these children. Further, parentally placed children with disabilities retain limited dispute resolution protections.

As I noted in my confirmation hearings, I respect the laws passed by Congress, and our budget proposal does nothing to undermine the IDEA or its current framework. The Administration intends that, under our 2018 budget proposal, IDEA will continue to function as authorized by Congress.

Department's Immigration Efforts

Ms. Roybal-Allard: What is the U.S. Department of Education (ED) doing to provide schools and districts with resources to address immigrant students and families?

Ms. DeVos: The Department provides formula grants under both Title I and Title III of the Elementary and Secondary Education Act (ESEA) that school districts may use to meet various needs of immigrant students. In particular, Title I funds may be used as part of schoolwide projects to meet both academic and non-academic needs of immigrant students and families. Title III funds are focused on English language acquisition, and include competitive grants that support professional development designed to improve instruction for English learners.

Department's Immigration Efforts and DOJ, DHS Collaboration

Ms. Roybal-Allard: Is ED working with the Department of Homeland Security and the Department of Justice to ensure that sensitive locations, including schools, are not targets for immigration activities? What assurances can you give families that parents and students can come and go from school without the fear of being detained by immigration officers?

Ms. DeVos: The Department of Education supports efforts by the Departments of Homeland Security and Justice to enforce our nation's immigration laws, but does not play a role in those efforts.

Safe Zones, Sanctuaries

Ms. Roybal-Allard: In response to these deep concerns amongst families about safely bringing their children to school, many schools across the country - both K-12 and postsecondary schools - have passed "sanctuary," "safe zone," or "welcoming" resolutions. Are you supportive of these efforts?

Ms. DeVos: The Department supports meaningful and effective enforcement of the nation's immigration laws, but does not play a role in enforcement activities.

Addressing Adult Educational Needs

Ms. Roybal-Allard: The Administration's budget proposes to cut Adult Education by \$96 million or more than 16 percent. I would like to emphasize to you how important Adult Education is in my state and in my district. In California alone, some 5.6 million people need services that Adult Education provides, yet the state is only able to serve about a half million. I believe that we must invest in Adult Education because the jobs of the future will require postsecondary education. According to the Georgetown Center on Education and the Workforce, by 2020, 65 percent of all jobs in the US will require some level of postsecondary education or training. A stronger economy will bring people back into the workforce but it won't train them for the jobs of the future.

According to PIAAC (OECD's Program of International Assessment of Adult Competencies), Americans lag behind the international average for basic skills in literacy and numeracy and "problem-solving in technology-rich environments (defined as "using digital technology, communication tools and networks to acquire and evaluate information, communicate with others and perform practical tasks"). Other nations show consistent progress in enhancing the education levels of their adult populations, while the U.S. is losing ground.

What is the Department's plan to address this shortage if the budget request is adhered to?

Ms. DeVos: The FY 2018 President's Budget request would continue to provide significant grant funding to support adult education programs that help adults without a high school diploma or the equivalent to become literate and obtain the knowledge and skills necessary for postsecondary education, employment, and economic self-sufficiency. The Administration's request reflects a marginal scaling back of the adult education program, with future decisions regarding the program being informed by the evaluation and by performance data based on the full implementation of WIOA. In addition, the request for level funding for Adult Education National Leadership Activities reflects the Administration's commitment to continue support for efforts to assist States to improve the quality of adult education programs and implement the requirements of the performance accountability provisions of WIOA.

K-12 Teaching Workforce Lack of Diversity

Ms. Roybal-Allard: Are you familiar with the report released by the Department of Education in July of 2016, entitled "The State of Racial Diversity in the Educator Workforce" which found an alarming lack of diversity in the K-12 teaching workforce?

Ms. DeVos: I am familiar with the report.

Value of Increasing Teacher Diversity

Ms. Roybal-Allard: What value, if any, do you see in increasing the diversity of the K-12 teaching workforce as the number of minority students continues to grow?

Ms. DeVos: While I think research shows the effectiveness of the teacher in the classroom is the really important variable, I agree that students benefit from a diverse teaching force that can provide insights based on personal experience and serve as role models highlighting the opportunities made available through a high-quality education.

Budget Pathways for Teachers of Color

Ms. Roybal-Allard: How does the Department's budget create better pathways for teachers of color and help districts attract and retain teachers of color, especially to high-need urban and rural school districts?

Ms. DeVos: States and school districts bear primary responsibility, and most of the costs, for recruiting and training effective teachers and school leaders, and thus have primary responsibility for increasing the diversity of the K-12 teaching workforce. At the same time, the Department administers key programs that both directly help States and districts achieve this goal and provide models that may adopted more broadly. For example, the 2017 competition for the Teacher and School Leader Incentive Grant (TSLIG) program includes a competitive preference priority for applicants who design projects to attract, support, and retain a diverse and effective workforce. In addition, the FY 2018 President's Budget request would continue to support the Supporting Effective Educator Development (SEED) program, which provides grants for a variety of projects to improve the teacher and school leader workforce, including grants that create alternate pathways to the teaching profession. Our 2017 competition for SEED awards under the Every Student Succeeds Act (ESSA) included a competitive preference priority on promoting diversity in the educator workforce. Applicants responding to this priority must design and implement projects to improve the recruitment, support, and retention of educators from diverse backgrounds.

Efforts to Lessen Expense of Becoming Teacher

Ms. Roybal-Allard: How is the Department working to lessen the cost of becoming a teacher - either through student loan programs or education awards to help offset the cost of certification - to help recruit a diverse teaching workforce?

Ms. DeVos: The FY 2018 President's budget maintains strong support for the postsecondary student aid programs that all students, including minority students who will become teachers, rely on to help pay college costs.

Upward Bound: Lessons Learned

Mr. Pocan: It has been brought to my attention that several weeks ago, the Department of Education rejected dozens TRIO Upward Bound grant applications because they had formatting issues, such as single spaced text in charts and graphs within the application, exceeding the page limit, and other minor technical issues. At Columbia University, the program has been in existence since the 1960s and serves hundreds of low-income students every year by preparing them and providing the necessary support for them to enroll in college.

I have been informed that the Department refused to even read the applications of dozens of colleges like Columbia because of minor formatting issues. The appropriations committee instructed the secretary to do review these applications through the FY17 Omnibus Appropriations Act, which just became law. The Omnibus also included \$50 million additional funding for TRIO, which clearly gives the Department additional funding flexibility to allow these applications to move forward while holding harmless any other applications.

Will you allow these applications that were rejected for minor and arbitrary formatting errors to simply be read and scored with the Upward Bound competition? Why aren't you

following the direction from Congress in the FY17 Omnibus? The Department's FY17 congressional justification budgeted \$50 million less for TRIO than what was appropriated. Why won't you use a portion of this additional funding to allow those rejected applications into the competition? Do you have any intention of helping these students this year? I understand you have changed the policy moving forward, but that leaves this year's students out. How will you help this year's students? Will you codify your internal to ensure this never happens again?

Ms. DeVos: 1. Will you allow these applications that were rejected for minor and arbitrary formatting errors to simply be read and scored with the Upward Bound competition?

Yes, I agree with you that the outright rejection of a number of Upward Bound applications for bureaucratic formatting issues, rather than the contents of the applications themselves, put process before kids. The Department is currently in the process of reviewing and scoring the applications -- including the application submitted by Columbia University -- that were initially rejected for minor page limit and formatting errors.

2. Why aren't you following the direction from Congress in the FY17 Omnibus?

As stated above, consistent with the explanatory statement accompanying the Consolidated Appropriations Act, 2017, we are, in fact, currently reviewing and scoring the Upward Bound applications that were initially rejected for minor page limit and formatting errors.

3. The Department's FY17 congressional justification budgeted \$50 million less for TRIO than what was appropriated. Why won't you use a portion of this additional funding to allow those rejected applications into the competition?

As stated above, consistent with the explanatory statement accompanying the Consolidated Appropriations Act, 2017, we are currently reviewing and scoring the Upward Bound applications that were initially rejected for minor page limit and formatting errors. We opted to review these applications because we believe a fair assessment of the application includes a review of the contents of the application itself. The increase in funding for TRIO programs allowed us to review these applications without denying grants to other applicants that had properly applied for funding.

4. Do you have any intention of helping these students this year?

I believe that the Department should focus its efforts on helping children be successful. The outright rejection of a handful of Upward Bound applications for bureaucratic formatting issues, rather than the contents of the applications themselves put process before kids. The Department is currently reviewing and scoring these applications — including the application submitted by Columbia University — and will make awards to those applicants whose scores would place them in the funding range.

5. I understand you have changed the policy moving forward, but that leaves this year's students out. How will you help this year's students? Will you codify your internal to ensure this never happens again?

On April 27, 2017, I issued a directive to the Department prohibiting such mandatory requirements in future Notices Inviting Applications for all grant programs. As a result, the Department will no longer declare as ineligible applications that do not comply with page limit and formatting rules, as such guidelines will no longer be mandatory going forward.

Vouchers and Religion -- Proximity to Private Schools

Mr. Pocan: If you were to forward a plan for a national voucher program, would you advocate for any restrictions on publicly funded vouchers paying for religious schools' religious activities and education? Would you advocate for any restrictions on publicly-funded vouchers paying for religious schools' discrimination against LGBT students?

As a follow up, I know my constituents—the 90 percent who attend public schools, and the 90 percent in school districts receiving Title I funding—would want specifics on a plan to redirect money from a program serving just about everyone—rural, suburban and urban—into one that would appear to benefit urban voters who live close enough to a private school to use their voucher. How do you see vouchers working for families who don't live close enough to a private school to use the voucher?

Ms. DeVos: Protecting students' civil rights under federal law is one of the Department's core missions. The Department of Education can and will intervene when Federal law is broken. All applicants for Education Innovation and Research (EIR) funding to develop school choice programs must adhere to Federal law.

We recognize that geographic diversity can create challenges for private school voucher programs, and we will both consider creating a priority for applicants that propose to serve rural students and evaluate the effectiveness of vouchers in rural areas.

Private Schools and Disabilities

Mr. Pocan: I have a very vocal coalition of parents of students with disabilities in my state. They have rightfully fought very hard to make sure their children are getting access to the same education as their non-disabled peers. Private schools are allowed to say that they can't serve certain students, including students with disabilities. What do I tell these parents?

Ms. DeVos: I believe that all children, especially children with disabilities, should have access to the very best education we can offer. Under any school choice framework, parents should have access to a wide range of educational options and should be able to choose the educational environment that they believe is best for their child. Not every

school will be able to meet the needs of every child. If a parent believes that a school will not help their child grow into the very best version of themselves, they should have a real choice to go elsewhere, where their student will excel. Ultimately, requiring every school to do the same thing for every student is a disservice to our children and their families.

Title IV and Fulbright Hays

Mr. Pocan: Title VI and Fulbright-Hays programs enable undergraduate and graduate students to develop capabilities and proficiencies in languages and areas of the world that greatly benefit national security. Your budget proposes eliminating funding for these programs that facilitate language education, the development of innovative teaching materials, and research to inform teaching practice in classrooms around the nation. What is your assessment of these programs and for what purpose are they cut?

Ms. DeVos: The Administration recognizes the critical need for our Nation to have a readily available pool of international area and advanced language experts for economic, foreign affairs, and national security purposes. The FY 2018 President's Budget request refocuses the Department's mission on supporting States and school districts in their efforts to provide high-quality education to all students while reducing or eliminating more than 30 programs that duplicate other programs, are ineffective, or are more appropriately supported with State, local or private funds. Title VI and Fulbright-Hays programs duplicate other Federal programs and can be supported with State, local, and/or private funds.

Rationale for IES Cuts

Mr. Pocan: The Institute of Education Sciences provides "rigorous and relevant evidence on which to ground education practice and policy and shar[ing] this information broadly." High-quality education research on the science of teaching and learning is critically important to improving schools and student outcomes. Robust funding for the peer-reviewed evidence-based programs within IES enables our nation's schools to deliver better education and opportunities for students. For what purposes does your budget cut IES research, which will negatively impact how our schools and educators develop and improve opportunities and outcomes for our nation's youth? What is the future of the science of teaching and learning when the only agency in the federal government with this mission is narrowed and limited?

Ms. DeVos: The FY 2018 President's Budget does not cut research funded by the Institute of Education Sciences (IES). In fact, the Administration requests \$616.8 million for IES for fiscal year 2018, \$11.6 million more than the 2017 enacted level. The Administration believes this investment in research is critical because high-quality information about effective practices is essential for improving education, providing valuable insight into how public dollars could be better used to improve student outcomes.

Reason for Eliminating School Leadership Program

Mr. Pocan: The Every Student Succeeds Act took critically important steps in elevating the importance of school leadership. The newly improved School Leader Recruitment and Support Program, which updated the School Leadership Program authorized under No Child Left Behind, is the only federally authorized program that explicitly focuses on evidence-based programs to recruit, train and support effective school leaders. In the past, this program seeded some of the country's most innovative and effective principal preparation programs, and continued investment in the program will make a huge difference in our collective efforts to ensure every teacher and student in this country gets to work and learn in a school led by a well-prepared, well-supported principal. Secretary DeVos, why have you proposed to eliminate this evidence-based program, especially in light of your comments on the importance of Federal programs having research to support their effectiveness?

Ms. DeVos: The School Leader Recruitment and Support Program, which was funded at \$14.5 million in 2017, is a small discretionary grant program that supports only 18 grantees and has minimal national impact. By contrast, the \$15.5 billion Title I Grants to Local Educational Authorities (LEAs) program allocates significant resources to all States and nearly every school district in the nation that may be used, at local discretion and in response to local needs, to support improved leadership in high-need schools. For example, to the extent that the School Leader Recruitment and Support Program has demonstrated the effectiveness of innovative principal preparation programs, the program arguably has achieved its purpose and school districts now may use Title I funds to adopt or otherwise implement similar practices.

Cuts to Recruitment and Training: Effect on Schools

Mr. Pocan: Secretary DeVos, research tells us that investments in principals and school leaders are incredibly cost-effective. When we invest in one principal, we are investing in the 25-30 teachers and hundreds of students he or she, on average, supports on a daily basis. Slightly shifting the balance of educator investments toward principals is a smart way to improve school working conditions to foster stronger teaching and better outcomes for kids. And increasing principal retention rates in our high-poverty schools to that of affluent schools can save U.S. school districts \$163 million annually.

However, with the elimination of Title II-Part A in President Trump's budget proposal, I am concerned that this Administration is turning its back on principals and educators that rely on this funding and support to do the important work they do every day. Additionally, we know that investment in principals makes a difference. What types of investments can we expect to see in the President's broader budget proposal that will focus on the teachers, principals, and other school leaders that work every day to ensure our kids receive a high-quality education?

Ms. DeVos: States and school districts bear primary responsibility, and, consistent with the limited Federal role in education, most of the costs associated with recruiting, training, and retaining effective principals and other school leaders. Nevertheless, the FY 2018 President's Budget request maintains strong, supplemental support for efforts to

improve school leadership through such programs as Teacher and School Leader Incentive Grants, Supporting Effective Educator Development, and Title I Grants to Local Educational Authorities (LEAs), which currently provides \$15.5 billion in flexible formula grant funds that school districts may use to strengthen school leadership.

Runcie's Resignation from FSA

Mr. Pocan: On May 24, 2017, Chief Operating Officer for Federal Student Aid abruptly resigned his post after leading the office since 2011. What is your explanation for Runcie's resignation and what process will follow as the Department seeks to replace him? Further- can you ensure that whomever fills the Chief Operating Officer role will be subject to a transparent process which includes proper compliance with relevant ethics standards including proper financial disclosure to avoid any conflicts of interest?

Ms. DeVos: Mr. Runcie resigned as Chief Operating Officer of Federal Student Aid rather than comply with a call from Congress to testify. After a careful search, I was pleased to announce the appointment of Dr. Wayne Johnson on June 20, 2017. Dr. Johnson is a highly regarded leader with more than 30 years of experience in the financial services industry and holds a Ph.D. in higher education leadership. He will comply with all federal ethical requirements.

WEDNESDAY, JUNE 7, 2017.

DEPARTMENT OF LABOR

WITNESSES

HON. R. ALEXANDER ACOSTA, SECRETARY, DEPARTMENT OF LABOR

OPENING REMARKS BY CHAIRMAN COLE

Mr. COLE. Good morning, Mr. Secretary, and welcome. It is my pleasure to welcome you to the Subcommittee on Labor, Health and Human Services, and Education. We are looking forward to the hearing today.

I happened to notice when I was reading your biography that you were sworn in on April 28. That happens to be my birthday. I hate to tell you it is also Saddam Hussein's birthday, but I still consider it an auspicious date in human history, so I know we are going to have a good relationship.

This hearing is to review the Department of Labor's fiscal year 2018 budget request. The committee understands that the Department had a target level of funding in this budget and that significant cuts needed to be proposed in many areas to achieve that. The committee's task is to carefully consider the budget request and to make recommendations for the funding needs of critical programs at the Department, including job training, worker safety, labor statistics, and others.

The committee also appreciates the Department's focus on job training and employment needs of hard-to-serve populations, including youth, Native Americans, formerly incarcerated citizens, and the Nation's veterans, particularly the Department's requested increase for the Homeless Veterans' Reintegration Program. I hope the Department will continue to work with the committee and the Congress to eliminate veterans' homelessness and to better serve all of these populations.

COMBATING THE SKILLS GAP

An issue I view as critically important is the skills gap. According to the Bureau of Labor Statistics, there are currently over 5 million open positions for which employers are unable to find qualified candidates. Many of these are high-paying jobs, and I believe the skills gap is a very significant opportunity cost for workers and for the economy overall. I look forward to hearing your views on how job training programs at the Department of Labor can better meet the needs of these employers and reduce the skills gap.

DOL WORKER PROTECTION PROGRAMS

The committee also recognizes that enforcement is an important part of the Department's worker safety programs, but we continue

to believe that worker safety should be the principal goal. It has been difficult to ignore the previous administration's adversarial and punitive pursuit of labor enforcement. I believe most employers want to do the right thing for their employees and have been understandably frustrated by their partnership with these agencies at the Department of Labor.

Beyond the shift of resources from enforcement to compliance assistance, I would suggest that the culture at some of these agencies needs to change. Inspectors and safety experts must view their roles as cooperative partners of the employers and employees to advance worker safety across the Nation's industries. Hardworking Americans deserve to know that the Federal Government has their back, both ensuring that good jobs are created and that safety is ensured.

FISCAL YEAR 2018 BUDGET

It is unfortunate that the final consolidated appropriations bill for fiscal year 2017 was not enacted prior to the time that funding decisions for your fiscal year 2018 budget request had to be finalized. In many cases, if the policy of the administration was to maintain current funding for a program that Congress increased in fiscal year 2017, the budget request would appear to be a reduction when, in fact, that was not necessarily your intention. We will simply need to carefully explain ourselves when discussing proposed increases and decreases in those categories today.

Finally, the subcommittee needs to know the specific details for how the proposed cuts in the Department's fiscal year 2018 budget would impact job training programs and the programs that target hard-to-serve populations. The budget provides some of these details. I know that some are still being developed. But we look forward to hearing what you are able to share with us today.

I am sure the members of the subcommittee will have many questions about the budget and policy issues, including the fiduciary rule. So, without further delay, I would like to remind members and our witnesses that we will abide by the 5-minute rule so that everyone will have a chance to get their questions asked and answered.

But before we begin, I would like to yield 5 minutes to the full—well, to the gentlelady—okay, to the—

Mr. FRELINGHUYSEN. To your ranking, please.

Mr. COLE. Well, we normally would do our ranking, so to the ranking member of the full committee. Then obviously, we will move to the full committee chairman for any remarks he cares to make.

Ms. DELAURO. Thank you very much, Mr. Chairman of the subcommittee and Mr. Chairman of the full committee. I appreciate it.

Good morning, Secretary Acosta, and welcome to the committee and to, I guess, your first appropriations hearing.

I would select the chairman's birthday as a date to focus on versus Saddam Hussein anyway.

Mr. Secretary, as we did speak, I will be blunt. I do not have anything complimentary to say about this budget request. In fact, I think it is a disaster for American workers and for their families. In your written testimony, you say that, quote, "We are going to

do more with less." Mr. Secretary, you cannot do more with less. You can only do less with less. And, in my view, that is exactly what this budget proposal will do, less for American workers.

CUTS TO EMPLOYMENT AND TRAINING PROGRAMS

The budget request for the Department of Labor would decimate the employment and training system by cutting more than \$2,000,000,000, roughly 40 percent of its funding, eliminating services for seven to eight million Americans who need help to find a job or move to a better-paying career.

The biggest economic challenge of our time is that too many families do not make enough money to live on. They are in jobs that don't pay them enough to live on. They are struggling today. And we need to enact policy that ensures that everyone can benefit from the economic recovery and that everyone has the training they need to get good jobs with fair wages.

By 2020, two out of three jobs will require training beyond the high school level. It is up to us to meet the need. This budget would cut Job Corps by about \$250,000,000, leading to a shuttering of Job Corps centers around the country. Thousands of at-risk youth would lose access to important skills training.

Your testimony says the budget eliminates programs that are less effective. In fact, it zeros out programs that are known to be very effective. The Senior Community Service Employment Program exceeds the Department's own performance targets in entered employment, employment retention, average earning. Migrant and Seasonal Farm Worker Training places participants into employment 90 percent of the time, increases wages threefold.

Through this committee, we have the opportunity to make important investments in job training that we know work, like providing the first-ever Federal appropriation to expand the apprenticeship model throughout the country. And if we are serious about job training, we would be making investments like we did through the TAACCCT, the T-A-A-C-C-C-T program, which provided \$2,000,000,000 to more than half of all community colleges nationwide.

IMPACT OF PROPOSED CUTS IN FY 2018 BUDGET

The President proposes to cut or eliminate programs that help low-income and working-class families, and yet, we are awaiting or at least we have an outline of a budget that includes a massive tax cut for corporations and for millionaires, a similar scenario that we saw with the healthcare bill, the underlying purpose being to cut taxes for the wealthy while cutting back on programs for middle class families.

It was on the campaign trail that the President claimed that he would be tough on trade. Yet, in his first budget he proposes to eviscerate the office whose mission is to identify cheating on trade deals. He wants to cut the Bureau of International Labor Affairs, known as ILAB, by almost 80 percent. It is the lead agency for investigating labor violations and trade agreements with our trading partners. It compiles annual reports on products that are made with child labor and with forced labor.

And the budget request should focus on modest increases to compliance assistance programs. And while I agree that there needs to be a balance between compliance assistance and enforcement, I am concerned that you plan to scale back on enforcement activities, which results in less oversight on those who are out there. Yes, most employers want to do the right thing, but, in fact, we do have bad actors, and you know that, particularly when it has dealt with wage theft over the years. This deprives workers of honest wages, exposes them to dangerous health and safety hazards.

OSHA, only enough funding to inspect every workplace under its jurisdiction every 159 years. Yet, the budget proposes to eliminate funding Susan Harwood Training Grants that protect and educate workers in the most dangerous jobs.

The budget also proposes to cut funding for the Women's Bureau, \$10,000,000, eliminates 70 percent of its staff. This is a critical function to improving work environments and opportunities for women. Pretty much unacceptable to slash its budget when today women make 80 cents on the dollar.

Taken as a whole, the President is proposing to cut the Department of Labor by \$2,300,000,000. It is a reduction of 19 percent.

MAINTAINING LABOR PROTECTIONS FOR THE AMERICAN WORKER

Mr. Secretary, I think we need to know today whether or not you agree that your Department should be cut by \$2,300,000,000. We also need to know if you are going to fight to defend the protections for safe workplaces that your Department has made in recent years, regulations to limit exposure to silica, beryllium, coal dust that will save thousands of lives.

We need to know if you are going to protect the financial safeguards to retirement savings that were put in place by the fiduciary rule. And I hope that you do agree that financial advisers should make recommendations in their clients' best interests, not in the interests of advisers.

The New York Times had a front page story this week alleging an upcoming rollback of worker protections. It says: At the request of industry lobbyists, the Department is planning to weaken regulations across the board, including regulations on silica, beryllium, which are known carcinogens. I hope that you will tell us, Mr. Secretary, that the report is wrong and that you plan to enforce the Department's worker protections.

Again, disappointed about the proposal to eliminate the Office of Federal Contract Compliance, OFCCP, by absorbing it into the EEOC, another area in which you have had experience. The OFCCP actively ensures that Federal contractors are held to a higher standard in their hiring practices, given that contractors are entrusted with taxpayer dollars. So I strongly oppose this proposal.

PAID PARENTAL LEAVE PROPOSAL

Final note, the administration has proposed what I view as a paltry 6-week parental-only paid leave scheme in their budget, despite the fact that more than 75 percent of people who take family or medical leave do so for reasons other than parental leave. Moreover, the intention is to fund its proposal through the overburdened State Unemployment Insurance Programs, which are insufficient to

sustain the program and would erode access to unemployment benefits should another recession hit.

The President's proposal does not reflect the reality that workers face. We need a real family and medical leave policy nationwide, funded responsibly and sustainably, without cuts to essential programs.

To close, let me share a quote from one of my heroes and the longest-serving Labor Secretary in our Nation's history, Frances Perkins. She said, and I quote: "The people are what matter to government, and a government should aim to give all the people under its jurisdiction the best possible life."

That is how I view the mission of this Department. I hope that that is the way that you view the mission of this Department and that you will assure us that you intend to improve the lives of working people.

Thank you very much, Mr. Chairman.

Mr. COLE. Thank you.

And now my pleasure to go to the chairman of the full committee, and a great privilege to have the distinguished gentleman from New Jersey, Chairman Frelinghuysen, for any opening remarks he cares to make.

REMARKS BY CHAIRMAN FRELINGHUYSEN

Mr. FRELINGHUYSEN. Thank you, Mr. Chairman.

And welcome to the appropriations process, Mr. Secretary.

Today's hearing is an important part of the oversight duties of this committee. Now that we formally have received the administration's budget request, the committee will undertake a thorough analysis of yours and every budget. We intend to put forward a complete set of appropriations bills that adequately fund important programs while working to reduce or eliminate waste or duplication.

This hearing is part of a process we follow to determine the best use of taxpayers' dollars. After all, the power of the purse lies in this building. It is the constitutional duty of Congress to make spending decisions on behalf of the people we represent at home.

REGULATORY BURDEN ON SMALL BUSINESS

When I travel across my congressional district in New Jersey, meeting with small-business owners and employees, I often hear about how excessive government regulations are hampering growth. According to The National Small Business Association, the average small-business owner is spending \$12,000 annually dealing with regulations. That is why we must work together to reduce these types of burdens, especially the Department's fiduciary rule, and cut red tape, which often requires resources that could be better utilized for other purposes.

DECREASING VETERAN UNEMPLOYMENT

May I also say that, like many of my colleagues, I host an annual veterans job fair in my congressional district with local employers to directly advertise their employment openings and retraining opportunities to those who have returned from the war front. I am

pleased to learn that the national veterans' employment rate fell to 3.7 percent in April, which remains below the national average. I know you will continue to promote veterans' employment and training service programs and many other programs, as these are critical investments directly resulting in improved quality of life for veterans and their families.

Welcome to the committee.

And I appreciate the time that the chairman has given me. Thank you.

Mr. COLE. Thank you, Mr. Chairman.

And, with that, Mr. Secretary, we will go to you for any opening comments you care to make.

OPENING STATEMENT BY SECRETARY ACOSTA

Secretary ACOSTA. Well, Mr. Chairman, thank you. Mr. Chairman and Ranking Member DeLauro, members of the subcommittee, thank you for the invitation to appear today.

And perhaps let me begin on a note of bipartisanship. The people are what matter, and I couldn't help but note that in all the opening remarks the focus was on the people. And I think if we keep that front and center, that is a great place to start.

It is an honor to appear before this subcommittee to outline the administration's vision for the Department of Labor in fiscal year 2018 and beyond. Supporting the ability of all Americans to find good jobs and safe jobs is a priority for President Trump and for myself. And, to be clear, a good job and a safe job are not and should not be mutually exclusive. It should be both, and we can have both. I am proud and I am humble to lead the Department in this critical work.

COMBATING UNEMPLOYMENT

Last week, the Department announced the U.S. unemployment rate. It is at a 16-year low, 4.3 percent. It hasn't been that low since 2001. This is amazing news. What is, I think, as important but less talked about is that there are now 6 million job openings. That is the highest number of job openings that we have had since we started keeping this statistic in the year 2000.

We can get most Americans that are unemployed back to work if we can simply match those job openings with who is looking for a job. And to facilitate this match, we need to better align job training, job education, and the skills the marketplace demands. And the evidence tells us that effective job education programs prepare workers for high-growth jobs that actually exist. There has to be a focus between the job that exists and the educational program that is preparing the worker.

FOCUS ON APPRENTICESHIPS

And one approach to preparing workers for these high-growth jobs are apprenticeships. It is a proven strategy that works. High-quality apprenticeships—and the emphasis on high quality—enable workers to be involved in the training of their future workforce so they can be sure that new hires possess the skills that are needed for the job. Apprentices receive wages and, just as importantly,

skills, and along the way they earn while they learn. And that is just as important, because that means they are not saddled with debt.

Apprentices earn nationally recognized certificates of completion leading to long-term career opportunities. Many registered apprenticeship programs also afford apprentices the opportunity to earn college credit toward their degree.

Last week I met with three apprentices at the Ford Rouge plant complex in Detroit, Michigan, and it was wonderful to meet with them. They were excited. They thought that they were learning, that their careers were expanding. They receive 600 hours of classroom instruction separate and apart from their job.

Upon completion of the program, the apprentices will have gained the skills to work in any department within the plant. They will have transferrable skills from department to department that will travel with them, irrespective of whether they stay at Ford or they go elsewhere. And as importantly, after the completion of the program, I was told that they only needed three additional classes to get their degree.

High-quality apprenticeship programs are a huge win for the apprentice and for the employer. The employer gains skilled trained workers and the workers themselves have a wonderful start to a prosperous career.

STREAMLINING DOL PROGRAMS

Getting Americans back to work also requires limiting programs that are less effective at helping the American worker. There are many programs intended to help Americans find jobs or train for jobs, but some of them are duplicative or less necessary or unproven or less effective. The Department is committed to streamlining or eliminating programs based on rigorous analysis of available data to access and to improve program effectiveness.

When we match Americans who are looking for work with available jobs, we want to ensure they are good and that they are safe jobs, as I said previously.

The Department believes that a vast majority of employers across the Nation are responsible actors, as was mentioned earlier, but we also understand that that is not 100 percent, and so we are fully committed to enforcing worker protection laws, as we have been doing. The budget includes funding increases of about \$16,000,000 to the Department's worker protection agencies to support this goal, with an emphasis on compliance as well as enforcement.

We are going to do more with less, as was noted, and we have to do more with less. We are going to focus the Department on its core mission by making smart investments in programs that work. The budget makes hard choices, and they are hard, but they are responsible choices that have to be made.

Americans want good and safe jobs. The Department is here to support Americans' desire to gain and hold these jobs, to support Americans' desire to have skills that are transferrable and that will set them on a career path that will ensure their future. The budget restores the Department to this fundamental vision, investing in programs that we know are successful. The proposals are evidence-

based and reflect the seriousness with which this administration takes its responsibility.

I look forward to working with you, and I would welcome your questions. Thank you.

[The information follows:]

STATEMENT OF R. ALEXANDER ACOSTA
SECRETARY OF LABOR
BEFORE THE
SUBCOMMITTEE ON LABOR,
HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES
COMMITTEE ON APPROPRIATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
June 7, 2017

Chairman Cole, Ranking Member DeLauro, and members of the Subcommittee, thank you for the invitation to testify today. It is an honor to appear before the committee to outline this Administration's vision for the Department of Labor in Fiscal Year (FY) 2018 and beyond. Supporting the ability of all Americans to find good and safe jobs is a priority for President Trump and for me. And to be clear, a good job and a safe job are not mutually exclusive. We can have both. I am proud and humbled to lead the Department of Labor in this critical work.

We have a lot of work to do at the Department. Too many Americans struggle to get by. Too many Americans have seen good jobs in their communities disappear. Too many Americans see jobs that are available, but require skills that they do not possess. We at the Department look forward to working with you in the Legislative Branch to fulfill the Department of Labor's critical mission: to foster, promote, and develop the welfare of our Nation's workers, job seekers, and retirees.

The Administration is committed both to fiscal responsibility and to restoring the Federal government to its proper role. We are going to do more with less and we are going to focus the Department of Labor on its core mission by making smart investments in programs that work. The Budget makes hard but responsible choices: it eliminates programs that are less effective or less efficient, and dedicates taxpayer dollars to programs that we know are successful.

Our American economy has changed rapidly and has left many Americans behind. Our unemployment rate is now at 4.3 percent, a 16-year low. Nonetheless, we have 6.9 million Americans who are unemployed. The good news is that we have 6.0 million job openings. We can get most Americans back to work if we can match those who are looking for work with available jobs. But businesses report difficulty hiring workers with the right skills for jobs they need to fill. There is a mismatch between the needs of employers and the skills of jobseekers. We need to close this skills gap. We need to do so within an overall budget that respects the Administration's commitment to fiscal responsibility and to national security.

As part of this approach, the Budget prioritizes the programs that *do* work. It includes a total of \$130.0 million for Reemployment Services and Eligibility Assessments, an increase of \$15.0 million. These assessments are proven to help unemployed Americans get back to work more quickly and at higher wages. They also save taxpayer dollars. A recent study showed that by getting Americans back to work more quickly and reducing improper payments, this approach saved an average of \$536 per claimant in unemployment insurance benefit costs, demonstrating its potential for real savings for American taxpayers.

We need to make better efforts to align job training with the skills the market demands. The evidence tells us that effective Federal job training programs prepare job seekers for high-growth jobs that actually exist. One approach to preparing workers for these high-growth jobs is apprenticeship, a proven strategy for raising trainee employment rates and wages. High quality apprenticeships enable employers to be involved in the training of their future workforce so they can be sure new hires possess the skills needed to do the job. Apprentices receive wages and, just as importantly, skills that enable them to thrive in today's workforce. Apprentices earn nationally recognized certificates of completion leading to long-term career opportunities. Many Registered Apprenticeship programs also afford apprentices the opportunity to earn college credit towards a degree.

Getting Americans back to work also requires eliminating programs that are less effective at helping Americans get jobs. There are many programs intended to help Americans find or train for jobs, but some of them are duplicative, unnecessary, unproven, or ineffective. The Department is committed to streamlining or eliminating programs based upon a rigorous analysis of available data to assess programmatic effectiveness. The Department also believes that giving states more flexibility to administer DOL resources in a way that best suits their needs is another way to ensure DOL resources are used as efficiently and effectively as possible.

The Department is also seeking to reduce burdens on taxpayers and increase efficiencies by requesting authority to establish and retain fees to cover the operating costs for foreign labor certification programs, which serve to ensure that foreign workers brought in under work-based visas do not displace or undercut the wages of American workers. Once the fee structure is fully implemented, only the employers who want to bring in foreign labor will pay for these programs. This is fair. This will allow for a more reliable, workload-based source of funding that removes the taxpayer from footing the bill and ultimately eliminates the need for appropriations. This proposal allows for timely processing of labor certifications that will proceed in parallel with the Department efforts to ensure that foreign labor does not illegally displace American workers. This approach is consistent with the Department of Homeland Security's management of the foreign labor programs and is crucial to protecting American workers.

Too many Americans are faced with the difficult choice between caring for a new baby and getting back to work to earn a paycheck. The Administration believes this is a choice parents should not have to make, which is why the Budget delivers on the President's promise to provide paid parental leave. The Budget includes a fully paid-for proposal to establish a Federal-state paid parental leave benefit program within the Unemployment Insurance program that will provide mothers and fathers, including adoptive parents, with six weeks of benefits after the birth or adoption of a child.

The Department believes that a vast majority of employers across the nation are responsible actors, fully committed to following worker protection laws and to providing good and safe jobs for their employees. However, these laws can be complex. The Department has placed a priority on helping American employers understand and remain in compliance with worker protection laws. The Budget includes funding increases of \$16.6 million to the Department's worker protection agencies to support this goal. When the Department collaborates and works in

partnership with employers, compliance with labor laws increases and American workers benefit.

Compliance assistance to the employer community is vital. The Wage and Hour Division (WHD), the agency that enforces laws establishing minimum standards for wages and working conditions, has developed compliance assistance tools through engagement with industry leaders and the employer community. The Budget includes an additional \$3.0 million for WHD to expand upon this work and perform compliance assistance projects to further educate employer groups and industry associations on how to comply with the law.

The Occupational Safety and Health Administration (OSHA) ensures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education, and assistance. The Budget supports the Department's emphasis on compliance assistance and provides an additional \$4.0 million for OSHA's federal compliance assistance activity. This investment will allow OSHA to broaden its assistance and support to employers who are trying to best protect their workers.

The Employee Benefits Security Administration (EBSA) ensures the security of the retirement, health, and other workplace related benefits of America's workers and their families. EBSA's enforcement authority extends to an estimated 685,000 private retirement plans, 2.2 million health plans, and a similar number of other employee welfare plans which together hold \$9.3 trillion in assets. These plans provide critical benefits to America's workers, retirees, and their families. Our experience indicates that the volume and complexity of Employee Retirement Income Security Act (ERISA) disclosures can be overwhelming for some participants and beneficiaries. Complying with ERISA's disclosure requirements and effectively communicating with employees can be a particular challenge for small businesses that may not have a dedicated human resources department with employee benefits specialists. The Budget includes a \$1.3 million funding increase to improve the quality, readability, and delivery of ERISA disclosures to people in plans sponsored by small businesses.

The Budget provides \$46.6 million for the Office of Labor-Management Standards (OLMS) to administer the Labor-Management Reporting and Disclosure Act (LMRDA) and related laws, which establish safeguards for labor union democracy and financial integrity. The FY 2018 funding level re-establishes the International Compliance Audit Program, through which OLMS will audit and provide technical guidance and assistance to International Union officials to achieve compliance with the LMRDA.

The Office of the Solicitor (SOL) will support the execution of these priorities. The Budget provides SOL with \$2.2 million to support these compliance assistance initiatives by providing legal advice regarding establishing new compliance assistance programs, developing public-facing materials, preparing and conducting internal training programs, responding to inquiries, and defending legal challenges that may arise in response to these programs.

The Administration is committed to moving the nation toward fiscal responsibility and restoring the Federal government to its proper role. The Department will focus on work that furthers the Department's mission, and the Budget makes long overdue changes to move in that direction.

These changes include sensible budget reductions, organizational changes to reduce operational costs, and the elimination of unproven or duplicative activities.

Some of those changes mean moving programs from the Department of Labor. Where there is duplication throughout the government, programs, offices, and agencies can and should be consolidated to increase efficiency. For this reason, the Budget proposes to consolidate the Office of Federal Contract Compliance Programs (OFCCP) with the Equal Employment Opportunity Commission (EEOC). This commonsense change combines two civil rights agencies that already work together closely.

Other commonsense changes involve refocusing the Department's agencies on their core missions. For the Bureau of International Labor Affairs (ILAB), that means focusing the agency on ensuring that U.S. trade agreements and preference programs are fair for American workers. In addition to their reporting requirements on international child labor and forced labor and their charge to represent U.S. interests in international settings like the International Labor Organization, ILAB has a critical role to play in leveling the playing field to make sure that other countries are not undercutting American workers by violating trade commitments. The Budget eliminates ILAB's new grants programs as we ask other countries to invest more in these areas, saving America's taxpayers \$67.5 million.

The Budget refocuses the Office of Disability Employment Policy (ODEP) by investing agency resources in an initiative that is based on a program with demonstrated success: the State of Washington's Centers of Occupational Health and Education program, which is part of its workers' compensation program. ODEP's investment builds on a model proven to increase labor force participation of individuals with injuries and disabilities. The demonstration project, which will be run in partnership with the Social Security Administration, will test the effects of implementing key features of the model in other states or municipalities for a broader population.

The Department also proposes sensible reforms for the Pension Benefit Guaranty Corporation (PBGC). PBGC acts as a backstop to insure pension payments for workers and retirees whose companies and pension plans have failed. The Budget proposes premium reforms for the multiemployer insurance program that will improve the solvency of the program.

These commonsense changes will restore the Department to a focus on its core mission, save taxpayer resources, and increase the Department's effectiveness by investing in programs known to have a meaningful impact on American workers.

Americans want good and safe jobs. The Department is here to support Americans' desire to hold these jobs. The Budget restores the Department to this fundamental mission, investing in programs that we know are successful. The proposals are evidence-based and reflect the seriousness with which the Administration is taking its responsibilities. We look forward to working with Congress on these important goals.

THE TRIBAL LABOR SOVEREIGNTY ACT

Mr. COLE. Thank you very much, Mr. Secretary. It is, again, very good to have you here.

Let me begin with an issue that I mentioned to you a moment ago when we had a chance to visit. And just to provide a little context, when the National Labor Relations Act was passed in the middle of the 1930s, the National Labor Relations Board was not given any jurisdiction over governmental employees, Federal, State, local.

The original legislation was silent about Indian tribes, but for 60 years the Department exercised no jurisdiction over tribes. In 2004, on its own, without a request from the Congress or, as far as I can determine, without a request from the administration at the time, they simply decided they would draw a distinction—an artificial distinction, in my view—between what they called governmental employees, law enforcement, healthcare, and the like, and people that were employed by tribes in commercial ventures, gaming obviously being the most prominent, but lots of other areas as well.

That was universally and violently resisted by tribes all across the country. There has been a lot of litigation about it. There has been a lot of legislation about it. Actually, last year the House of Representatives actually passed legislation called the Tribal Labor Sovereignty Act that my friend Mr. Rokita from Indiana carried, bipartisan majority, to take that jurisdiction away from the National Labor Relations Board.

The Senate failed to act, but this year the Senate actually has already moved that legislation through the Indian Affairs Committee, so there is at least a good prospect. And I think certainly if that legislation comes to the floor here, it would pass again.

So I wanted to give you an opportunity to at least, if you have any thoughts about that, if you have a concern, because it is something we have placed at least in the House-passed version of your appropriations bill before. So this is apt to be a legislatively live round, so to speak, in the coming months.

Secretary ACOSTA. Mr. Chairman, thank you for the question. As you know, I served on the National Labor Relations Board in 2003, so your question brings back memories that are more than a dozen years old at this point.

You know, during my days as a U.S. Attorney something that I was very sensitive to is understanding that there is a sovereign-to-sovereign relationship between the United States and tribes, and that is something that I tried to respect as U.S. Attorney when engaging in law enforcement activities with the tribes.

I haven't read the decision that the NLRB issued, it was after my time on the NLRB, and I haven't seen the statute. But at a general level, I would say this: That the United States has made commitments that we would respect the sovereign-to-sovereign nature of tribes, and that those commitments should not be violated unless there is clear language to that effect.

And so I don't know where the NLRB found that language. But ultimately, I think that Congress should carefully consider this. And unless there is good reason, the sovereign-to-sovereign relationship that we have with tribes is something that goes beyond

any one area and that has sort of been a fundamental tenet of the relationship that we hold with those entities.

Mr. COLE. Well, I appreciate that answer. And I would hope that if you have time that you take a look at this issue, because it is something that, again, we will be dealing with probably on the floor of the House, certainly within the confines of this committee.

JOB CORPS BUDGET CUTS

Let me ask you in the time that I have left, obviously—and this was raised by a number of members—you have proposed pretty serious cuts or substantial cuts in the Job Corps program. Could you give the committee some idea about the criteria you would use in making the decisions whether closures were involved, how you see redistributing the funds that you would have left, and, again, where you think there are areas that could be reduced without costing us any effectiveness in training young people to go into the labor market?

Secretary ACOSTA. Certainly, Mr. Chairman. As you are aware, the Job Corps program encompasses many centers. Some of them are quite effective, some of them much less so. And there are formulas in place to measure Job Corps effectiveness.

At a personal level, I have looked at those formulas, and one concern that I have with respect to those formulas are do they focus on the end result. The Job Corps center is there to teach skills so that individuals could get jobs. And my question is, are they getting jobs?

And I think that is a very easy criteria in one sense, and a very complicated criteria in another sense, because in some hard-to-serve communities, if 50 or 75 percent of the individuals find a job, that is a big win, because in some hard-to-serve communities, given the population that Job Corps serves, that is an outstanding result.

And so I think it is important that any decision on Job Corps first be based on what the budget ultimately provides or what the appropriations ultimately provide.

Second, it looks at the cost of running individual centers. There are some centers that may need repair to maintain them. That would be very expensive.

And thirdly, it looks on a rigorous data-based, evidence-based, using evidence-based methodology, at ultimately are the participants getting jobs, compensating for the fact that some Job Corps programs serve hard-to-serve communities and what may on its face be a less effective program may actually be quite effective, given the community that it serves.

Mr. COLE. Thank you very much, Mr. Secretary.

I am going to go next, if the gentlelady has no objection, to the full committee chairman, because I know he has many time constraints.

So, Mr. Chairman.

Mr. FRELINGHUYSEN. Thank you, Mr. Chairman.

Just one comment and then a question.

FOCUSING ON VETERAN EMPLOYMENT

As you look at our workforce, three of us on this committee, on this panel, serve on the Defense Appropriations Committee. I

chaired that over the last couple of years. There is an enormous need for welders out there. It is a tough job. I think you know many of those in that type of occupation are second or third generation. I do think as we look at sort of opportunities, there could be more of a focus, which would be beneficial to veterans and others.

And the other area, which is quite different but does require particular skills, mostly found in the young, a cyber workforce that is capable to meet sort of the challenges we have today.

STATUS OF THE FIDUCIARY RULE

And so my question is unrelated. Where do we stand relative to the fiduciary rule? I mean, I have to say I think Members of Congress have been bombarded by a lot of their constituents over the last 3 or 4 years. I have probably had 2,500 letters, electronic and snail mail, on that issue. Could you just walk us through briefly where we stand relative to the fiduciary rule?

Thank you, Mr. Chairman.

JOB TRAINING AND APPRENTICESHIPS

Secretary ACOSTA. Mr. Chairman, I am happy to do so. And first, let me acknowledge the earlier point that you raised. Just this morning, I was talking with a major corporation that has entered into a cybersecurity partnership with the University of Maryland, where they are working with the University of Maryland on the curriculum so that Maryland will graduate individuals trained in cybersecurity, educated in cybersecurity, ready for jobs.

And on the welder point, let me note that apprenticeships, according to our data, on average, when they complete it, enter professions where they earn an average of \$60,000 a year, which is an amazing salary for an entry level job, quite honestly, higher than a lot of lawyers. And it is something that I think individuals don't hear enough about.

UPDATE ON THE FIDUCIARY RULE

Going to your question on the fiduciary rule. As you are aware, the fiduciary rule was adopted by the prior administration. It was postponed for 60 days. The effectiveness of part of it was postponed for 60 days to analyze it. This administration looked at whether it should be postponed further and concluded that there was no basis to postpone the effective June 9 date any further.

The rule is being looked at. Just this morning at the OMB website, at the OIRA website, a request for information went public asking industry, asking consumers a number of questions about the rule, about how the rule is being implemented, about the impact that the rule has, and that is the first step in this administration's review of that rule. But we need that information and we need that data in order to decide how to proceed.

Mr. FRELINGHUYSEN. Thank you.

Mr. COLE. Thank you, Mr. Chairman.

With that, we will go to my good friend, the ranking member, the gentlelady from Connecticut.

CLOSING THE SKILLS GAP UNDER PROPOSED BUDGET

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

Mr. Secretary, in your testimony you note that with 6.9 million unemployed Americans, and there are 6 million job openings, that we need to do a better job equipping workers with in-demand skills and matching them with businesses that are hiring.

So, as I pointed out earlier, I find it perplexing that as you advocate to address the skills gap, your budget proposal slashes \$2,300,000,000 from job training. Forty percent, \$1,100,000,000 cut to the Workforce Innovation and Opportunity Act, WIOA grants. Job Corps, my colleague asked about, 15 percent, \$256,000,000. I was interested to hear your comment.

In terms of these cuts which are being proposed, you reference an evaluation process that must go into decisionmaking. I don't know, what was the decisionmaking process that went into the evaluation of \$256,000,000 to cut Job Corps, \$256,000,000 to cut the employment service, \$10,000,000 to cut Reintegration of Ex-Offenders, \$5,000,000 to the apprenticeship program.

Yes, apprenticeships, Germany, U.K., over the top on what they are doing with apprenticeships. We added money in the omnibus bill, which is a good thing. Why aren't we going back to the program that we had and looking at the TAACCCT program, \$2,000,000,000, which went to community schools in order to be able to close that skills gap and to be able to apply for apprenticeships? You can't cut a program and say that you are for the program.

Complete elimination, job training for migrant and seasonal farm workers, \$82,000,000; Senior Community Service Employment Program, \$400,000,000. These are all job training programs that have been proven.

How do we provide workers with the skills we know they need under your budget proposal?

Secretary ACOSTA. Well, I thank the ranking member for the question, and it is an important one. As you noted, the skills gap is real. Just this morning I was at a meeting of businesses—

CRITERIA FOR BUDGET CUTS

Ms. DELAURO. How does your—I am sorry and I don't mean to—I have very limited time, as it turns out, always on this committee, because everybody comes. There is such good stuff we deal with here.

How do you propose, with the cuts that have been proposed in worker training, to go where you want to go, and what was the process of evaluation of these programs with the initial cuts that we see here? Who evaluated them? What were the criteria that said we should cut Job Corps \$256,000,000, we should eliminate this program?

Secretary ACOSTA. So let me take your questions seriatim, if I could.

With respect to what was the evaluation process, I think what I was referencing is that there has to be an evaluation process that is data-based and that is rigorous in order to implement those reductions that are ultimately determined to take place on programs

like Job Corps, that it shouldn't simply be we don't cut it because it's in this Member's district or that Member's district, but it needs to be data-based. And I was referencing the formula and thoughts on how to engage in that evaluation process in order to implement the cuts that—I am sorry?

Ms. DELAURO. All I just want to say is, I understand, we understand evaluation here. We have program integrity dollars where we look into what is fraud, waste, and abuse, all of the above. I have no idea, and if somebody could tell me and get back to me on what were the criteria that went into the cuts that are here, \$2,300,000,000, and the cuts to programs that have been proven effective.

We all on this committee understand Job Corps to a fare-thee-well. We have said close down those that don't work. I don't know where you come up with \$256,000,000 and what is going there.

SHIFTING RESPONSIBILITY TO STATE AND LOCAL GOVERNMENT

The other piece of this which was interesting to me is, do you really believe that States and localities are going to pick up the slack on this effort? We are looking at, if I look at overall of what the administration's proposals are, new costs, you gut Medicaid, SNAP, TANF, LIHEAP, to name a few, and the higher education spending per student is down by about 18 percent and we are going to get that to the States. How are we going to do that?

Secretary ACOSTA. So, Congresswoman, I can't comment as to the higher education spending, but what I can say with respect to an important element of this budget is there are 37 different programs at DOL, many of those that flow down to the States. And one element that I think will be helpful to the States is increased flexibility in how to spend the money that they have rather than line item each to a particular program.

Ms. DELAURO. They don't have the money, and we are cutting further back in what they do. I just look to the State of Connecticut. In no way could they take up the slack on these programs.

Thank you very much, Mr. Chairman.

Thank you, Mr. Secretary.

Mr. COLE. I thank the gentlelady.

Next, based on the order of arrival, we move to the distinguished vice chairman of the committee, the gentleman from Arkansas.

Mr. WOMACK. Thank you, Mr. Chairman.

REVIEWING THE FIDUCIARY RULE

Thank you, Mr. Secretary, for your service and your testimony here this morning.

The overall chairman asked about fiduciary. I want to go back to that for just a minute because on Friday the rule takes effect. But you said in your testimony two things: That OMB has published a request for information and that you will continue to look at it. What does "look at it" actually mean to the average person?

Secretary ACOSTA. So, Congressman, let me be precise. I think what I said was that OMB—it appeared on the OMB website, and any request for information still needs to go through the OIRA process.

Mr. WOMACK. I see.

Secretary ACOSTA. And so it has not yet been published.

So, as I tried to indicate—and I have to be very careful because this is an ongoing litigation—as I tried to indicate, this rule was enacted under the Administrative Procedure Act. And through that act, Congress provided a methodology for administrations to enact rules.

And I guess if I was talking to the average person, I would say, when Congress enacts a law, you need a new law to change the old law, and that new law needs to go through the same process as the old law. When a rule is enacted, you need a new rule to change the old rule, and that rule needs to go through the same process as the old rule. And this is an oversimplification to try to address your request, to sort of oversimplify.

And so if there were to be a change, that change would have to be based on information that is obtained through a record process, the first step of which is a request for information that establishes the beginning of additional information in the record. And based on that information and if that information supports it, then the administration could look to a new rule that could change the previous rule, just like Congress, as it gets new information, could say, we want to enact a law that is somewhat different.

Now, that sounds cumbersome and that sounds—some have said it is about process. But it is not about process, it is how the democracy works. And no one in government should be able to snap their fingers and undo laws or undo rules, because that is not a respect for fundamental democracy.

Mr. WOMACK. There are concerns about inhibiting job growth, job creation, cost-benefit questions, impacts on, say, younger generation who are just now beginning to save for retirement.

Is it not obvious that this is going to limit their options? Does it have some far-reaching effects that would be counterproductive to particularly younger generation saving opportunities?

Secretary ACOSTA. Congressman, there are concerns. Those concerns were voiced in the original rulemaking process. And the prior administration made a decision that those concerns were outweighed by what the prior administration wanted to do.

At this point, the Administrative Procedure Act and administrative law prohibit me from prejudging a rule. And so I need to be careful. I will acknowledge those concerns, but we need the data to substantiate those concerns, because the decisions have to be based on the record or else it becomes prejudgment. But those concerns certainly surfaced the first time around and, unfortunately, they were not heard, and that is what happens.

Mr. WOMACK. I hope they are heard in the next review.

CONSOLIDATING GOVERNMENT PROGRAMS

In the time that I have left, I do want to congratulate you for attempting some consolidation to save money, because we do operate under a finite resource environment. But specifically, the OFCCP and the EEOC, are there other opportunities out there to consolidate and create some economies of force, if you will, among our departments?

Secretary ACOSTA. Well, Congressman, I do think an area of consolidation, referencing the ranking member's question earlier, we

have, I believe, 37 different job education programs just at the Department of Labor alone, and that doesn't include the job development programs that we have at Veterans Affairs, at the Department of Education and elsewhere.

And ultimately, we all want to provide job education. We really, really do. Everyone wants to see the unemployment rate remain low, everyone wants to see the job openings filled, and that is something I think we can all share. The question is, is that best done with the 50 or more programs throughout government or is that best done with a handful of programs that are highly successful?

Mr. WOMACK. Thank you.

I yield back.

Mr. COLE. Thank you.

We now go to my good friend, the distinguished lady from California, Ms. Lee.

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

Good morning, Mr. Secretary.

Secretary ACOSTA. Good morning.

Ms. LEE. Good to meet you.

IMPACT OF CUTS TO WORK FORCE TRAINING PROGRAMS

I want to follow up with regard to the cuts as it relates to workforce training. But first let me just say there have been several estimates about the overall Trump budget as it relates to job losses, even though, unfortunately, we heard the President talk about putting America First and creating jobs in America. But I know one estimate has the overall budget totaling a 1.4 million job loss by 2020, given this budget. Your agency has a large part of this job loss responsibility, quite frankly.

With regard to the workforce training, for example, the 40 percent cut under Title I for adults, youth, and dislocated workers, it is really shameful, especially when you look at what, for example, other departments are requiring in terms of work requirements as eligibility for food stamps, for example. Yet you are cutting the very work training programs that would help people get jobs. And yet, on the other end, the Trump administration is saying, but if you don't have a job, you are not eligible for food stamps.

These cuts are outrageous as it relates to communities of color. And I want to go and hear your understanding of why the unemployment rate is still twice, for example, in the Black and Latino community, 4.3 percent nationally, 7.5 percent in the African American community, 5.2 percent in the Latino community.

So investments in workforce training, in reintegration of ex-offenders, you are cutting 12 percent out of that account. You are cutting the 5 percent out of the apprenticeship programs.

What is your analysis as it relates to communities of color? And don't we need—and do you believe we need targeted investments in communities of color where this unemployment rate is still twice what the national average is?

Secretary ACOSTA. Congresswoman, thank you. Thank you for the question.

Let me start off by saying I don't know where the data came from regarding the job impact of the budget, but—

Ms. LEE. Economic Policy Institute is one organization that has indicated about a 1.4 million job loss by 2020 by the Trump budget.

FOCUSING ON JOB TRAINING WITH A LEANER BUDGET

Secretary ACOSTA. So I will have my staff pull that information. But let me say, I am exceedingly focused on jobs, jobs, and jobs. That is a very clear, a very, very clear priority. And so I hear everything you are saying.

You know, just a few days ago I found out that—I was told, and I don't know if it is factual or not, but I was told that the Bureau of Prisons doesn't open—doesn't allow access once individuals are moving into the community and starting to reenter into apprenticeships, private sector apprenticeships. And I directed my staff to call over and start finding out why, because that does have a disproportionate impact on communities of color.

And just this morning I was talking about the cybersecurity apprenticeship program at the University of Maryland, and one of the—

Ms. LEE. Mr. Secretary, I want to go to your budget, in terms of the cuts and the impact on communities of color, especially given the unemployment rates and given the cuts in workforce training in Job Corps and employment services and apprenticeship services as it relates also to the work requirements of other programs.

Secretary ACOSTA. And that is where I was trying to go. The point I was making about the apprenticeship program at the University of Maryland is that they were telling me that it disproportionately helps communities of color, because it is a cohort program that provides a community and a support system. And so I think your points are very, very important.

I think one of the issues raised by the budget and one of the themes that I am hearing that I would push back against a little bit is the notion that it is all about just how much you spend. The budget overall makes very, very hard decisions. And as part of that, we are going to have to reallocate the money from some programs that are less effective to some programs that are much more effective.

Ms. LEE. Mr. Secretary, how do you then allocate Department of Labor cuts, in terms of workforce training, to create the type of job training programs that everyone who is unemployed who is trying to get a job needs with those cuts? And I specifically ask because in communities of color you are looking at 7.5 percent unemployment rate in the Black community and 5.2 percent in the Latino community.

And so specifically, with regard to those cuts, how do you create the skill sets and the eligibility requirements for people to get these jobs that exist yet aren't filled?

Secretary ACOSTA. Congresswoman, and that is why I was referencing programs like apprenticeships and others, where you do not saddle individuals with debt, where you help them gain job skills, and where particularly communities of color can benefit and have been shown to benefit from gaining these jobs.

Ms. LEE. Mr. Secretary, there is a \$5,000,000 cut in your apprenticeship programs. And so what I am concerned about—

Mr. COLE. I would ask the gentlelady and the Secretary to please—we are at time, and I want to give everybody a second round if we can.

Ms. LEE. Okay. Thank you, Mr. Chairman.

But I still don't quite understand when you cut apprenticeship programs and workforce training programs how you help create a pathway to middle class jobs for people.

Mr. COLE. I appreciate that very much.

And now we will go to my good friend, the distinguished doctor from Maryland, Dr. Harris.

Mr. HARRIS. Thank you very much.

Thank you, Mr. Secretary, for being here. Congratulations on your appointment.

PRIORITIZING FEDERAL SPENDING

Look, I agree with the framework of the President's budget. The bottom is, we do have to finally prioritize spending. We have a \$500,000,000,000-a-year deficit, a \$20,000,000,000 debt, and the last President never presented a budget that ever, ever balanced. Now, no family can do that. No business can do that. It is about time the Federal Government doesn't do that.

So we do need to prioritize spending to undo the defense rollback of the last administration and to reduce our deficit and eventually balance the budget. So I support the President's framework, no question about it.

With regards to the Economic Policy Institute, I wouldn't spend too much time looking into what they do. It is a union-backed organization that—look at their website, look at the front page—that is just a President-bashing site. I get it, I understand there is division in the country, but their alternative facts are just not correct.

H-2B VISA CAP RELIEF

Let me talk about two specific issues very important to Maryland and my district. First is H-2B cap relief. We have industries in my district, specifically the seafood processing industry, that simply cannot find American workers to do those jobs. Those jobs exist for only 4 or 5 months out of the year. My idea of full American employment is not having every American have a job that lasts 4 or 5 months if we can do that with temporary foreign workers.

As you know, the omnibus bill did authorize up to an additional 69,000 temporary worker visas, but after consultation between DHS and DOL.

So I just want to ask you, what is the status of those consultations and are we going to begin to see an increase in the numbers of H-2B visas processed this year, especially for the summer season, so important in my district?

Secretary ACOSTA. Congressman, thank you. Thank you for the question.

And first, let me clarify, as the chairman mentioned earlier, one of the confusions here is that, because there wasn't a budget and there had to be a midyear change, the increases and the decreases are difficult to measure.

But with respect to apprenticeships, the budget is being—there is reduction in apprenticeship spending. It is the same level as the 2017 continuing resolution.

Now, moving to your question on H1Bs. I am very sensitive to your question and the concern. H1Bs generally I think fall into—

Mr. HARRIS. H-2B.

Secretary ACOSTA. I am sorry. H-2Bs generally fall into two categories, what I will call the truly seasonal worker, such as you are referencing, and that is a very specific industry and a specific geography and a more general worker. And something that I think we need to look at are long-term fixes in a few areas.

First, employers have to apply for jobs no more than 3 months in advance, but there is a 6-month window. And so if you have to apply 3 months in advance for a 6-month window and the caps are reached almost immediately in January, unless you are starting employment in April, you are locked out of the system. And that has an impact on a few geographical locations where they are, in essence, locked out of the system. And my staff has already started talking to staff about ways to address that, possibly breaking down the number in a more logical way that doesn't disadvantage certain geographies over others.

I think the second question that needs to be addressed is, how do you address the needs of certain geographies that have extreme peaks in demand that are seasonal for a short period of time? And how do you address those without opening the program broadly? Because for those geographies with extreme peaks, that demand simply cannot be met by the local workforce or even a workforce that is brought in.

And so those are two very complicated fixes that I very much hope to work with Congress on a long-term solution.

As to the shorter-term solution, we are in discussions with DHS that has the ultimate authority on this. And what I can say is I am sensitive to your concerns, but there is also the concern that raising the overall cap may not really address what is a unique situation in your State and about half a dozen other States throughout the country.

Mr. HARRIS. Thank you. Obviously, you understand the issue and hopefully maybe this can be a bridge to solving it.

OVERTIME RULE

I just want to in the remaining few seconds just mention that the overtime rule is very significant for educational institutions, and in the University of Maryland system, it would increase cost between \$16,000,000 and \$40,000,000 in a year. So I would urge you to look at that cap and perhaps just do an inflation adjustment instead of raising it as far as it is, because it is so important to our educational institutions.

Thank you. I yield back.

Mr. COLE. Thank you.

We will now go to my good friend from Wisconsin, Mr. Pocan.

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

And nice to meet you, Mr. Secretary.

FOCUSING ON APPRENTICESHIP

I am very encouraged to hear what your personal goals are around apprenticeship. I strongly believe that too. I wish we had apprenticeship programs in technology and healthcare and a whole bunch of other areas. I think that would be very useful.

And we do have a bill that was introduced, the LEARNS Act, you might want to take a look at. We haven't reintroduced it yet this Congress. It was bipartisan in the Senate. It talks about some initiatives around that. But a strong supporter of apprenticeships and glad to hear your commitment, and I know you made comments when you came back from Germany.

MAINTAINING THE ADVISORY COMMITTEE ON APPRENTICESHIP

The questions I have, hopefully, are fairly brief, just trying to get some idea. One is, are you going to maintain the Department's Advisory Committee on Apprenticeship?

Secretary ACOSTA. Congressman, I have no current plans not to. I think advisory committees are very, very helpful.

Mr. POCAN. All right, thank you.

CRANE OPERATION CERTIFICATION RULE

Second, I know there is a rule, a promulgated rule around crane operation certification, crane operator certification, and I know that there is some consensus around the industry. I know they would like to talk to you about some changes. Are you open to talking to them? I think there seems to be a consensus among the industry, and if we could just make some changes, the rule might turn out to be a little stronger for everyone.

Secretary ACOSTA. I love talking to both industry and representatives of workers. I have already started outreaching to many different organizations, and I would welcome the opportunity for them to come in. And if your office or your staff would provide the contacts, I would welcome that.

Mr. POCAN. Thank you. Appreciate that.

WAGE THEFT ENFORCEMENT STRATEGIES

On the Wage and Hour Division, you know, in the past they have used a lot of the tools and penalties in order to have some strategic enforcement around wage theft issues. Do you intend to pursue similar enforcement strategies regarding wage theft?

Secretary ACOSTA. And so I am not—

Mr. POCAN. Independent contractors especially.

Secretary ACOSTA. So I am not certain exactly what you are referencing, but let me tell you at least my approach. Something that when I was U.S. Attorney that I tried to find is the high-impact cases. And there are different ways of measuring effectiveness. One is, how many cases do you bring? And another one is, do you bring what I will call impact cases? And impact cases are larger cases that have broad-based impact, and it is not just on the individual worker in this context, but it is also the deterrent effect that it has.

And I do think there is a high value to bringing impact cases, but that also has to be balanced with you can't give a free pass to the small actor. And so while you are focusing on the large impact

cases, you also have to recognize that you need to bring a reasonable amount of smaller cases so that the small actor that is behaving wrongly doesn't feel that they have a free pass.

Mr. POCAN. I would just encourage you to look. I think some of the past actions were very helpful. When we met with the Department of Labor last session when I was on Education and Workforce, they are estimating up to 70 million people might be independent contractors right now. Clearly, that is not the realistic case that is out there. I have been an employer for three decades. So if you can continue to look at that, we would really appreciate that.

ELIMINATION OF SUSAN HARWOOD GRANT PROGRAM

Another question, a lot of concerns around the OSHA outreach program that is being cut, the one that kind of does work directly with workers, the Susan Harwood Training and Education Grant Program. Could you just talk about that cut briefly?

Secretary ACOSTA. Certainly. The Susan Harwood grants are being cut. At the same time, though, there is a budget increase of, I believe, \$4,000,000 for compliance assistance. And so our approach to that is we recognize that the money for the grants around compliance will be reduced, but at the same time our intent is to invest in providing that training and that compliance assistance ourselves directly.

Mr. POCAN. Okay. We might just want to follow up with you a little bit on that.

Secretary ACOSTA. Happy to do that.

Mr. POCAN. Appreciate you looking at that.

PRIORITIZING LOW-INCOME WORKERS

Also, how are you going to prioritize helping low-wage workers? Specifically, I think one of the concerns we had last session is people could be making \$24,000 a year and then working way beyond the 40 hours a week without any compensation. Can you address how you are going to take a look at that?

Secretary ACOSTA. Well, do you mean within the wage and hour context or more generally?

Mr. POCAN. Wage and hour context.

Secretary ACOSTA. Well, let me answer both. How is that? Within the wage and hour context, we are going to enforce, and we are going to enforce vigorously. You know, just this week we announced some really interesting enforcement actions that I will provide—

Mr. POCAN. Excuse me, Mr. Secretary. I think broader, you are right. I am sorry. How are you going to look at it? Because the one thing the last administration, they were targeting that \$24,000 figure, just because it seemed so low, you shouldn't have to work beyond the 40 hours for no extra compensation. If you could just address that maybe more generally then, how you are going to deal with it.

Secretary ACOSTA. Certainly.

So I think for lower income, there are two parts. One is, where the law is being violated, we need to look at it and we need to look at it carefully and vigorously.

And just this week, we announced two cases, one of which I thought—I am a little over time—but I thought it was very interesting because it involved what I will call severe mistreatment of individuals that were here on visas. And we will provide your staff with that.

[The information follows:]

PENNSYLVANIA LANDSCAPING COMPANY FAILED TO RECRUIT, HIRE US WORKERS

DAWSON, Pa. – A Southwestern Pennsylvania farm and landscaping company has paid nearly \$22,000 in back wages and penalties after the U.S. Department of Labor found the operator failed to recruit and hire U.S. workers before hiring workers under the H-2A visa program, in violation of section 218 of the Immigration and Nationality Act.

Investigators with the department's Wage and Hour Division found Dawson-based Christner Farms LLC illegally denied one qualified U.S. worker the opportunity to work on the farm, resulting in the back wages due.

"The H-2A visa program provides protections against employers hiring foreign workers over qualified U.S. workers," said John DuMont, director of the division's district office in Pittsburgh. "We will continue to make every effort to ensure that U.S. workers are not unfairly denied jobs."

The division also found that Christner failed to cooperate with the state's workforce agency by not accepting referrals of all eligible U.S. workers who applied for the job opportunity. The company also failed to provide housing for agricultural workers that met required housing safety and health standards, and post required information about the temporary agricultural employment of foreign workers.

Christner has paid \$11,275 in back wages and \$10,463 in civil money penalties to resolve the matter.

The division is committed to providing companies with the tools they need to understand and comply with the variety of labor laws the division enforces. It offers useful resources ranging from an interactive Employment Laws Assistance for Workers and Small Businesses advisor to a complete library of free, downloadable workplace posters. In addition, Community Outreach and Resource Planning specialists conduct ongoing activities to educate stakeholders, including employers, employees, business and labor groups and professional associations with accessible, easy-to-understand information about their rights and responsibilities.

For more information about federal wage laws, call the agency's toll-free helpline at 866-4US-WAGE (487-9243). Information also is available at <http://www.dol.gov/whd/>.

WHD News Release: 06/07/2017

Contact Name: Leni Uddyback-Fortson
Email: uddbyback-fortson.lenore@dol.gov

Phone Number: (215) 861-5102

Contact Name: Joanna Hawkins
Email: hawkins.joanna@dol.gov
Phone Number: (215) 861-5101

Release Number: 17-0585-PHI

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US DEPARTMENT OF LABOR OBTAINS HISTORIC PRELIMINARY INJUNCTION REGARDING ENTITIES ACCUSED OF PROVIDING DANGEROUS SUBSTANDARD LIVING CONDITIONS TO WORKERS

SAN FRANCISCO – For the first time in its history, the U.S. Department of Labor has successfully obtained a preliminary injunction order under the H-2A visa program against entities accused of providing illegal and life-threatening living conditions to its employees. G Farms, its owner, and three other defendants are accused of providing the dangerous and substandard housing to agricultural workers in El Mirage, Arizona.

G Farms claimed in its H-2A visa application that it would provide shelter for its workers in mobile housing units. Instead, G Farms appears to have forced its workers to sleep in converted school buses and semi-truck trailers in violation of numerous safety, sanitation and fire code regulations. The buses and trailers also appeared to be dangerously overcrowded, with beds stacked end-to-end, and had inadequate ventilation systems, which allowed daytime temperatures to exceed 100 degrees Fahrenheit.

"What G Farms is accused of doing is simply inhumane," said U.S. Secretary of Labor Alexander Acosta. "No worker deserves to be treated this way. And honest employers cannot compete against those who break the law by underpaying and mistreating their workers."

"The conditions here were truly shocking and posed a serious threat to the lives of these farmworkers, who appear to have been expressly lied to before they arrived about the nature of their accommodations. The carelessness shown for the ability of these workers to survive until the next work day is as troubling as the abuse by this employer and recruiting agents of the strict requirements of the H-2A visa program. Violation of this federal law also hurts American workers who might well want these jobs if the employers provided safe housing and fair wages, and harms law-abiding employers who pay and treat workers fairly," said Janet Herold, regional solicitor in San Francisco.

The U.S. District Court for the District of Arizona granted the preliminary injunction on May 19, 2017, following a request submitted May 12, 2017, by the department's Office of the Solicitor. The department continues to investigate the violations and has also been in contact with its Office of Inspector General.

The H-2A temporary agricultural program establishes a means for agricultural employers, who anticipate a shortage of domestic workers, to bring non-immigrant foreign workers to the U.S. to perform agricultural labor or services of a temporary or seasonal nature.

The program requires an employer to attest to the department that it will offer a wage that equals or exceeds the highest of the following: the prevailing wage for the occupation and geographic area, applicable federal minimum wage, state minimum wage or local minimum wage. This wage will be paid to the H-2A workers and certain similarly employed U.S. workers during the entire period of the approved labor certification. The program also establishes recruitment and displacement standards to protect similarly employed U.S. workers.

For more information about the H-2A program, the Fair Labor Standards Act and other federal wage laws, call the Wage and Hour Division's toll-free helpline at 866-4US-WAGE (487-9243). Information also is available at <http://www.dol.gov/whd>.

WHD News Release: 06/06/2017

Contact Name: Leo Kay

Email: kay.leo.f@dol.gov

Phone Number: (415) 625-2630

Contact Name: Jose Carnevali

Email: carnevali.jose@dol.gov

Secretary ACOSTA. But the kind of working conditions that no one should have to work under. They were being asked to sleep in a bus that was un-air-conditioned, you know, so that they could be by the work site.

And so, as far as I am concerned, we are going to enforce all that.

More broadly, going back to the skills gap, it is not just about enforcement. You have to provide people a pathway out. And I hate to sort of be one note on this, but particularly for lower-income folks, providing those skills is, I think, critical.

Mr. POCAN. Thank you.

Mr. COLE. We will next go to the distinguished member from Michigan, my good friend, Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

H-2B VISA PROGRAM

Mr. Secretary, thank you for being here with us today. And I wanted to build on some of the discussion that you were having with Dr. Harris about the H-2B visas. And I strongly support the points that he made, and I appreciated your understanding of this issue and also the idea that there are a few things you are able to do in the short term to look at some of the timing issues and also geographies with extreme peaks. And also it may require more complicated legislative solutions, and I would just offer to work with you on that in any way I can be helpful.

Secretary ACOSTA. I appreciate it.

Mr. MOOLENAAR. You know, in Michigan the H-2B visa program is extremely important to seasonal employers, and resorts and other seasonal businesses throughout my district in northern Michigan rely on the H-2B program to operate, especially during the summer tourism season. And right now there are dozens of businesses in northern Michigan, especially on Mackinac Island, facing the prospect of limiting hours that they are opening—or not opening at all—due to labor shortages and the early exhaustion of H-2B visas.

And I don't know if you are familiar with that situation, but it is something that I do want to bring to your attention. And I was pleased that you have been consulting with Homeland Security and would just want to raise that issue, because it is a jewel of Michigan and I have heard repeated concerns about the lack of workers that are projected.

Secretary ACOSTA. Congressman, if I could just—I am not sure that was a question—but if I could just reemphasize my comment. You know, I think it is very important that we look at a way to address the truly seasonal demand and separate that from the broader, because I understand and feel for those businesses that are engaged in the truly seasonal demand, but the current program does not separate those.

POSTPONING THE FIDUCIARY RULE

Mr. MOOLENAAR. Okay. And then just as a follow-up, you have talked some about the fiduciary rule as well. And I understand the point you are making about not wanting to prejudge. My concern is that as we approach this June 9 timeline, I wonder if you do have the ability to postpone it going into effect until you are able

to review it or if you have considered that. I know that is something that would—if you were able to postpone it until the review was done and any recommendations you have, I think that would clarify and eliminate some of the confusion on this issue.

Secretary ACOSTA. Congressman, thank you.

We looked very carefully at whether we could postpone it. And to sort of fall back on the earlier analogy, when Congress passes a law, the executive branch can't just postpone implementation of that law. And when a rule is adopted, the executive branch cannot—with very, very narrow exceptions—just postpone implementation of that rule.

And if the executive branch was allowed to do that, then that would be an immense power that the executive branch would have. And so one of the difficulties is folks may say, well, sometimes the executive branch takes upon itself power that it shouldn't have, but that is not what the law says, and rules can't just be postponed even if there are concerns.

So we have looked at it, we have looked at it very carefully, attorneys at various levels have examined this, and we have come to the conclusion that there simply is no basis to postpone the June 9 date.

I should add that the full rule does not come into effect on June 9. Several important provisions of the rule do not come into effect until January 1. So the prohibition on arbitration doesn't go into effect until January 1 and the State law causes of action do not go into effect until January 1.

But as to the June 9 date, which is what is before us now, we have looked at it very carefully, multiple attorneys have looked at it, and the conclusion has been that there is no basis to postpone the rule.

Mr. MOOLENAAR. Okay. Thank you.

PRIORITY APPRENTICESHIP PROGRAMS

And then just one last question, on the skilled trades and some of the things you learned while you were in Michigan, the apprenticeship programs. Are there certain apprenticeship programs that you think should be at the top of the priority list?

Secretary ACOSTA. So I think particularly the skills trades are looking at a shortage. And something that concerns me—I mentioned earlier that apprentices make an average of \$60,000 starting wage and joked that that is higher than a lot of lawyers, and it is, as a factual matter. But if you look at welders, if you look at carpenters, if you look at so many others, these are professions that aren't attracting as many youth, and these are professions that pay really good money at the end of the day.

And we need to figure out a way to work through apprenticeship programs and others. And these are also professions, I should add, that have established apprenticeship programs that are very effective. So the first thing is don't break what is working, right? But let's find ways to increase and scale what is already working, because we need folks, particularly with the upcoming infrastructure, we know folks that know how to build.

Mr. MOOLENAAR. Thank you.

Mr. COLE. The chair is going to gently admonish the panel, please don't ask the second question 7 seconds before the end of your time. Not very fair to the Secretary. Not very fair to the next people in line. And I do want to give people an opportunity to ask as many questions as possible.

With that, my other good friend from California, Ms. Roybal-Allard is next.

Ms. ROYBAL-ALLARD. Welcome, Mr. Secretary.

JOB TRAINING BUDGET REDUCTIONS

Before I ask my question, I just want to say that I am equally confused about your emphasis on the dire state of the skills gap and then what your budget proposal does to impose a staggering 40 percent cut to WIOA State formula grants, which would actually shatter the successful sector partnerships and career pathways that currently benefits businesses at the local level. And I just want to point out that it is estimated that your budget would result in the loss of job training programs for over 31,000 workers in California alone.

REVOKING FAIR PAY AND SAFE WORKPLACES ORDER

As you know, President Trump signed an executive order to revoke the 2014 Fair Pay and Safe Workplaces order, which required Federal contractors to give wage statements detailing pay and hours to employees to guard against wage discrimination and reduce the wage gap between men and women. The Fair Pay and Safe Workplaces order also stopped companies with government contracts from using forced arbitration clauses to keep sex discrimination claims out of the courts and off the public record. I am deeply concerned by the President's elimination of these protections.

In the absence of the Fair Pay and Safe Workplaces order, what are your plans to protect workers from Federal contractors who violate labor and civil rights laws?

Secretary ACOSTA. Well, Congresswoman, let me answer your question broadly and specifically.

First, let me say that the revocation of any particular order is not intended to lessen enforcement. And more specifically, let me go to the OFCCP and the responsibilities that it has, as well as the Women's Bureau, where we are going to—we have authority over Federal contractors, and we will use that authority and we will use that authority fully and vigorously.

The Women's Bureau, as well, is I think an important part of DOL. And one of the areas that I think it is important for the Women's Bureau to pursue is to look at these issues and to make recommendations within DOL and within government as to what can be done to address issues that are of importance to women, issues that impact women disproportionately. I am glad that the Women's Bureau is within this budget because it will allow the Department of Labor to focus a particular entity on exactly these issues.

MAINTAINING PROTECTIONS FROM FAIR PAY AND SAFE WORKPLACES
EO

Ms. ROYBAL-ALLARD. Okay. If this executive order is not intended to lower enforcement, you said, then what is the purpose of this executive order in revoking the safety measures that are in the pay equity of Fair Pay and Safe Workplaces?

Secretary ACOSTA. So, Congresswoman, I think there are different ways things are measured, and sometimes effectiveness is measured by dollars and sometimes effectiveness measured by outcome. And sometimes protections are measured by process and regulation, and sometimes effectiveness is measured by outcome.

And a reduction in process or a reduction in regulation does not as a matter of necessity imply, nor should it be read as, a reduction in protections. You can protect without having the regulations that overburden or that require excess disclosure.

Ms. ROYBAL-ALLARD. My colleague here just points out that the Women's Bureau is cut by \$9.6 million and 29 FTEs. So you continue to cut the very programs that are meant to do exactly what you said, and that is oversight and protection.

Let me just ask you this. What actions will you take to prevent millions of dollars of Federal contracts from going to companies that partake in labor and civil rights abuses, particularly in pay equity?

Secretary ACOSTA. So, Congresswoman, let me answer your question differently. The Fair Pay and Safe Workplaces EO that you are referencing was the so-called—some in the media called it a blacklisting provision. A CR was passed by this Congress on that matter. We are still going to go after the bad actors irrespective. We still have debarment authority. We have enforcement authority. And we intend to use those fully.

Ms. ROYBAL-ALLARD. Can I just ask you, based on what information? If this information isn't being provided, then what are you going to use as a basis to go after these bad actors?

Secretary ACOSTA. So my understanding of this is that the information is available. The question is whether there is a list that is kept that sort of automatically bars or prevents without additional process or additional safeguards. And that is different from enforcement. The United States engages in all sorts of enforcement activity without keeping lists of potential bad actors.

Ms. ROYBAL-ALLARD. Do you believe that companies—

Mr. COLE. The gentlelady—

Ms. ROYBAL-ALLARD. Just yes or no, do you believe that companies with government contracts should be able to use forced arbitration clauses?

Secretary ACOSTA. Congresswoman, I believe that when engaging in contracting the government has the authority and right to look at what is appropriate in any particular contract situation. I believe it is the policy of Congress, as enacted by legislation and, thus, the policy of the United States, to favor arbitration as a general matter.

Ms. ROYBAL-ALLARD. Sorry, Mr. Chairman, I thought it was going to be a yes-or-no answer.

Mr. COLE. Well, the gentlelady got extra time, but only because the next gentleman asked for an untimed personal announcement that he wanted to make.

Mr. SIMPSON. Yes. We have an announcement that we would like to make. I spent the last 2 nights—this has absolutely nothing to do with this hearing, but it is very important anyway.

Mr. COLE. Yes, it is.

Mrs. DELAURO. Fire away.

MISCELLANEOUS COMMITTEE MEMBER COMMENTS

Mr. SIMPSON. I spent the last 2 nights watching two incredible women's softball teams playing for the national championship. Monday night's game went 17 innings. And I turned on to watch the Nationals play the Dodgers, but it just kept going and going and going. It was an incredible game to watch.

And last night the Oklahoma Sooners won the national championship for the second time in a row, fourth time in their history. And I am really getting tired of saying this, I want to congratulate my chairman and his Oklahoma Sooners for the women's national championship softball game.

Mr. COLE. Third time in 5 years.

Mr. SIMPSON. Yep. It was an incredible game to watch.

Ms. DELAURO. Do they get paid as much as the men get paid?

Mr. SIMPSON. In college they do.

Mr. COLE. Since you brought it up, just for the record, the OU men's golf team won the national title 2 weeks ago, and for the second year in a row, we are the only school to ever have the men and women's gymnastic team claim the national title in the same year. So for those of you who think we just play football, we actually do other things very well.

Ms. DELAURO. Or those of us in Connecticut just play basketball.

Mr. SIMPSON. The question is, did they do any educational services, too?

Mr. COLE. These are brilliant young women. These are brilliant young women. The men's golf team, maybe not so much. But they are awfully a special bunch. But thank you very much.

Mr. SIMPSON. Thank you.

Mr. COLE. My friend is recognized for a normal round of questioning.

Mr. SIMPSON. Thank you, Mr. Secretary. And thanks for being here.

OVERTIME RULE'S IMPACT ON SEASONAL WORK

I want to talk for just a minute about this overtime rule that was proposed by the Obama administration, and this has had a disproportionate impact on seasonal recreation businesses operating on public lands, like guides and outfitters. They are required to obtain a permit to operate on public lands, including in national parks and forests, and that permit makes them a Federal contractor.

The regulations promulgated as a result of this executive order is pushing these businesses off public lands. For an experienced guide, he or she is really on the job 24/7 during the season that they are working, and a week-long trip now becomes prohibitively

expensive. In fact, I have talked to many college students who used to have great jobs working in the summer as an outfitter or a guide or working with an outfitter or a guide who now work in a Burger King, because the outfitter or guide can't hire them anymore because of the overtime rule.

Does the Department have any plans to review and propose changes to this regulation that has been promoted?

Secretary ACOSTA. So I am not certain what your question is. Let me ask answer both possibilities that I think it may be.

So we do have plans to look at the overtime as a general manner, the overtime rule, as I mentioned at my confirmation hearing. I think that any rule that has a dollar amount that isn't updated for as long as this has been is a problem, because life gets a lot more expensive. But I also think that the way it was done created a shock to the system. And the Department is in the process of drafting a request for information that I think will be filed probably in the next 2 to 3 weeks asking for public information and public comment on the overtime rule.

With respect to the more narrow question of how this applies to public lands, that is something that I would have to look into more carefully, and that certainly may be part of that request for information.

Mr. SIMPSON. There are people who believe that the Forest Service, as an example, shouldn't have to comply with this, because they are just getting a permit to operate on public lands, so they don't qualify as a contractor. But the Forest Service feels that they have to comply with this. So that is a question that needs to be resolved.

CONSOLIDATING DOL PROGRAMS

Secondly, when you are talking about jobs and consolidating programs and finding those that work and stuff, we have talked about this on this panel, I suspect there are, in different areas in different States, different programs work differently. And some are successful in one area, where they might not be in another.

I will tell you one that works very well in Idaho. I had the opportunity to visit a few weeks ago the Community Council of Idaho's YouthBuild Program. It does incredible work with young people that they are working with, giving them the skills for the future. And so I hope you would work with this committee as you look at trying to make these programs as cost effective as possible.

IMPROVING THE EEOICPA PROGRAM

Lastly, I need to ask a question for Congressman Fleischmann, who was ill today and couldn't be here, and he asked me to ask this. It says: "I strongly support a Department of Labor program that partially compensates workers who contracted serious illnesses from harmful substances and radiation exposure as a direct result of their national security work. The government, nor its workers who were diagnosed with radiation-related cancers, chronic beryllium disease, and other life-threatening diseases did not fully understand the risk of their weapons-related work during World War II and the Cold War. While major improvements were

made last year to implement the Energy Employees Occupational Illness Compensation Program, more needs to be done."

He has two requests. "Will you personally review this program to understand its importance along with examining the two recent sets of recommendations by the Advisory Board?"

Secretary ACOSTA. Yes.

Mr. SIMPSON. And secondly, in addition, will you encourage your staff to meet with his staff to work on these issues? We work closely with workers in our districts—actually in my district also—and need a good relationship with your Department.

Secretary ACOSTA. I see no problem with that, absolutely.

Mr. SIMPSON. Okay. Thank you.

OFCCP COMPLIANCE ASSISTANCE AND ENFORCEMENT

Since I have got 51 seconds, and I won't go to 7 seconds, the Department of Labor's Office of Federal Contract Compliance Programs is tasked with the mission of protecting Federal contractors and subcontractors by promoting diversity in enforcement of the law. In some instances there be opportunities for the OFCCP to partner with industries and companies who are already working to create equitable and inclusive workplaces.

How can the Federal Government be a better industry partner to create these equitable workplaces, share best practices, and work with contractor communities to further programs? In fact, we put language in our last bill that was Senate language relative to that issue.

Secretary ACOSTA. Congressman, so as a general matter, I think compliance assistance alongside enforcement is very important, and part of compliance assistance certainly is highlighting best practices. I am happy to take that point back, and I believe they are already doing that, but I am happy to take that point back and re-emphasize it.

Mr. SIMPSON. Thank you.

Mr. COLE. I am inclined to be gentle with my friend because of his announcement, but for the record, you went to 9 seconds, and that is just not a big help.

Mr. SIMPSON. I was trying to follow your instructions.

Mr. COLE. Yeah. Okay.

Now to my good friend, the distinguished gentlelady from Massachusetts, Ms. Clark.

Ms. CLARK. Thank you, Mr. Chairman.

And thank you, Secretary Acosta, for being with us today.

RESPONSES TO CONGRESSIONAL INQUIRIES

I want to go back briefly, there has been some mention of the H-2B visa program, certainly a problem seasonally in New England as we go forward. But, specifically, on February 17 I sent you a letter regarding this program with 32 of my colleagues, all of whom happen to be Democrats.

Last week it was reported that agencies have been instructed by the administration not to respond to letters from Democrats requesting oversight-related information. So my question is, is that why I have not had a response?

Secretary ACOSTA. Congresswoman, I, you know, knowing that I was going to come before you all, I checked last week to see if we had responded to the letters that were submitted. And as of yesterday I am told that we have responded to all letters from all members of the subcommittee and the committee, the larger committee.

And so I will—I see my staff writing furiously behind me. So we will check to see where that letter is. I believe it—I believe it has already gone out. But what we will do is we will, if it has not, we will get back and we will get you a copy of it as soon as possible.

Ms. CLARK. Okay. So the good news is my response may be on the way?

Secretary ACOSTA. That is the good news.

Ms. CLARK. And is the better news that that report that you have been instructed not to respond to Democrats is a false report?

Secretary ACOSTA. So I am not going to comment on reports, but I will say that we have responded to the members of this committee, and both the subcommittee and the full committee, and we are in the process of responding to the letters we have received.

Ms. CLARK. Were you ever told by the administration not to respond to Democrats.

Secretary ACOSTA. I have not been told by the administration.

H-2B VISAS AT MAR-A-LAGO

Ms. CLARK. So I will look forward to my response. But in the meantime, I did want to ask you about that letter while I have you here. And one of our concerns was the H-2B visa program as it specifically applies to the 64 visas that are held at Mar-a-Lago.

We have an unprecedented situation where the President has spent almost 40 percent—almost 30 percent of his time as President visiting one of his private businesses and has stayed almost 20 percent of his time as President at Mar-a-Lago where there are these H-2B visas.

Given the security implications of having a President present, are you relooking at the issuance of visas for what the President deems his winter White House?

Secretary ACOSTA. Congresswoman, I am sorry, I don't mean to be difficult. Are you saying are we treating any particular business differently because of the ownership of that business? Is that the question?

Ms. CLARK. I guess that is the question, because we are sort of in uncharted territories. I mean, would you consider—I would assume normally your answer would be no—but since it is now the President of the United States, with all the security issues that are raised, would you consider relooking at—these visas where issued before he took office.

Would that be a particular concern where we now have a President of the United States sitting in a—staying at a private business entity with these visas? Do you see any national security concerns being raised?

Secretary ACOSTA. So what the Department of Labor does is the Department of Labor does a wage certification with respect to any particular visa and sends it over to the Department of Homeland Security. Whatever security concerns may or may not exist I think should be addressed by the Department of Homeland Security.

As to the Department of Labor, I think we need to process visas without picking and choosing which business we give preferential treatment to. And our job, which is a labor certification, is something that we should do and we do do expeditiously.

Ms. CLARK. And that certification says that there are no Americans that could fill those jobs. Is that the certification for H-2B, not enough workers who are able, willing, qualified, and available to do the work? Is that the process?

Secretary ACOSTA. So the labor certification looks at the wage levels and does look at whether or not there are, depending on the program, in some cases, whether there are available workers in other programs. There is no requirement as to work availability, it depends on the type of visa. And so what the Department of Labor does, the Department of Labor processes it in its usual course irrespective of what business that would be, and I think that is the right approach.

Ms. CLARK. Thank you, Mr. Chairman.

Mr. COLE. Thank you.

And before we go to my good friend the gentlelady, the ranking member of the full committee, I just want to—number one, I want to tell you, I listened very carefully to the response you gave Representative Clark and appreciate it. I was very reassured about that in terms of your being forthcoming and responsive to inquiries.

But just for the record, certainly the chairman, I think every member of this committee would be very upset if we ever saw some sort of systematic attempt to not respond to congressional inquiries on the basis of partisanship. And I thank you for making it clear that you do not. And I would hope—and expect, quite frankly—that other members of the administration would operate in the same forthright manner. So thank you for clearing that up.

With that, let me go to my good friend, the ranking member of the full committee. The demands that the chairman and the ranking member have are extraordinary, so obviously she has whatever time she needs to make whatever statement she cares to and then to ask whatever questions she needs to.

Mrs. LOWEY. You are very gracious. And I do apologize for being late, but there are several hearings at the same time.

And I think I will get right to the questions because I know that my colleagues have additional questions. So thank you for appearing before us.

READY TO WORK PROGRAM (H-1B TRAINING GRANTS)

I would like to begin by talking about the Ready to Work program. It is an impressive partnership that is a novel worker training initiative. It was created by the Obama administration. And it used funds from H-1B visa applications to finance job training for the long-term unemployed.

Ready to Work does identify open jobs in a community and trains Americans to fill those jobs. My district fortunately received a \$9,800,000 Ready to Work grant to fund a local program, Jobs Waiting. It is designed to provide 425 individuals with intensive training for jobs in the healthcare and IT sectors.

To date, 350 Hudson Valley employers are involved across a seven-county region, 152 participants have been hired for new jobs. Many more have gone on to additional trainings for specific skills. Job Waiting is set to exceed its initial enrollment goal by the end of June, more than 16 months early.

For many participants, this training has been life changing, and it is an excellent example of the good that can come from leveraging federal investments in the local economy.

Can you share with us the administration's plans for Ready to Work? Will you commit to using funding to support this initiative?

Secretary ACOSTA. Congresswoman, thank you for the question.

H-1B training grants, as a general rule, I think, target particular areas where, you know, we are bringing folks in because we are seeing there aren't enough Americans that hold those jobs. So alongside that we should work to find and prepare Americans to hold those jobs. A should follow B.

And I can't talk with specificity as to that particular program in your district, but from what you are saying it sounds like a good program and a productive program, and one of the things that as we are looking at H-1B issues we would want to keep in the forefront, because ultimately if we are saying there aren't enough folks to fill particular needs, let's also try to find Americans that can be educated to fill those positions. That to me seems very logical.

Mrs. LOWEY. I am with you.

APPRENTICESHIP PROGRAMS

Let me get on to something that I think is relevant, apprenticeships. It really does offer a ticket to the middle class. And research shows that 91 percent of those who complete apprenticeship programs find employment with average wages above \$60,000. However, women are significantly underrepresented. And while women make up nearly half of the labor force in 2015, they comprise less than 10 percent of registered apprenticeships. And strangely enough, this statistic has not budged for the past 20 years.

This committee helped create an apprenticeship grant program in 2016, increased funding in the fiscal year 2017 omnibus. And the explanatory statement accompanying the omnibus included language that directs the Department to prioritize grant applications that recruit and serve women and underrepresented populations. Your budget proposal cuts apprenticeships, and the budget justification does not propose targeted funding to reach underrepresented populations.

I would be interested to know how you arrived at a \$5,000,000 cut. Maybe people working with you didn't explain how successful this program is. What research was done to explain this cut? And why should the American people pay for an unnecessary border wall while cutting funding for worker training and apprenticeship programs?

Secretary ACOSTA. Congresswoman, thank you for those questions.

First, as I referenced earlier, there is a confusion because there are sort of multiple base lines because of the budget process. But fiscal year 2018 has apprenticeships at \$90,000,000, which is the

same level as the 2017 continuing resolution. So from that perspective, I believe there is no cut.

UNDERREPRESENTATION OF WOMEN IN APPRENTICESHIPS

Let me address the broader issue that you raised because I think it is important. Women are underrepresented in apprenticeships, and I think that is important to address. In part, it is because currently many of the apprenticeship programs are in the building trades and women as a whole are underrepresented in the building trades.

From my perspective, I think it is important to broaden apprenticeships far beyond the building trades to many other areas and professions. Just this morning I was saying, if you can see apprenticeships sort of from a big picture—you know, a physician is an apprenticeship. They get education and they get on-the-hands training and they are a resident. And so you could rename a resident an apprentice, right?

And so I think it is important to reconceive apprenticeships broadly, because I think that would be good for industry, but that will also bring more women into the apprenticeship program. I also think it is important that existing apprenticeship programs focus on being accessible to diverse populations, both women and underserved populations, and we should be doing that within existing programs already.

Mrs. LOWEY. Well, I just want to say that this is such an important program, and it is very disappointing to me as we are beginning to approach our focus on the 2018—I think the administration has called it the skinny budget—and there are 30 days left before the end of this cycle, before August. So I do hope that you and your staff are really focusing on programs such as the apprenticeship program, which has been so invaluable, and not accept any proposed cuts in that program. In fact, we should really expand it.

And I want to thank you, Mr. Chairman, for your graciousness. I am sorry, I was at another hearing. Thank you.

Mr. COLE. Well, actually, we are sorry you were at another hearing. We always like you at this hearing.

Well, since we are still in the first round, the gentlelady from Alabama has just arrived, and so I want to recognize her as next up.

Mrs. ROBY. Thank you, Mr. Chairman.

And thank you, Mr. Secretary, for being here today.

OSHA VOLUNTARY PROTECTION PROGRAM

As you know, one of the most important functions of your Department is to ensure compliance with laws and regulations meant to keep the workplace safe. There are a lot of inherently dangerous jobs out there, and we need sensible rules to keep workers safe.

The Occupational Health and Safety Administration, or OSHA, has broad authority when it comes to enforcing workplace rules. But for the last several years, industries in States like Alabama have felt targeted because of our Right to Work status. I hope you will agree with me that advancing a political agenda has no place in enforcing workplace compliance.

I strongly support OSHA's Voluntary Protection Program, or VPP, which focuses on partnering with companies to bring them into compliance rather than targeting them with aggressive punitive penalties. I was happy to see in your budget request that OSHA will, quote, "continue to recognize VPP sites and will continue to prioritize this activity in fiscal year 2017 and fiscal year 2018."

Additionally, your budget request asked for an increase in resources for compliance assistance to increase both the number of outreach and compliance assistance activities and the number of participants in its signature cooperative programs, such as VPP.

I have actually worked on legislation for a number of years to make the VPP program permanent. It just makes sense to help companies become compliant with workplace safety rules on the front end, to avoid costly fines and harmful penalties on the back end, unless, of course, your whole goal is to penalize businesses, which I suspect it is not.

So, Mr. Secretary, can you please speak to your views on this issue? And will your Department prioritize its policy and funding toward partnerships and not penalties?

Secretary ACOSTA. Congresswoman, thank you for the question.

As a general matter, I think it is important that enforcement have both an enforcement component and a compliance assistance component.

The VPP program is particularly successful. I have talked with Department staff about it, and they think it is quite helpful because it really partners with industry and leverages industry staff so that industry staff supports OSHA's work in bringing places up to compliance and then certifying that they are in compliance. And, in fact, the budget calls for an increase in the VPP program. That is something that this administration strongly supports, and that would be a positive from, I think, just about everyone's perspective.

Mrs. ROBY. I appreciate that, Mr. Secretary. And please know that I want to be a partner to help you broaden your Department's outreach compliance assistance activities in support to small businesses and employees in all types of works with compliance issues.

So thank you, Mr. Chairman.

And I appreciate, again, you being here today. Thank you so much.

I yield back.

Mr. COLE. I thank the gentlelady.

And in the interest of time, if I can, I am going to move to like 2 minutes apiece so we have an opportunity to get more people in. And I will go first.

IMPROVING WORKFORCE MOBILITY

We have had some discussion today, Mr. Secretary, about the skills gap, and I appreciate you focusing on that. As we all know, part of the problem is not just a training problem, quite often it is a location problem. We have people literally that are caught in inner cities or caught in depressed rural areas or Indian reservations where literally you can train them but the jobs that they need probably aren't going to be there.

I am just curious as to what efforts can be made in addition to the training, in your view, to try and, if you will, match people with available jobs. It may sometimes require them to move. Those are tough personal decisions, given family considerations and those sorts of things, but sometimes, again, getting the training, there is not enough. So do we do anything or should we do anything that would actually make it—facilitate a move for somebody if there is a job at the other end of it?

Secretary ACOSTA. Well, Mr. Chairman, you raised an important issue because the workforce has become a bit less—you know, I have seen information, I don't want to attest to its accuracy, but I have seen information that the workforce is a bit less mobile.

This morning before this hearing I was at a breakfast and I was talking with some businesses that are engaged in apprenticeships. And one of the issues that we are talking about is now that we have online—increasing use of online education, is there a possibility that apprenticeships can start with some kind of online education so that individuals know if they move, they have a job. In other words, if you complete A, B, and C, and you then move, you have a job waiting for you.

Because it is, I think, unrealistic to expect people to move in the hopes of a job, and it is hard for them to have a job in another locality without actually physically being there. So apprenticeships may provide, through the online education system, a mechanism for doing that.

Mr. COLE. Well, thank you very much on that. And we would look forward to working with you on that kind of issue. I think it is an important thing to think through.

With that, I want to go to the ranking member of the full committee for 2 minutes—oh, I am sorry, I misunderstood. So we will go to the ranking member of the subcommittee.

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

MERGING OFCCP WITH EEOC

Mr. Secretary, the budget proposes to eliminate the Office of Federal Contract Compliance Programs, merging it with the Equal Employment Opportunity Commission, EEOC, which I said at the outset I am opposed to.

OFCCP has an important mission. It ensures that taxpayer dollars do not support discriminatory employment practices. It ensures that Federal contractors are held to a higher standard in their hiring practices, given that contractors are funded with taxpayer dollars.

I know you understand this because I have here, as when you were chair of the ABA's Hispanic Commission, you are familiar with the barriers that minorities and women encounter in the workplace and you have spoken eloquently about those issues.

EEOC, on the other hand, responds to individual complaints of employment discrimination. There is now a backlog of 70,000 cases. Adding the duties of the OFCCP, cutting its budget by \$17,000,000, flat funding the EEOC, only exacerbates EEOC's backlog while eroding nondiscrimination in the Federal contractor workforce.

REDRAFTING EXECUTIVE ORDER 11246

OFCCP enforces Executive Order 11246, prohibit employment discrimination on the basis of race, religion, color, sex, national origin, sexual orientation, gender identity. It ensures that employees can't be punished for discussing pay levels, which is important because many women and minorities aren't even aware that they are being paid less for doing the same.

Now, the budget request calls for a redrafted Executive Order 11246. Know where that order is, whether or not it is being redrafted?

But the questions that come to me from that: Are you planning to allow Federal contractors to discriminate in their hiring, using taxpayer dollars based on race or sex, religion? What about sexual orientation and gender identity? Are you going to remove or revise the requirement that Federal contractors take proactive steps to promote diversity and workplace fairness? Are you going to remove or revise protections for workers who discuss their pay with colleagues?

Tell me what a redrafted Executive Order 11246 is going to include.

Secretary ACOSTA. So, Congresswoman, there are multiple questions in there. I cannot predict what a redrafted order that I haven't seen a draft of, if there is, in fact, a draft, would include. But what I can tell you is, from my knowledge of the policy, the answer—the short answer to your question is no.

Ms. DELAUBRO. Okay. I understand that and you said something about that earlier, I guess, to my colleague, Ms. Clark. But, Mr. Secretary, you are the Secretary of the Department of Labor. That redrafted executive order, if it is—

Secretary ACOSTA. Congresswoman, with respect, I think—I think I said.

Ms. DELAUBRO. Are you going to help to redraft it?

Secretary ACOSTA. Congresswoman, with respect, I think I said the answer—the short answer to all those questions is no, it will not. So I think that—

Ms. DELAUBRO. So we have your word—

Mr. COLE. The gentlelady's time has expired.

Ms. DELAUBRO [continuing]. That Federal contractors are not going to be able to discriminate based on the issues that are out there now.

Thank you, Mr. Chairman.

Mr. COLE. Thank you.

I now go to my good friend from Maryland, Mr. Harris.

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

H-2B VISAS

I am kind of glad we brought up the issue of the potential security problems when Presidents are exposed to H-2B workers somewhere. It is kind of interesting.

Just so you know, Mr. Secretary, and I will follow up with the Secret Service, but, you know, the last President in his last term played 47.5 rounds of golf per year—this is from Golf Digest—306

rounds total for his Presidency. But he actually accelerated things the second half.

And the National Golf Course Owners Association has a place on their web page where they say: We really depend on H-2B workers because golf in some places is very seasonal. So I will follow up with the Secret Service to see if the President, while he was spending, roughly—by the way, 47.5 rounds per year is about 20 percent of your workday time over the course of the year on a golf course.

I personally would rather have a President spending his time at what is deemed the winter White House. But other Presidents choose to spend 20 percent of their professional time on a golf course. I hope the last President wasn't threatening his security because H-2B workers are employed by golf courses.

OVERTIME RULE AND INFLATION

Onto probably a more serious matter than whether the Presidents are exposing themselves to danger when H-2B workers are present. I just want to follow up a little bit about the overtime issue because I neglected to ask you your opinion on the inflation issue with regards to automatic inflator of that overtime threshold, because I don't think statute allows that. Does—thank you. I appreciate being allowed to ask questions without noise coming from the other side of the dais.

Do you intend to adhere to statute and allow Congress to decide when that threshold should be increased, or could it do an automatic inflator? And with that, I yield back awaiting your answer.

Secretary ACOSTA. Congressman, it is always my intent to adhere to statute. You know, again, as I said, it would not be appropriate for me to prejudge any future regulation, but it is always my intent to adhere to statute.

Mr. COLE. Thank you, Mr. Secretary.

With that, we go to the ranking member of the full committee.

WOMEN IN STEM OCCUPATIONS

Mrs. LOWEY. Well, thank you so much, Mr. Chairman.

By the way, Dr. Harris, I don't play golf at all, but this President owns the golf course, not only in New Jersey, not only in the Bronx, but several in Westchester County, and certainly Mar-a-Lago. So I will stay away from the golf issue.

What I would like to ask you is about women in STEM programs. By the year 2020, two out of three jobs will require education and training beyond high school. Women make up just a little over a third of growing middle-skill jobs. Those jobs that require less than a bachelor's degree but more than a high school diploma. And while STEM jobs are driving economic growth and offer jobs with family-sustaining wages, women are only 29 percent of workers in information technology and they make up fewer than 10 percent of workers in advanced manufacturing or transportation, distribution and logistic occupations.

So I really want to work with you to make sure that women have the access to these jobs of the future. But your budget cuts the core workforce development programs by a staggering 40 percent. And given the magnitude of these cuts, how can the administration meet the needs of the workforce? And what impact would your

budget have on women trying to gain the skills necessary for these middle-skill jobs?

Secretary ACOSTA. So, Congresswoman, I was smiling when you started your question because it brought up a really nice memory. In our family we have something called Science Sunday. I have two wonderful little girls, and every Sunday we do something around science. So we started at ages 5 and 7 with an earthworm and proceeded all the way up to a frog dissection.

And I do that because I think from really young it is important to expose them to science, because along the way I think society will push back, and I want to develop that as much as I can, as early as I can. And so it is something I am very personally committed to, and I think it is very important.

The budget makes very hard choices, and the budget makes choices that are tradeoffs. And within those choices we are going to work, and we are going to work hard, to address the needs that you raise because they matter. And I should say, that is not just within the workforce, but that is starting at an early age, starting when someone is 5 years old, because that is when you really, really get them interested in these issues.

And so I am with you. I agree with you. And that is something that we will do.

Mrs. LOWEY. Well, I appreciate that, and I also agree with you that it starts early, because I visit schools all throughout my district on a regular basis, as I know many of us do, and I always ask the class about the science programs. And so much depends on the teacher. Not everyone is fortunate enough to have you as a dad.

So supporting these programs, making sure we are supporting our schools in science training, in apprenticeship programs, all the issues we talk about, are important. So we don't really have to make those cuts, we can look very carefully, and I know we will work together with our chairman to prevent cuts in really important programs that we fund in this committee.

Thank you.

Mr. COLE. I thank the gentlelady.

I think if everybody can stick to 2 minutes, everybody is going to get a second question. I think Ms. Clark would be the most grateful member here for that.

Mr. Secretary, you will have a quick version of the political equivalent of Murderers Row, but they are professional and polite.

With that, I am going to go with Ms. Roybal-Allard.

OFCCP ENFORCEMENT

Ms. ROYBAL-ALLARD. Mr. Secretary, I want to go back to the question as to whether or not government contractors should be able to use forced arbitration clauses. I am concerned that allowing forced arbitration to continue as the President has done will conceal corporate cultures where sexual harassment, sexual assault, and discrimination may be rampant. What happens is when corporations are legally able to keep sex discrimination claims out of the courts and off the public record protections for victims are often weakened.

In the absence of the Fair Pay and Safe Workplaces orders, what are your plans to protect victims of sexual harassment, sexual assault, and discrimination from retaliation by their employers?

Secretary ACOSTA. So, Congresswoman, first, I think there are a few parts to that question.

First, with respect to arbitration, I believe that it is Federal policy to favor arbitration as a general matter because arbitration results in fast resolution of issues, and that is a policy that has been in place for a number of years throughout administrations.

Secondly, as to the Department of Labor-specific plans, we will enforce the laws and we will enforce them fully. OFCCP certainly has authority around gender issues and enforcement. There is also, beyond the Department of Labor, enforcement authority within contracting, disbarment is certainly an option for employers that are bad actors in the contracting process, which you referenced.

And, finally, let me say that above and beyond that, we shouldn't necessarily assume that arbitration is going to result in bad results, because arbitration does have a long history. And, again, as a general matter, it is something that this Congress has favored.

Ms. ROYBAL-ALLARD. The issue isn't just arbitration.

Mr. COLE. The gentlelady—

Ms. ROYBAL-ALLARD. The issue is about forced arbitration.

Mr. COLE. The gentlelady will hold. I really am serious. I want to give everybody a chance that stayed here a long time.

So with that, I want to go to Ms. Lee.

DOL BUDGET PROPOSAL

Ms. LEE. Okay. Mr. Secretary, let me just say that, once again, it appears that most Cabinet members are okay with these huge cuts, including yourself, which, again, I have to refer to Steve Bannon's notion that you all are really deconstructing the administrative state. This budget shows that. A 16 percent cut is outrageous.

Here now you are trying to merge the Equal Opportunity Commission, the EEOC, that enforces discrimination laws, with the Office of Federal Contract Compliance. And to merge these two and to reduce the budget overall, the NAACP and the U.S. Chamber of Commerce both oppose this. These entities usually don't agree with each other. And so why would you, again, reduce—merge these important agencies, given what we know about discrimination in America?

OFCCP AND EEOC MERGER

Secretary ACOSTA. So, Congresswoman, the budget is making, as I said before, hard decisions. And as an administration, those are decisions that have to be made.

With respect to the specific question regarding the merger of the OFCCP and EEOC, as it proceeds, one of the issues that we are going to have to look at—and it is going to require separate legislation, because they are agencies that have two different functions. They overlap in many ways, but they also have separate authorities.

One proceeds from the contracting authority and is, in essence, an auditing agency. The other one is charged with antidiscrimina-

tion law enforcement and proceeds based on complaints. And that is a distinction that is important.

So while overall there will be cost savings by the merger, and the budget shows that it actually doesn't reduce the enforcement, it reduces—the cost savings all come from streamlining a process by the merging, certainly in that process it is going to be important to, when it is legislated, if it is legislated, understand that there are different—

Ms. LEE. So our Department of Labor is going to allow now discrimination to run rampant in the workplace in the country with Federal contractors, and it is outrageous.

Secretary ACOSTA. Congresswoman, with respect, I don't think that is the case.

Ms. LEE. I think it is.

Mr. COLE. With that, we will move on to Mr. Pocan.

Mr. POCAN. Great. Thank you, Mr. Chairman.

WISCONSIN BIG STEP APPRENTICESHIP PROGRAM

So with your sincere interest in apprenticeships, let me extend an invitation to you to come to Wisconsin. There is a program in Milwaukee and Madison called BIG STEP, it is part of the Wisconsin Regional Training Partnership that takes a lot of underserved populations to get them into the trades. They are doing a great job, they have been around for over a decade.

When I was in legislature a decade ago I helped find them some funding. I think it could be a national example for you and I would love to show that to you. Summer is a good time to come to Wisconsin, not winter. I would love to have you there.

MAINTAINING DOL STANDARDS AND 2018 BUDGET CUTS

Two quick questions so I don't get into Ms. Clark's time. One, just would ask just to see if you could make sure that we can commit to defend and maintain and implement the silica standard to protect people from exposure to silica.

Second is just a concern in the budget about the cuts to the Bureau of International Labor Affairs and the grants for that department being eliminated. It seems like from conversations that the President has had he understands the connection to working standards overseas, what they mean to labor and trade agreements here. But those cuts, I think, could be detrimental.

I would just like to have you answer those two questions.

Secretary ACOSTA. Certainly. Let me first respond with respect to the silica. I believe that the enforcement on that has been delayed until September 23 to allow for compliance for general industry and maritime, but I think that that is proceeding.

And I apologize, I got distracted with respect to the second part to your question.

Mr. POCAN. On the ILAB funding, the cuts.

Secretary ACOSTA. Yes. So with respect to the ILAB funding, the cuts that are being—that are within the budget are focused almost entirely on foreign grants. And so it would not reduce the enforcement part of ILAB that focuses on trade enforcement. The cuts focus on the grants that are given to foreign governments, to assist foreign governments in compliance and to sort of act as training for

foreign governments. With respect to the enforcement part of ILAB, that would virtually remain unchanged.

And happy to go to Wisconsin.

Mr. COLE. For the last questions of the day, Ms. Clark from Massachusetts.

MAINTAINING OFCCP CORE FUNCTIONS

Ms. CLARK. Thank you, Chairman. I want to go back also to the OFCCP and putting this together. I think the real concern is that the EEOC responds to complaints that are made and the OFCCP proactively audits companies to make sure that they are complying with discrimination.

In the priorities that you have set forth, you have specifically said that the OFCCP will continue to focus on pay discrimination. There is no mention of discrimination based on race, religion, gender, sexual orientation, gender identity, or national origin. Is the Department of Labor still asking the OFCCP to do that work?

Secretary ACOSTA. So, A, absolutely. Are you referring to the priorities set forth in—which document are you referring to? Because the answer is absolutely.

Ms. CLARK. Okay.

Secretary ACOSTA. So the second point that I would make is the two agencies are different in nature. And the point that I was making when your earlier colleague asked her question is that any merger necessarily should, in fact, take into account that one is, in essence, an auditing agency and the other is, in essence, a complaint-based agency. And, therefore, while there is overlapping purpose, there are different mechanisms for enforcement and investigation, and that is an important distinction.

Ms. CLARK. I understand your testimony. Those will both be preserved, the proactive auditing and the complaint response that we currently have. Is that correct?

Secretary ACOSTA. Yes.

Ms. CLARK. Yes. Okay.

So just a quick example. In April, OFCCP reached a \$1,700,000 settlement with Palantir Technologies over allegations of anti-Asian-people hiring practices and discrimination. Is that the type of proactive case you will continue to pursue, even when putting these two together?

Secretary ACOSTA. So, Congresswoman, I am not familiar with that example. But, again, my understanding of the proposal is that it is a streamlining proposal and not a change-of-nature proposal, and that is something that will have to be addressed when there is legislation that unifies these.

CLOSING REMARKS

The CHAIRMAN. I thank the gentlelady.

Mr. Secretary, thank you very much for being with us today. It was a very informative, complete, and thorough hearing. We appreciate your forthcoming manner and the cooperative style you displayed, and we look forward to working with you as we go forward.

With that, the hearing is adjourned.

Secretary ACOSTA. Thank you.

[The following questions were submitted to be answered for the record:]

Questions for the Record from Mr. Cole

FOCUSING ON JOB TRAINING

Addressing the skills gap continues to be one of my highest labor priorities.

Mr. Cole: What do you believe are the most effective things Congress should be focused on in order to ensure Americans obtain the skills they need to fill the job openings employers tell the government they can find enough workers for?

Mr. Acosta: Federal workforce development programs should prepare job seekers for high-growth jobs that actually exist. Work-based education, including high quality apprenticeships, are effective approaches to help narrow the skills gap—enabling employers to be involved in the education of their future workforce so they can be sure new hires possess the skills needed to do the job. Apprentices receive wages and, just as importantly, skills that enable them to thrive in today's workforce. They earn while they learn.

Mr. Cole: What kind of jobs are these and how do we ensure the job training system is preparing workers for jobs that are currently available?

Mr. Acosta: High-growth industry sectors include advanced manufacturing, infrastructure, cybersecurity, and health care. But businesses all over the country need skilled workers, and our education and workforce development programs need to be market-responsive. Employers looking for skilled workers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations.

JOB TRAINING STRATEGIES FOR SKILLED LABOR

Many industries, including construction, continue to experience significant shortages of high-skilled and skilled labor.

Mr. Cole: In your view, what are the most effective job training strategies and ways to ensure sufficient supply of skilled workers for the building trades in the future?

Mr. Acosta: Effective strategies include work-based education, and high-quality apprenticeships are a good example. According to Department statistics, graduates of apprenticeship programs have a high average starting wage—\$60,000. They are likely to have a job upon completion of their program and often receive certifications recognized across an industry. A 2012 Mathematica study also found that apprenticeship program completers earned an average of \$250,000 more than similar non-completers over the course of their careers. Apprenticeships provide paid, relevant workplace experiences and opportunities to develop skills that employers value, including in the building trades.

ENSURING A PIPELINE OF SKILLED WORKERS

A major concern for water utilities across the country is filling jobs left behind by the aging workforce.

Mr. Cole: What are some of the most promising job training strategies to ensure a pipeline of skilled workers will be in place to provide clean and safe water for the public and to maintain the water infrastructure necessary to keep service areas economically viable both nationwide, and specifically in rural areas?

Mr. Acosta: High-quality apprenticeships can effectively help industries fill positions critical to their operation. The Department of Labor strives to maximize the efficient use of federal resources so that individuals are well-prepared to meet workforce needs—whether after college, after obtaining an associate's degree or other recognized postsecondary credential like a certification, or after high school, regardless of whether one earned a diploma. I look forward to working with all industries, including water utilities, to expand job opportunities for Americans and help fill open positions in vital industries throughout the nation.

**UPDATE ON WORKFORCE INNOVATION AND OPPORTUNITY ACT (WIOA)
TECHNICAL ASSISTANCE FUNDING**

Mr. Cole: Please update the table provided in fiscal year 2016 to reflect the actual use of fiscal year 2014-17 funds for technical assistance and other activities related to the implementation of WIOA. Please also include on the table all funds requested in the fiscal year 2018 budget for technical assistance and other WIOA implementation activities.

Dislocated Worker (DW) Technical Assistance and Training (TAT) Funds Spent on WIOA Technical Assistance and Implementation Activities				
Activity	PY 2014 DWTAT Obligated	PY 2015 DW TAT Obligated	DWTAT and WIOA TA Appropriated but Not Obligated	PY 2016* Requested
WIOA Implementation & IT	\$0	\$8,200,000	Up to \$11,100,000	Up to \$11,100,000
Technical Assistance	\$0	\$3,215,900	At least \$3,232,000	At least \$3,232,000
Grants to States & Others	\$10,856,352	\$0	TBD	TBD
Total	\$10,856,352	\$11,415,900	Estimated \$14,332,000	Estimated \$14,332,000
Other Funds Spent on WIOA Implementation Activities				
Activity	PY 2014 WDQI Obligated	PY 2015 WDQI Obligated	PY 2016** WDQI Appropriated but Not Obligated	PY 2017 WDQI Requested
WDQI	\$6,000,000	\$4,000,000	\$6,000,000	\$40,000,000
FY 2014	FY 2015	FY 2016	FY 2017	
Spending to Date				Requested
Program Administration	\$3,235,796	\$3,787,588	\$265,000	\$11,226,000
ES TAT	\$0	\$80,000	\$750,000	\$0

*The FY 2016 funds for PY 2016 become available in July and October of 2016. We are planning to prioritize these funds for several key IT projects, technical training for the WIOA regulations, and technical assistance to implement strategies for success. For PY 2016, technical assistance funds will include the additional 5 percent of Dislocated Worker TAT funds authorized for WIOA implementation, and technical assistance as needed, as well as the \$3,232,000 authorized for the first time in the FY 2016 Consolidated Appropriations Act for technical assistance activities under Section 168 of WIOA.

**In FY 2017, the Department requested \$3,232,000 for WIOA TA and continued flexibility within the appropriations language to expand the allowable use of the National Reserve technical assistance and training funds (DW TAT) to include activities that support WIOA implementation. These funds are also available on a Program Year basis and will become available in July 2017.

***The PY 2016 funds are appropriated in FY 2016 and do not become available until July 2016.

Mr. Acosta:

**Dislocated Worker (DW) Technical Assistance and Training (TAT)
Funds Spent on WIOA Technical Assistance and Implementation Activities**

Activity	PY 2014 DWTAT Obligated	PY 2015 DWTAT Obligated	PY 2016 DWTAT and WIOA TA Obligated	PY 2017* DWTAT and WIOA TA Appropriated but Not Obligated	PY 2018** Requested
WIOA Implementation & IT	\$0	\$8,200,000	\$11,010,000	Up to \$11,100,000	\$0
Technical Assistance	\$0	\$3,215,900	\$3,227,000	\$2,500,000	At least \$5,226,000
Grants to States & Others	\$10,856,352	\$0	\$0	\$0	\$0
Total	\$10,856,352	\$11,415,900	\$14,237,000	Estimated \$13,600,000	Estimated \$5,226,000

Other Funds Spent on WIOA Implementation Activities

Activity	PY 2014 WDQI Obligated	PY 2015 WDQI Obligated	PY 2016 WDQI Obligated	PY 2017 WDQI Appropriated but Not Obligated	PY 2018 WDQI*** Requested
	FY 2014	FY 2015	FY 2016	FY 2017 Spending to Date	FY 2018 Requested
WDQI	\$6,000,000	\$4,000,000	\$6,000,000	\$6,000,000	\$0
ES TAT	\$0	\$80,000	\$807,446	\$230,000	\$0

* For PY 2017, technical assistance funds will include the additional 5 percent of Dislocated Worker TAT funds authorized for WIOA implementation, and technical assistance as needed, as well as the \$2,500,000, reduced from \$3,232,000 in the FY 2017 Consolidated Appropriations Act for technical assistance activities under Section 168 of WIOA. The PY 2017 funds are appropriated in FY 2017 and do not become available until July 2017.

**In the FY 2018 President's Budget, the Department requested \$5,226,000 for WIOA TA. WIOA Implementation may no longer be expressly authorized within anticipated levels of PY 2018 DW TAT funding, and as a result this amount of \$5,850,000 is the total for DW TAT, with \$0 set aside for WIOA Implementation. These funds are also available on a Program Year basis and will become available in July 2018.

***PY 2018 WDQI has been requested to be discontinued in the FY 2018 President's Budget.

CHANGES IN EXPECTED USE OF WIOA TECHNICAL ASSISTANCE FUNDS

Mr. Cole: Please describe the rationale for any changes over the past year to the expected need and use of technical assistance funds.

Mr. Acosta: The Department of Labor will continue to oversee effective and efficient implementation of Workforce Innovation and Opportunity Act through a variety of technical assistance efforts.

USE OF WIOA TECHNICAL ASSISTANCE FUNDS

Mr. Cole: Please describe the purposes and types of activities being undertaken with technical assistance funds for WIOA implementation.

Mr. Acosta: Program Year 2016 technical assistance funds were used to support several activities. Funds supported the Innovation and Opportunity Network (ION) on the Employment and Training Administration's online technical assistance platform WorkforceGPS, used by all six core federal programs and one-stop partner programs to hold Workforce Innovation and Opportunity Act (WIOA) regulations education and to communicate information, toolkits, online education, and discussions on WIOA implementation. Funds also supported in-person WIOA regulations education and established the WIOA IT Support Center, to help states implement IT solutions that support cross-program integrated service delivery. Funds also supported coaching and education for work-based learning and business engagement strategies, performance reporting implementation, customer-centered design, and financial management.

COMPETITION OF LOW-PERFORMING CIVILIAN CONSERVATION CENTERS

The Department does not propose to retain General Provision Section 108 from the fiscal year 2017 Appropriations Act. Section 108 gives the Department the authority to compete low-performing Civilian Conservation Centers.

Mr. Cole: Is the assumption in the budget that the Department will not compete any such centers in fiscal year 2018 or that the Department may carry out the competition under the authority provided in WIOA and that Sec. 108 is not necessary for that purpose in fiscal year 2018?

Mr. Acosta: The Department has the authority to carry out a competition under the authority provided in section 159(f)(4) of the Workforce Innovation and Opportunity Act (WIOA).

UPDATE ON OVERPAYMENT RECOVERIES IN THE UI PROGRAM

Mr. Cole: Please provide an update on the Department's efforts to improve the rate of overpayment recoveries in the Unemployment Insurance program including the use of additional funds appropriated in fiscal year 2017 for reemployment services and State IT infrastructure.

Mr. Acosta: The Department coordinates with states to recover unemployment insurance (UI) overpayments. Each state's Benefit Payment Control (BPC) unit is responsible for promoting and maintaining UI program integrity through prevention, detection, investigation, establishment, and recovery of improper payments.

States collect overpaid claims through offsets of UI benefits, federal income tax refunds under the Treasury Offset Program (TOP), state income tax offsets, and direct cash reimbursement from the claimant. For the most recent fiscal year, states recovered \$904,060,551 (83.20%).

The Department developed the state-driven UI Integrity Center of Excellence with the goal of promoting the development and implementation of innovative integrity strategies to support all states. The Center is currently developing new integrity tools to assist state BPC operations, including training for fraud detection, improper payments prevention, and fact finding; a secure data hub for state UI agencies to access characteristics of known UI fraud claims; and a model BPC blueprint to highlight integrity practices, including recovery practices, that should be part of state UI administrative practices.

The Reemployment Service and Eligibility Assessment (RESEA) program is an evidence-based strategy that supports the reemployment of unemployed individuals, including recently separated veterans, and the integrity of state UI systems. The FY 2017 RESEA funding allowed for an expansion of the program to two additional states while maintaining service levels at approximately 18 percent of UI beneficiaries. The Department also implemented a series of improvements to RESEA intended to further align the program with other workforce programs, to increase available performance data, and to provide more intensive services to participants.

RESEA funding for FY 2017 was \$115 million, which is the same amount provided in FY 2016. The FY 2017 funds were awarded in two installments. The first installment, which reflected the amount available under the continuing resolution, was announced in January 2017. The second installment, reflecting the passage of appropriations for the remainder of the fiscal year, will be distributed in early July 2017. The President's FY 2018 budget increases the funding to \$130 million and includes a legislative proposal that would allow funding for these services to fluctuate each year with the number of UI claimants. In addition to the RESEA proposal, the Administration's FY 2018 Budget also proposes a comprehensive legislative proposal designed to provide States with the tools and resources to reduce UI improper payments and improve UI program integrity.

Pursuant to the Report accompanying the Consolidated Appropriations Act of 2017, enacted on May 5, 2017, Congress indicated that \$50 million of the funding provided in the State Unemployment Insurance and Employment Services Operations appropriations for state administrative funding should be used "for the continued support of State consortia to modernize their Unemployment Insurance tax and benefit systems." The Department is currently preparing a grant solicitation to offer the full \$50,000,000 to state consortia in FY 2017 to support continued modernization of state UI tax and benefit systems. This funding will continue the Department's support for improvements of these UI IT systems and will make it easier for states to implement integrity solutions that rely on technology. The Department anticipates

announcing this grant solicitation in the summer of 2017 and issuing awards to state consortia in the fall. The Federal obligation deadline is December 31, 2017.

EMPLOYEE STOCK OWNERSHIP PLANS

Research has shown that employee-owned companies offer retirement security and drive employee engagement.

Mr. Cole: What do you believe are the most important benefits of Employee Stock Ownership Plans (ESOPs)?

Mr. Acosta: I strongly support empowering Americans to save and prepare for retirement. A well-run ESOP, like other employment-based retirement plans, can provide valuable benefits to participating workers. It encourages not only employers to invest in employees, but encourages greater employee engagement in the business.

ENFORCEMENT ACTIONS AGAINST EMPLOYEE STOCK OWNERSHIP PLANS

For many years, enforcement actions brought against ESOPs by the Department were quite rare.

Mr. Cole: In your view, what are the reasons behind the significant increase in law suits and enforcement actions against ESOPs since 2010?

Mr. Acosta: A critical mission for the Department of Labor is to promote and protect the retirement security of America's workers. I agree that a well-run ESOP, like other employment-based retirement plans, can provide valuable benefits to participating workers, and I believe that Congress and the Department have a shared responsibility to take steps to make sure that ESOPs fulfill their important mission of providing benefits and enhancing employee ownership.

The Employee Benefits Security Administration (EBSA) investigates ESOPs to determine their compliance with the law to ensure that employees receive the full value of their benefit entitlement. EBSA has data on ESOP enforcement cases going back to 1989. EBSA resolves the majority of its ESOP investigations through the voluntary compliance process. According to that data, the Department filed 55 ESOP lawsuits between 1989 and 2009, and 42 lawsuits since 2010.

Mr. Cole: How can the Department ensure that ESOPs comply with legal and regulatory requirements while continuing to encourage the employee ownership model?

Mr. Acosta: The Department of Labor is committed to providing guidance and to working with the regulated community to help them understand their obligations.

DELAYING THE FIDUCIARY RULE

The Committee understands that the Department is allowing the fiduciary rule to take effect as scheduled rather than issuing a new delay. I also understand that the Department's review of this rule remains ongoing.

Mr. Cole: Can you describe your rationale for not further delaying the implementation of the final rule and whether you intend to propose changes or rescind the rule if the Department's review finds that the rule eliminates jobs, inhibits job creation and/or imposes costs that exceed the intended benefits?

Mr. Acosta: As I stated in my May 22, 2017, Wall Street Journal op-ed, federal agencies can act only as the law allows. The law sets limits on the power of federal agencies and establishes procedures agencies must follow when they regulate or deregulate, including the Administrative Procedure Act (APA). Generally, the APA requires federal agencies to engage in the following process before regulating or deregulating: (1) issue a notice of proposed rulemaking; (2) solicit public comments on the proposed rule; (3) issue a final rule after considering the public comments received in response to the proposal; and (4) establish an effective date at least 30 days after publication of the final rule in the Federal Register. This process ensures that all Americans have an opportunity to express their concerns before a rule is finalized or revised. After carefully reviewing the administrative record for the fiduciary rule and the APA requirements, the Department of Labor found no principled legal basis to change the June 9, 2017, applicability date of the rule while we seek and review public input on the rule.

We are currently conducting a careful process to review the fiduciary rule and associated exemptions to decide whether further changes are necessary. As part of its ongoing review, including the Request for Information published in the Federal Register by the Department of Labor on July 6, 2017, the Department will take a careful look at all the exemptions' conditions and could propose to eliminate or alter the contract conditions based on its findings and the comments received from the public. The Request for Information also specifically sought public input regarding the advisability of extending the current transition period for certain provisions in the exemptions beyond January 1, 2018. Based on the comments received in response to the Request for Information, the Department submitted to the Office of Management and Budget (OMB) a proposed amendment to the exemptions titled: "Extension of Transition Period and Delay of Applicability Dates From January 1, 2018 to July 1, 2019; Best Interest Contract Exemption; Class Exemption for Principal Transactions; PTE 84-24." OMB is currently reviewing the proposed amendment.

The Department also announced a temporary enforcement policy in a Field Assistance Bulletin (FAB) published on May 22, 2017, that applies while the Department reviews the fiduciary rule. The FAB states that the Department's general approach to implementing the fiduciary rule will emphasize providing compliance assistance to (rather than citing violations and imposing penalties on) plans, plan fiduciaries, financial institutions, and others who are working diligently and in good faith to understand and come into compliance with the rule. This will encourage entities affected by the rule to engage in good faith compliance efforts without facing the risk of enforcement action and litigation by the Department while we conduct our

examination of the fiduciary rule. The Department anticipates that private actions are unlikely to be brought or be successful if entities are engaged in good faith compliance with the rule.

EFFECTS OF PRIVATE RIGHT OF ACTION

As part of the final fiduciary rule, the Department created a private right of action. Aspects of the private right of action came into effect on June 10th.

Mr. Cole: Can firms now be sued under the private right of action?

Mr. Acosta: The Employee Retirement Income Security Act (ERISA, Act) gives plan participants a statutory claim for violations of Title I of the Act, and plan participants can accordingly bring an action under the statute for violations of their fiduciary obligations. By expanding the scope of who is a fiduciary and what constitutes advice, the current rule expands the number of entities subject to the Title I private right of action should they violate ERISA; however, the fiduciary rule itself does not create a private right of action.

The Department, however, has announced a non-enforcement policy in a Field Assistance Bulletin (FAB) published on May 22, 2017, that applies while the Department reviews the fiduciary rule. The FAB states that the Department's general approach to implementing the fiduciary rule will emphasize providing compliance assistance to (rather than citing violations and imposing penalties on) plans, plan fiduciaries, financial institutions, and others who are working diligently and in good faith to understand and come into compliance with the rule. This will encourage entities affected by the rule to engage in good faith compliance efforts without facing the risk of enforcement action and litigation by the Department while we conduct our examination of the fiduciary rule. The Department anticipates that private actions are unlikely to be brought or be successful if entities are engaged in good faith compliance with the rule.

Mr. Cole: Do you believe the Department is within its legal authority to create a private right of action?

Mr. Acosta: With regard to the Best Interest Contract Exemption, courts have determined that the Best Interest Contract Exemption does not create a private right of action and that the Department has the authority as delegated by Congress to grant an exemption that is conditioned, in part, on the existence of a written contract.

Mr. Cole: Will the Department consider whether the private right of action is within its legal authority as part of its ongoing review of the rule?

Mr. Acosta: As part of its ongoing review, including the Request for Information published in the Federal Register by the Department of Labor on July 6, 2017, the Department will take a careful look at all the exemptions' conditions and could propose to eliminate or alter the contract conditions based on its findings and the comments received from the public.

SEC REVIEW OF INVESTMENT ADVICE

Mr. Cole: If the SEC were to review investment advice and propose its own regulations related to retirement advice would DOL withdraw the fiduciary duty rule?

Mr. Acosta: The Securities and Exchange Commission (SEC) and Department of Labor have separate statutory roles and enforcement responsibilities, but each agency's regulations pertaining to the investment space may impact the other agency. The SEC has critical expertise in this area, yet in the Obama administration, the SEC declined to move forward in rule-making. SEC Chairman Clayton and I stated our intentions to engage constructively as each agency decides how to move forward in this area. I look forward to continuing this constructive dialogue.

PLANS FOR THE OVERTIME RULE

At your Senate confirmation hearing, you indicated the Department's overtime rule salary increase of more than \$47,000 created a shock to the system. The Committee understands that the rule is currently blocked by temporary injunction.

Mr. Cole: To the extent you have made any determination, what are the Department's plans going forward to revise or rescind the overtime rule?

Mr. Acosta: On July 26, 2017, the Department of Labor published a Request for Information (RFI) regarding the overtime rule in the Federal Register. The RFI offers the public the opportunity to comment on a broad range of questions and issues related to the 2016 overtime rule. The comments received in response to the RFI will aid the Department in formulating a proposal to revise the regulations.

REFORMING OSHA REGULATIONS

Under the prior administration, the Department of Labor placed a heavy emphasis on enforcement and promulgation of new standards at the cost of crucial compliance assistance to businesses subject to the Department's regulatory requirements.

Mr. Cole: Do you intend to reallocate funds traditionally budgeted for the development of new standards towards reforming regulations that are duplicative, onerous, and do not achieve their statutory objectives?

Mr. Acosta: On February 24, 2017, President Trump issued an Executive Order regarding Enforcing the Regulatory Reform Agenda. This Executive Order requires agencies to review and identify, among other things, standards or requirements that are "outdated, unnecessary, or ineffective." The Department of Labor, and the Occupational Safety and Health Administration (OSHA), will review regulations pursuant to the Executive Order while fulfilling OSHA's core mission to assure safe and healthful working conditions. When OSHA is regulating or deregulating, OSHA must as a matter of law follow its statute and the Administrative Procedure

Act (APA). One of the principal components of the APA is providing notice and seeking comment from the public.

INVESTING IN OSHA COMPLIANCE ASSISTANCE

I believe most employers share our goal of worker safety and want to be compliant with existing standards, however, it is not always easy. There are numerous regulations at the Department that are complex and difficult to understand, and, in some cases, it can be difficult to achieve full compliance. Sufficient guidance is not always available and when it is, it can be hard to find.

Mr. Cole: Will the Department make greater investments in compliance assistance initiatives, especially for the small businesses for which compliance can be additionally burdensome?

Mr. Acosta: The President's Fiscal Year (FY) 2018 Budget would provide the Occupational Safety and Health Administration (OSHA) an increase of \$4 million for Federal Compliance Assistance, which would enable the agency to hire 20 Compliance Assistance Specialists (CASSs) and provide funding to support additional outreach and training. With the requested funding, OSHA will expand its compliance assistance and outreach activities for high-risk industries and small- and medium-sized businesses. The additional CASSs will increase the agency's capacity to meet directly with small businesses and related professional associations to ensure they have the tools they need to provide a safe workplace for their workers. Increased staffing will enable the agency to provide more outreach to help employers comply with OSHA regulations.

OSHA also will promote the On-site Consultation Program, which is the agency's small- and medium-sized business safety and health assistance program that operates in all States and several territories. The On-site Consultation program offers free and confidential safety and health advice to small businesses, which often cannot afford to hire in-house safety and health experts or outside consultants. Program Consultants work with employers to identify workplace hazards, provide advice on compliance with OSHA standards, and assist in establishing safety and health programs. In FY 2018, the On-site Consultation Program will continue to focus their efforts on the identification, assessment, and abatement of workplace hazards. Consultants will also assist with outreach and education efforts for small businesses to support OSHA's mission to assure safe and healthful working conditions. To better assist small businesses with practical and affordable solutions to hazard abatement, the On-site Consultation Program will continue to focus on development and improve communication of Low Cost/No Cost abatement methods gleaned from visits and provide this information in innovative and web-accessible formats. The On-site Consultation Program plans to conduct 26,870 Consultation visits in FY 2018.

ELIMINATING THE SUSAN HARWOOD GRANT PROGRAM

OSHA's Susan Harwood Grant Program is proposed for elimination in the Department's budget.

Mr. Cole: Please explain why you believe this program should be eliminated?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) is proposing to use alternative methods to develop and deliver training to reach the broadest possible audience. The House Appropriations Committee also eliminated funding for these grants in both Fiscal Years (FY) 2017 and 2018. In the FY 2017 report House language, the Committee specifically noted their concern that these grants are inefficient and ineffective. OSHA has a variety of programs and tools available that provide training, outreach, and assistance to employers and employees. These include Alliances, Strategic Partnerships, On-site Consultation, and numerous targeted outreach events, such as the Fall Stand Down in Construction, which provide information on workplace safety and health to the public. Training and outreach programs delivered directly by the agency can more efficiently provide the same type of information currently delivered through the training grants to a broader audience. Additionally, many Alliance Program agreements contain a training element, and numerous training and information resources are available on OSHA's website.

The President's Fiscal Year 2018 Budget includes a proposed increase of \$4 million and 20 full-time equivalent employees to provide additional outreach and training to high-risk workers. This includes funds for additional Compliance Assistance Specialists, new training materials, and support for OSHA's Cooperative Programs, Strategic Partnerships, and Alliances to address hazards in high-risk industries.

INTERNATIONAL LABOR AFFAIRS BUDGET CUTS

The Department's International Labor Affairs Bureau (ILAB) has played a critical role in reducing forced labor and child labor. The president's budget calls for cutting ILAB's grant programs.

Mr. Cole: How would ILAB's role be changed under your tenure if the grant programs are eliminated?

Mr. Acosta: The mission of the Bureau of International Labor Affairs (ILAB) is to promote a fair global playing field for workers and businesses in the United States by enforcing trade commitments; strengthening labor standards; and combatting child labor, forced labor, and human trafficking. United States trading partners receive an unfair subsidy when they fail to comply with their trade-related labor commitments, including not doing enough to prevent and address cases of forced labor and child labor. This puts workers and businesses in the United States at a competitive disadvantage. ILAB will use its expertise to address these issues and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

ILAB will continue to monitor and enforce the labor provisions of free trade agreements and trade preference programs. The Department's approach will include prioritizing proactive monitoring of labor conditions in key countries; expediting the review of trade complaints by streamlining procedures; using ILAB experts to provide direct technical support to trading partners to improve laws and enforcement; and aggressively engaging with trade partners that are deemed to be out of compliance. In addition, as part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor.

Mr. Cole: What are other ways I LAB and the federal government can continue to reduce forced and child labor internationally?

Mr. Acosta: Combatting child labor and forced labor is a priority for this Administration. At the same time, we should hold our trading partners accountable and ask them to do their share by investing their own resources to effectively enforce their labor laws and fund initiatives to combat child labor and modern slavery.

ILAB will provide direct technical support to our trading partners to improve laws and enforcement and will use its existing technical assistance portfolio to combat forced labor and child labor and improve labor enforcement and working conditions around the world. As part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor. ILAB will also improve its impact by strengthening partnerships with other U.S. government agencies, such as the Office of the U.S. Trade Representative and Department of Homeland Security, as well as with private sector stakeholders to prevent the importation of goods made with forced labor and make trade fairer for workers and businesses in the United States.

Mr. Cole: Do you believe ILAB has effectively address the concerns raised by GAO in 2014?

Mr. Acosta: ILAB addressed all of the recommendations from the Government Accountability Office (GAO) in 2014 and GAO closed each of these recommendations.

FY 2017 PROGRAM EVALUATION PLANS

Mr. Cole: Please provide a list of evaluations the Department expects to undertake with fiscal year 2017 funds. Please also provide estimated costs of each evaluation activity and the amounts the Department expects to transfer from each of the accounts authorized under General Provision Section 107 of the fiscal year 2017 Appropriations Act.

Mr. Acosta: The Department of Labor is finishing the list of evaluations it expects to undertake with Fiscal Year 2017 funds as well as the amounts expected to be transferred from each of the accounts authorized under General Provision Section 107 of the Fiscal Year 2017 Appropriations Act. The Department will transmit this information to the Committees on Appropriations of the House of Representatives and the Senate when the list and amounts are finalized, pursuant to Section 107.

Questions for the Record from Mr. Fleischmann**DISABILITY INSURANCE REGULATION**

Secretary Acosta, disability insurance provides Americans with crucial income protection from unexpected disability due to illness or injury. Access to disability insurance depends on affordability, which is directly affected by regulatory, administrative, and litigation costs. In December, the Department of Labor issued a final regulation regarding disability insurance claims administration. This regulation will significantly increase the cost of disability insurance by encouraging litigation and will inappropriately apply Affordable Care Act claims procedures to disability plans.

Mr. Fleischmann: Do you have plans to take steps to delay and reexamine the regulation to prevent harm to working families?

Mr. Acosta: On June 20, 2017, The Office of Information and Regulatory Affairs at the Office of Management and Budget published the first Current Unified Agenda of Regulatory and Deregulatory Actions of this Administration. Included on the list is a notice that the Department of Labor intends to review the Employee Benefits Security Administration's (EBSA) final rule pertaining to Claims Procedure for Plans Providing Disability Benefits, for questions of law and policy.

Questions for the Record from Dr. Harris**OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS (OFCCP)
ENFORCEMENT TACTICS**

The previous administration radically changed how OFCCP approached its role and enforcement. It went from one that was positioned to work with employers to advance affirmative action, to one that was focused on identifying potential discrimination and pushing for broad class-based remedies. To pursue this new focus, the agency routinely demanded excessive amounts of data before there was any suggestion of a problem, which many employers regarded as enforcement fishing expeditions. Not only were the data requests controversial, but so were the deadlines for producing this information, all with a tone and underlying implied message of trying to intimidate federal contractors or threatening debarment. Dr. Harris: Is the secretary aware of the high level of concern of OFCCP's overreaching discovery tactics?

These tactics were exposed in OFCCP's investigation of Google where, in January 2017 just before leaving office, the agency alleged that the company had wrongfully refused to produce data in connection with a 2015 audit despite having produced data on all of its more than 20,000 employees at its headquarters and hundreds of thousands of other related records. OFCCP requested further detailed information including complete job salary and history for all employees in the snapshot (some had been with the company since its founding in 1998) as well as contact information for employees and interview notes for approximately 54,000 interviews. Google declined to provide this further data citing privacy and burden arguments. OFCCP filed an administrative complaint against Google and the ALJ denied the agency's motion for summary judgment noting that the cost to Google for producing the interview notes would be around \$1 million while the company's contract with the federal government was only about \$600,000. The ALJ further criticized OFFCP: "There has been no finding of wrongdoing. This is not litigation that the government is prosecuting based on investigative findings." Because the motion for summary judgment was denied, a hearing was held April 7, 2017 during which the agency alleged that "systemic compensation discrimination against women pretty much across the entire workforce" had been found. This was the first time Google had heard such a charge against them and they have vigorously denied any such finding.

Mr. Acosta: I am aware that some employers have concerns with the Office of Federal Contract Compliance Programs. As a general matter, the Department of Labor does not comment on open matters in litigation.

Questions for the Record from Ms. Roby**UPDATE ON OVERTIME RULE**

Mr. Acosta-- at your Senate confirmation hearing, you indicated the Department's overtime rule salary increase of more than \$47,000 created a shock to the system. The Committee understands that the rule is currently blocked by temporary injunction.

Ms. Roby: To the extent you have made any determination, what are the Department's plans going forward to revise or rescind the overtime rule?

Mr. Acosta: On July 26, 2017, the Department of Labor published a Request for Information (RFI) regarding the overtime rule in the Federal Register. The RFI offers the public the opportunity to comment on a broad range of questions and issues related to the 2016 overtime rule. The comments received in response to the RFI will aid the Department in formulating a proposal to revise the regulations.

ADMINISTRATIVE PROCEDURE ACT EFFECTS ON CHANGING FIDUCIARY RULE

Ms. Roby: Mr. Acosta, can you briefly walk me through specifically what in the Administrative Procedure Act led you to the conclusion that you – and the Department of Labor – lack the authority to either change, delay, or otherwise provide some kind of a buffer for enforcement of the fiduciary rule while you review its purposes to fit with the Administration's goals you outlined in your WSJ op-ed?

Mr. Acosta: As I stated in my May 22, 2017, Wall Street Journal op-ed, federal agencies can act only as the law allows. The law sets limits on the power of federal agencies and establishes procedures agencies must follow when they regulate or deregulate, including the Administrative Procedure Act (APA). Generally, the APA requires federal agencies to engage in the following process before regulating or deregulating: (1) issue a notice of proposed rulemaking; (2) solicit public comments on the proposed rule; (3) issue a final rule after considering the public comments received in response to the proposal; and (4) establish an effective date at least 30 days after publication of the final rule in the Federal Register. This process ensures that all Americans have an opportunity to express their concerns before a rule is finalized or revised. After carefully reviewing the administrative record for the fiduciary rule and the APA requirements, the Department of Labor found no principled legal basis to change the June 9, 2017, applicability date of the rule while we seek and review public input on the rule.

We are currently conducting a careful process to review the fiduciary rule and associated exemptions to decide whether further changes are necessary. As part of its ongoing review, including the Request for Information published in the Federal Register by the Department of Labor on July 6, 2017, the Department will take a careful look at all the exemptions' conditions and could propose to eliminate or alter the contract conditions based on its findings and the comments received from the public. Based on the comments received in response to the Request for Information, the Department submitted to the Office of Management and Budget (OMB) a proposed amendment to the exemptions titled: "Extension of Transition Period and Delay of

Applicability Dates From January 1, 2018 to July 1, 2019; Best Interest Contract Exemption; Class Exemption for Principal Transactions; PTE 84-24." OMB is currently reviewing the proposed amendment.

The Department announced a non-enforcement policy in a Field Assistance Bulletin (FAB) published on May 22, 2017, that applies while the Department reviews the fiduciary rule. The FAB states that the Department's general approach to implementing the fiduciary rule will emphasize providing compliance assistance to (rather than citing violations and imposing penalties on) plans, plan fiduciaries, financial institutions, and others who are working diligently and in good faith to understand and come into compliance with the rule. This will encourage entities affected by the rule to engage in good faith compliance efforts without facing the risk of enforcement action and litigation by the Department while we conduct our examination of the fiduciary rule. The Department anticipates that private actions are unlikely to be brought or be successful if entities are engaged in good faith compliance with the rule.

FINANCIAL CHOICE ACT EFFECTS ON FIDUCIARY RULE

As you know, enforcement of this standard begins on June 9th, this Friday. In the House this week, we're voting on the Financial CHOICE Act, legislation that will more or less nullify the rule as-is and tell the SEC to write a new one, if they believe it is necessary. And, as you stated in your op-ed, we need their expertise in this area and I firmly believe that if we are going to change the definition for fiduciary duty as it relates investment advisors – the SEC should be intimately involved in that process. Their lack of involvement in the original rule is one of the main concerns that I have with how things stand today.

Ms. Roby: That being said, what is your vision for the Department of Labor's plan to enforce the rule beginning on Friday? Can you briefly walk us through what that looks like in practice?

Mr. Acosta: The Securities and Exchange Commission (SEC) and Department of Labor have separate statutory roles and enforcement responsibilities, but each agency's regulations pertaining to the investment space may impact the other agency. The SEC has critical expertise in this area, yet in the Obama administration, the SEC declined to move forward in rule-making. SEC Chairman Clayton and I stated our intentions to engage constructively as each agency decides how to move forward in this area. I look forward to continuing this constructive dialogue.

Enforcement of the fiduciary rule during the transition period will be about compliance assistance and education. The Department of Labor announced a temporary enforcement policy in a Field Assistance Bulletin (FAB) published on May 22, 2017, that applies while it reviews the Fiduciary Rule. The FAB states that the Department's general approach to implementing the Fiduciary Rule will emphasize providing compliance assistance to (rather than citing violations and imposing penalties on) plans, plan fiduciaries, financial institutions, and others who are working diligently and in good faith to understand and come into compliance with the rule. This will encourage entities affected by the rule to engage in good faith compliance efforts without facing the risk of enforcement action and litigation by the Department while we conduct our examination of the fiduciary rule.

FIDUCIARY RULE ENFORCEMENT

I believe that the best, practical way to operate is to promote compliance. Not to go around and slap a bunch of wrists, collect fines, then show back up for another shakedown in 12-months.

Ms. Roby: Can I get a commitment from you that enforcement of the fiduciary rule – while it is still under review – will be about compliance? About working with the industry you regulate to truly protect consumers, both ensuring access to the marketplace and the high standard of advisor/client relationship?

Mr. Aeosta: : The Department of Labor announced a temporary enforcement policy in a Field Assistance Bulletin (FAB) published on May 22, 2017, that applies while the Department reviews the fiduciary rule. The FAB states that the Department's general approach to implementing the fiduciary rule will emphasize providing compliance assistance to (rather than citing violations and imposing penalties on) plans, plan fiduciaries, financial institutions, and others who are working diligently and in good faith to understand and come into compliance with the rule. This will encourage entities affected by the rule to engage in good faith compliance efforts without facing the risk of enforcement action and litigation by the Department while we conduct our examination of the fiduciary rule. The Department anticipates that private actions are unlikely to be brought or be successful if entities are engaged in good faith compliance with the rule.

Ms. Roby: And can I also get a commitment from you to keep me and this subcommittee informed of your progress in enforcement through follow-up letters?

Mr. Acosta: Information on open enforcement cases is not generally made public; but there are certainly appropriate ways for us to keep you apprised of significant developments in our enforcement activities.

EMPLOYEE STOCK OWNERSHIP PROGRAMS

Research shows that employee-owned companies not only drive employee engagement, but also give people more retirement security. For example, over the past decade or so, layoff rates from employee-owned companies in the U.S. were 4 to 8 times less than layoff rates for conventionally owned companies. In short, ESOPs (employee stock ownership plans) are an excellent jobs policy. That's why I, along with my colleagues on both sides of the aisle, support ESOPs. Unfortunately, the Obama Administration didn't share our views, and they waged an unfair and unprovoked campaign against the ESOP community, taking a sue-first-question-later approach.

Consider this - From 1974 to 2010, the Department only brought about twenty-five ESOP-related enforcement actions. That's not even one action per year on average. From 2010 until today – just eight years - the Department has brought nearly thirty enforcement actions. That's four to five lawsuits a year - a 400% - 500% increase. And that's not to mention the overzealous enforcement and scare tactics being employed by investigators.

I know you were just confirmed and that you are still trying to fix some of the broken policies of the previous Administration. But I am sad to say that the persecution of the ESOPs has continued. There were two actions filed just last month by your career staff.

Ms. Roby: Can I have your commitment that you will take immediate steps to stop the unfair targeting of ESOPs and instead engage with the community to encourage employee ownership?

Mr. Acosta: A critical mission for the Department of Labor is to promote and protect the retirement security of America's workers. I agree that a well-run ESOP, like other employment-based retirement plans, can provide valuable benefits to participating workers, and I believe that Congress and the Department have a shared responsibility to take steps to make sure that ESOPs fulfill their important mission of providing benefits and enhancing employee ownership.

The Employee Benefits Security Administration (EBSA) investigates ESOPs to determine their compliance with the law to ensure that employees receive the full value of their benefit entitlement. EBSA has data on ESOP enforcement cases going back to 1989. EBSA resolves the majority of its ESOP investigations through the voluntary compliance process. According to that data, the Department filed 55 ESOP lawsuits between 1989 and 2009, and 42 lawsuits since 2010.

Questions for the Record from Ms. Herrera Beutler**STATEMENT ON ASSOCIATION HEALTH PLANS**

Mr. Secretary, my home state of Washington is fortunate to have a robust association health plan market that has become essential to providing cost-effective health insurance choices to small employers. As a result of bipartisan legislation enacted in Washington State in 1995, about 400,000 Washingtonians currently receive employer-based health coverage through one of these plans. In the case of one AHP operating in my state, roughly 40% of participating small employers did not previously offer health coverage.

Recent investigations by the Seattle office of the Employee Benefits Security Administration (EBSA) appear to be a regional effort targeting long-standing, respected association health plans (AHPs) in my state. While I strongly support the mission of EBSA to ensure the security of the benefits of America's workers and their families, there is no historical reason for EBSA to devote significant resources to fully-insured AHPs for frequent and burdensome audits. Fully-insured plans pose no risk to plan participants because claims and benefits are handled by insurance companies which are subject to rigorous oversight by state insurance regulators. The nature of EBSA's questioning and document requests raises concerns that there may be a policy bias against AHPs.

Undermining AHPs in Washington State will negatively affect small businesses, and their employees and families, which have come to rely on AHPs for high quality, affordable health coverage.

Ms. Herrera Beutler: While this is an issue carried over from the previous Administration, I ask that you examine this important issue, and I look forward to working with you to get it appropriately addressed.

Mr. Acosta: I fully support allowing employers, especially small businesses, to band together to purchase health coverage through an Association Health Plan (AHP). AHPs can reduce the cost of health insurance coverage due to increased bargaining power, economies of scale, and administrative efficiencies. I will continue to support the goal of making quality health care benefits affordable to small business employers and employees and I will look into the particular issue you raise.

IMPROVEMENTS TO H-2A VISA PROCESSING

Mr. Secretary, Southwest Washington's agriculture sector is critical to the local and regional economy and it includes a wide variety of Washington-grown products, including labor intensive perishable crops, such as tree-fruit, which require flexible and timely labor to produce and harvest crops. Agricultural employers are increasingly dependent on the Office of Foreign Labor Certification (OFLC) for their labor needs through the H-2A program. It is critical that OFLC make improvements to speed up (and make more predictable) the H-2A processing times. Growers in my district are advocating for improvements to be at the agency level through

directives and regulatory relief which would greatly improve the efficiency and reliability of the program.

Ms. Herrera Beutler: What are your thoughts on how we might address the difficult position many of our growers are in? Will you work with our office on addressing this issue?

Mr. Acosta: The number of applications being filed has continued to increase every year. The Office of Foreign Labor Certification (OFLC) fee authority is needed to provide consistent, long term stability to the organization that will enable it to provide better and more efficient service into the future. If enacted, the proposal would provide the appropriate level of resources necessary to reduce processing times. This would also ensure that only employers that use these services pay for them.

COMBATING CHILD AND FORCED LABOR IN TRADING PARTNER COUNTRIES

Mr. Secretary, Child labor is estimated to cost the world 2.4-6.6% of gross national income annually. Child labor and forced labor in trading partner countries not only harms children and families, but it also creates an uneven playing field for American workers.

Ms. Herrera Beutler: Within the budget proposal, how would you propose the Department of Labor work to address this issue?

Mr. Acosta: The mission of the Bureau of International Labor Affairs (ILAB) is to promote a fair global playing field for workers and businesses in the United States by enforcing trade commitments; strengthening labor standards; and combatting child labor, forced labor, and human trafficking. At the same time, we should hold our trading partners accountable and ask them to do their share by investing their own resources to effectively enforce their labor laws and fund initiatives to combat child labor and modern slavery.

ILAB will provide direct technical support to our trading partners to improve laws and enforcement and will use its existing technical assistance portfolio to combat forced labor and child labor and improve labor enforcement and working conditions around the world. As part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor. ILAB will also improve its impact by strengthening partnerships with other U.S. government agencies, such as the Office of the U.S. Trade Representative and Department of Homeland Security, as well as with private sector stakeholders to prevent the importation of goods made with forced labor and make trade fairer for workers and businesses in the United States.

Ms. Herrera Beutler: Do you believe that addressing forced labor and child labor helps give American workers an opportunity to effectively compete in global markets?

Mr. Acosta: United States trading partners receive an unfair subsidy when they fail to comply with their trade-related labor commitments, including not doing enough to prevent and address cases of forced labor and child labor. This puts workers and businesses in the United States at a

competitive disadvantage. ILAB will use its expertise to address these issues and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

Questions for the Record from Ms. DeLauro**ETHICS WAIVERS**

Mr. Secretary, we've learned that the Trump Administration has issued more waivers for lobbyists in only four months than President Obama issued in his entire eight years in office. That means some of the most influential positions in government could be filled by former lobbyists with personal conflicts of interest.

Ms. DeLauro: Have any former lobbyists, now employed at the Department of Labor, been given waivers to work on issues on which they used to lobby? If so, please include a list of those lobbyists in your response to the subcommittee.

Mr. Acosta: No, to my best knowledge.

Ms. DeLauro: Have any other political appointees now employed at the Department of Labor been given waivers to work on issues related to their previous employment? If so, please include a list of those political appointees (and the underlying policy issues) in your response to the subcommittee.

Mr. Acosta: No, to my best knowledge.

Ms. DeLauro: What is the Department's policy toward former lobbyists or other political appointees who used to lobby or otherwise work on issues under the jurisdiction of the Department? Are they required to recuse themselves? Is recusal mandatory or voluntary?

Mr. Acosta: Every Department of Labor employee is required to fully comply with all statutes, regulations, and executive orders applicable to their ethical conduct.

RESPONDING TO CONGRESSIONAL INQUIRIES

Ms. DeLauro: What is the policy at the Department with regard to responses to Congressional inquiries?

Mr. Acosta: I have the utmost respect for Congress and want to be very clear: I have instructed my staff to provide responses to all Members of Congress.

Ms. DeLauro: Is there a policy or guidance that would prohibit or delay responses to Democratic Members of Congress?

Mr. Acosta: I have instructed my staff to provide responses to all Members of Congress.

Ms. DeLauro: If such policies or guidance are in place to prohibit or delay responses to Ranking Members or all Democratic Members, was such policy developed in consultation with the White House Office or the Office of Management and Budget?

Mr. Acosta: I have instructed my staff to provide responses to all Members of Congress.

Ms. DeLauro: At the hearing, you said you have responded to all letters from members of the Appropriations Committee. Is it your policy to respond to all Members of Congress, including those not on the House Appropriations Committee?

Mr. Acosta: I have instructed my staff to provide responses to all Members of Congress.

Ms. DeLauro: You said you have not been told by the Administration not to respond to inquiries from Democrats. To the best of your knowledge, have your staff been instructed not to respond to Democrats?

Mr. Acosta: I have instructed my staff to provide responses to all Members of Congress.

Ms. DeLauro: More specifically, was there a policy or guidance provided to the Department to prohibit or delay responses to Ranking Members of Congressional Committees or subcommittees of jurisdiction?

Mr. Acosta: I have instructed my staff to provide responses to all Members of Congress.

OFCCP – EEOC MERGER

Mr. Secretary, your budget proposes to eliminate the Office of Federal Contract Compliance Programs – OFCCP – by merging it into the Equal Employment Opportunity Commission, or EEOC. I strongly oppose this proposal and I would note that the business community and the civil rights community oppose it as well.

The OFCCP enforces Executive Order 11246 to prohibit employment discrimination on the basis of race, religion, color, sex, national origin, sexual orientation, or gender identity. It also ensures that employees can't be punished for discussing pay levels, which is important because many women and minorities aren't even aware they're being paid less for doing the same work. In addition, the OFCCP is required to enforce workplace protections for veterans and individuals with disabilities. In fact, the OFCCP is responsible for helping federal contractors reach specific targets for hiring individuals with disabilities.

Ms. DeLauro: Does the Administration believe that Congress would need to amend Title VII of the Civil Rights Act, which created the EEOC?

Mr. Acosta: Statutory changes to amend portions of Title VII of the Civil Rights Act of 1965 establishing the Equal Employment Opportunity Commission (EEOC), its structure, the scope of its authority, and its general enforcement scheme would be required to begin implementing the proposed merger. Under Title VII, EEOC is primarily complaint driven and does not have the authority to require affirmative action or to debar federal contractors. Moreover, the EEOC's enforcement structure is judicial in nature while the Office of Federal Contract Compliances' (OFCCP) process is administrative in nature using the Department of Labor's Administrative Law Judge and Administrative Review Board process.

Executive branch action would be required to amend Executive Order (EO) 11246, which provides the Department authority to enforce the contractual obligation of nondiscrimination in employment based on race, color, religion, sex, sexual orientation, gender identity, or national origin. Additionally, the EO prohibits federal contractors and subcontractors from, under certain circumstances, taking adverse employment actions against applicants and employees for asking about, discussing, or sharing information about their pay or the pay of their coworkers. The EO requires covered contractors to provide equal employment opportunity through affirmative action.

Ms. DeLauro: And does the Administration believe that Congress would need to amend section 503 of the Rehabilitation Act of 1973 and the Vietnam Era Veterans' Readjustment Assistance Act of 1974 to implement this merger?

Mr. Acosta: Legislative action amending Section 503 of the Rehabilitation Act and the Vietnam Era Veterans' Readjustment Assistance Act (VEVRAA), creating the Department of Labor's authority to enforce nondiscrimination and equal employment opportunity through affirmative action for individuals with disabilities and veterans, would also be required.

ROLES AND RESPONSIBILITIES OF EEOC POST OFCCP MERGER

OFCCP focuses on contract compliance – if a federal contractor doesn't abide by contracting requirements, the OFCCP's final recourse is debarment. The EEOC focuses on the conciliation process and its final recourse is litigation in federal court.

Ms. DeLauro: Would a new EEOC that absorbed OFCCP be required to exhaust the conciliation process in its oversight of federal contractors before pursuing next steps?

Mr. Acosta: Required statutory changes determined by Congress, in addition to new implementing regulations, guidance, and compliance assistance developed by the Department of Labor and Equal Employment Opportunity Commission (EEOC), would be necessary to clarify the enforcement structure.

Ms. DeLauro: And would the new EEOC have the capacity to debar federal contractors, or would litigation remain its only ultimate recourse?

Mr. Acosta: Required statutory changes determined by Congress, in addition to new implementing regulations, guidance, and compliance assistance developed by the Department and EEOC, would be necessary to clarify the enforcement structure.

Ms. DeLauro: OFCCP has the authority to audit federal contractors, while the EEOC does not. Would a new EEOC have the authority to audit federal contractors?

Mr. Acosta: Required statutory changes determined by Congress, in addition to new implementing regulations, guidance, and compliance assistance developed by the Department and EEOC, would be necessary to clarify the enforcement structure.

Ms. DeLauro: OFCCP enforces the Vietnam Era Veterans Readjustment Assistance Act, while the EEOC does not. Would a new EEOC be expected to enforce the rights of veterans?

Mr. Acosta: Required statutory changes determined by Congress, in addition to new implementing regulations, guidance, and compliance assistance developed by the Department and EEOC, would be necessary to clarify the enforcement structure. Legislative action amending Section 503 of the Rehabilitation Act and the Vietnam Era Veterans' Readjustment Assistance Act (VEVRAA), creating the Department's authority to enforce nondiscrimination and equal employment opportunity through affirmative action for individuals with disabilities and veterans, would also be required.

CUTS TO THE ILAB BUDGET

Mr. Secretary, your budget proposes to cut the Bureau of International Labor Affairs – known as ILAB – by almost 80 percent. Under your proposal, ILAB would be slashed from \$86 million to \$18.5 million.

ILAB leads U.S. government efforts to ensure that U.S. workers and businesses compete on a fair and level global playing field, where foreign competition does not gain a competitive advantage by exploiting workers. It is the lead agency for investigating violations of labor requirements in trade agreements with our trading partners.

Ms. DeLauro: Mr. Secretary, how can you justify cutting a bureau whose mission is to create a level playing field for American workers? Do you support these cuts and believe that they would benefit the U.S. middle class?

Mr. Acosta: The mission of the Bureau of International Labor Affairs (ILAB) is to promote a fair global playing field for workers and businesses in the United States by enforcing trade commitments; strengthening labor standards; and combatting child labor, forced labor, and human trafficking. United States trading partners receive an unfair subsidy when they fail to comply with their trade-related labor commitments, including not doing enough to prevent and address cases of forced labor and child labor. This puts workers and businesses in the United States at a competitive disadvantage. ILAB will use its expertise to address these issues and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

ILAB will continue to provide direct technical assistance to our trading partners to improve laws and enforcement. As part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor. ILAB will continue to achieve measurable progress in combating forced labor and child labor, and in improving labor enforcement and working conditions around the world. ILAB is also focused on working with other U.S. government agencies as well as private sector stakeholders to accomplish its stated goals and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

Ms. DeLauro: What impact would these cuts have on ILAB's ability to prevent unfair and illegal practices that drain good jobs from the United States?

Mr. Acosta: United States trading partners receive an unfair subsidy when they fail to comply with their trade-related labor commitments, including not doing enough to prevent and address cases of forced labor and child labor. This puts workers and businesses in the United States at a competitive disadvantage. ILAB will use its expertise to address these issues and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

IMPACT OF ELIMINATING ILAB LABOR ATTACHES

The budget request calls for eliminating labor attaches who provide expert oversight of our trade agreements, particularly in countries with brutal crackdowns on workers who try to exercise internationally recognized rights to freedom of association.

Ms. DeLauro: Doesn't this undermine the President's commitment to ensure that other countries are not violating their trade agreements?

Mr. Acosta: I share the President's commitment to strengthening our trade enforcement efforts and ensuring that our trade policies benefit workers and businesses in the United States. While the Bureau of International Labor Affairs (ILAB) has utilized labor attaches as one means of monitoring our trade partners' compliance with their trade commitments, it is not the only effective way of doing so. ILAB will continue to provide direct technical assistance to our trading partners to improve laws and enforcement. As part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor. ILAB will continue to achieve measurable progress in combating forced labor and child labor, and in improving labor enforcement and working conditions around the world. ILAB is also focused on working with other U.S. government agencies as well as private sector stakeholders to accomplish its stated goals and ensure that U.S. workers and businesses are able to compete on a fair global playing field.

Ms. DeLauro: How would ILAB be able to fulfill its critical role in NAFTA renegotiations if its staff is reduced by 30 percent? Which of ILAB's responsibilities are you proposing to eliminate?

Mr. Acosta: With the requested resources for Fiscal Year 2018, ILAB will play an essential role in negotiations with Canada and Mexico, and will help to ensure that the United States secures a deal that is truly fair for our workers and businesses. We are not proposing to eliminate any major program areas of ILAB's work, but will work more effectively and efficiently.

REPORTS ON COMBATTING CHILD LABOR AND CHILD TRAFFICKING

Your budget asks Congress "to be able to report less frequently on international progress in combatting the worst forms of child labor, including child trafficking".

Ms. DeLauro: Why would the Trump Administration want to issue fewer reports on the worst forms of child labor, or fewer lists of goods and products made with child labor and forced labor? Is reducing child labor or forced labor not a priority for this Administration?

Mr. Acosta: Combating child labor and forced labor is a priority for this Administration. Child labor and forced labor conditions do not change drastically from one year to the next. Reporting less frequently would allow our staff the necessary time to more actively engage with governments and other key stakeholders regarding the key findings and suggested actions from our research and to develop concrete plans to reduce child labor and forced labor.

WOMEN'S BUREAU BUDGET CUTS

Mr. Secretary, during your confirmation hearing, Senator Patty Murray inquired about your commitment to the Women's Bureau. In your answer, you expressed the importance of having an office within the Department of Labor that focuses on women's issues and you said this is a priority for you. In fact, I believe you pledged to charge the Women's Bureau with addressing gender pay discrimination and the gender wage gap. And during your official visit to Germany, you stated that women are "invaluable players in the global economy, and investing in women is absolutely critical for full mobilizing the economy in the United States and throughout the world."

Ms. DeLauro: Given your expressed commitment, could you explain how that comports with the proposed 77 percent cut in your budget to the Women's Bureau and the elimination of the women's apprenticeship program?

Mr. Acosta: The Department will more effectively support and advance the mission of the Women's Bureau by focusing the Bureau's resources on conducting research and collaborating with Department agencies, including the Employment and Training Administration and worker protection agencies. At the time of its inception in 1992, the Women in Apprenticeship and Non-Traditional Occupations (WANTO) grant program was the only federal program of its kind and that is no longer the case. The President's Fiscal Year 2018 Budget proposal includes \$90 million for grants to make the apprenticeship model available to a broader group of industries and workers. In addition, the President's Executive Order on Expanding Apprenticeships in America demonstrates this Administration's commitment to workforce development for all Americans.

Ms. DeLauro: How would you explain that decision to the millions of women, many of them working women themselves, who gathered to march the day after the Inauguration, arguably the largest single demonstration in history?

Mr. Acosta: The Women's Bureau serves an important role at the Department of Labor, promoting and advancing the interests of working women. The Department will more effectively support and advance the mission of the Women's Bureau by focusing the Bureau's resources on conducting research and collaborating with Department agencies, including the Employment and Training Administration and worker protection agencies.

Ms. DeLauro: Which 77 percent of the Women's Bureau work do you find to be unnecessary?

Mr. Acosta: The Women's Bureau serves an important role at the Department of Labor, promoting and advancing the interests of working women. The Department will more effectively support and advance the mission of the Women's Bureau by focusing the Bureau's resources on conducting research and collaborating with Department agencies, including the Employment and Training Administration and worker protection agencies.

OVERTIME REGULATION

Mr. Secretary, I hope you agree that workers who are not executive, administrative, or professional employees deserve overtime pay for working more than 40 hours per week. I strongly support the final rule – issued last year – which would require that anyone earning less than \$913 per week (or approximately \$47,500 per year) be eligible for overtime pay.

Ms. DeLauro: Do you plan to continue to appeal the temporary injunction of the rule to the Fifth Circuit?

Mr. Acosta: The Department of Justice, on behalf of the Department of Labor, is arguing that the Secretary has the authority to establish a salary level test. As stated in its reply brief filed in the Fifth Circuit on June 30, 2017, the Department has decided not to advocate for the specific salary level set in the 2016 final rule at this time and intends to undertake further rulemaking to determine what the salary level should be.

Ms. DeLauro: Will you fight to make sure that workers who earn less than \$47,500 per year receive overtime pay for working more than 40 hours per week?

Mr. Acosta: On July 26, 2017, the Department of Labor published a Request for Information (RFI) regarding the overtime rule in the Federal Register. The RFI offers the public the opportunity to comment on a broad range of questions and issues related to the 2016 overtime rule.

Ms. DeLauro: Do you believe the Department has the statutory authority to link overtime pay to a salary threshold? If so, do you believe a salary threshold should be automatically adjusted for inflation?

Mr. Acosta: The Department of Justice, on behalf of the Department of Labor, is arguing that the Secretary has the authority to establish a salary level test. As stated in its reply brief filed in the Fifth Circuit on June 30, the Department of Labor has decided not to advocate for the specific salary level set in the 2016 Final Rule at this time and intends to undertake further rulemaking to determine what the salary level should be.

Ms. DeLauro: If you don't support the current rule, what is your position on the proper salary threshold to ensure overtime pay? Do you believe that \$23,660 – the level since 2004 – is a

reasonable amount to be considered an executive or supervisor? Do you think it should be higher?

Mr. Acosta: On July 26, 2017, the Department of Labor published a Request for Information (RFI) regarding the overtime rule in the Federal Register. The RFI offers the public the opportunity to comment on a broad range of questions and issues related to the 2016 overtime rule.

FIDUCIARY RULE

Mr. Secretary, I hope you agree that financial advisers should have a fiduciary responsibility to give financial advice that is in the best interests of their clients—rather than the best interests of the adviser.

The White House Council of Economic Advisers has estimated that retirement savers lose \$17 billion every year due to conflicted advice from financial advisers—that is, the advice is not in the best interests of their clients.

In developing the Fiduciary Rule, the Department of Labor produced a 400-page economic analysis on the likely impact of the rule. The analysis found that:

“adviser conflicts are inflicting large, avoidable losses on retirement investors, that appropriate, strong reforms are necessary, and that compliance with this final rule and exemptions can be expected to deliver large net gains to retirement investors.”

I appreciate that you did not further delay partial implementation of this rule. But the Department is not enforcing the rule until next January and, in the meantime, you have stated your preference to “freeze” or “revise” the rule.

Ms. DeLauro: Mr. Secretary, will you commit to enforcing a fiduciary requirement on financial advisers to ensure that financial advice is in the best interest of retirement savers, instead of Wall Street banks or financial advisers?

Mr. Acosta: On April 7, 2017, the Department of Labor promulgated a final rule extending the applicability date of the fiduciary rule by 60 days from April 10, 2017, to June 9, 2017. It also extended from April 10 to June 9, the applicability dates of two prohibited transaction exemptions—the Best Interest Contract Exemption and the Principal Transactions Exemption—and required investment advice fiduciaries relying on these exemptions to adhere to the Impartial Conduct Standards as conditions of those exemptions during a transition period from June 9, 2017, through January 1, 2018. The Impartial Conduct Standards require fiduciaries to provide advice in retirement investors’ best interest; charge no more than reasonable compensation; and avoid misleading statements. The Department has a responsibility to enforce the law and its regulations. Compliance assistance and education is the general approach to implementing the fiduciary rule during the transition period; however, if we find firms and advisers are not acting in good faith to comply with their new fiduciary obligations, the Department will fully and fairly enforce the law.

Ms. DeLauro: If not, please explain why you believe that financial advisers should be able to steer retirement savers into high-cost vehicles that are designed to benefit the financial firm instead of maximize their clients' long-term savings.

Mr. Acosta: On April 7, 2017, the Department of Labor promulgated a final rule extending the applicability date of the fiduciary rule by 60 days from April 10, 2017, to June 9, 2017. It also extended from April 10 to June 9, the applicability dates of two prohibited transaction exemptions—the Best Interest Contract Exemption and the Principal Transactions Exemption—and required investment advice fiduciaries relying on these exemptions to adhere only to the Impartial Conduct Standards as conditions of those exemptions during a transition period from June 9, 2017, through January 1, 2018. The Impartial Conduct Standards require fiduciaries to provide advice in retirement investors' best interest; charge no more than reasonable compensation; and avoid misleading statements. The Department has a responsibility to enforce the law and its regulations. Compliance assistance and education is the general approach to implementing the fiduciary rule during the transition period; however, if we find firms and advisers are not acting in good faith to comply with their new fiduciary obligations, the Department will fully and fairly enforce the law.

OSHA SILICA RULE

Last year, OSHA finally issued a long-needed standard to protect workers against deadly silica dust which causes silicosis and lung cancer. The silica standard was 19 years in the making and is projected to prevent nearly 700 silica-related disease deaths and 900 cases of silicosis a year.

The Department of Labor first started working to prevent silica-related diseases in the 1930's, when Secretary of Labor Francis Perkins launched a major campaign to stop silicosis deaths in this country. But unfortunately the exposures, deaths, and diseases continue.

The rule has been challenged in court by industry groups who claim it isn't needed. Recently those same industry groups petitioned OSHA to stay the rule and reopen it for reconsideration. The Department of Labor is defending this rule in court.

Ms. DeLauro: Mr. Secretary, will you commit to defending, maintaining, and fully implementing the silica standard that is currently in place?

Mr. Acosta: In a statement issued April 6, 2017, the Occupational Safety and Health Administration (OSHA) announced that it would delay enforcing the Construction Industry standard until September 23, 2017. Enforcement of the General Industry and Maritime standards is not scheduled to begin until June 2018. In addition, several industry and labor parties filed challenges to the standard, which are currently pending in the U.S. Court of Appeals for the District of Columbia Circuit. Oral argument is scheduled for September 26, 2017. The Department is currently preparing for oral argument and will comply with any order issued by the court.

WAGE THEFT

Mr. Secretary, wage theft has become an epidemic. According to a three-city survey conducted in Los Angeles, New York, and Chicago, two-thirds of workers in low-wage industries experienced at least one pay-related violation in any given week. The researchers estimated that the average loss per worker over the course of a year was \$2,634, out of total earnings of \$17,616. This is particularly harmful, given that these workers are already economically distressed.

In recent years, the Wage and Hour Division made excellent use of relevant data to identify the industries and employers most likely to be violating wage and hour laws, and the types of workers most likely to be exploited, and in addition to processing complaints, also engaged in strategic enforcement audits and actions using the data that pointed to the places where violations were likely happening.

Ms. DeLauro: Will you commit to continuing the practice of targeted strategic enforcement? If so, please tell us how you plan to identify and address problem industries and repeat violators?

Mr. Acosta: Strategic enforcement in high violation areas, alongside individual complaints, is a balanced enforcement strategy I support. By taking an evidence-based approach, the Department of Labor's Wage and Hour Division (WHD) will prioritize compliance assistance and enforcement resources where the agency is most likely to uncover violations.

CLARIFYING EMPLOYEE MISCLASSIFICATION

Misclassification is a serious problem. States lose millions of dollars when employers misclassify workers as independent contractors—undermining workers compensation, unemployment insurance, and State payroll taxes. Misclassification also hurts responsible employers who correctly classify their workforce.

Ms. DeLauro: Why did you withdraw guidance that makes it clear to employers their responsibilities under existing law and court opinion in regard to properly classifying their workers?

Mr. Acosta: Traditional common law doctrines that have served this nation for centuries have been eroded without passage of any law by Congress and without due process like notice and comment. Such fundamental questions should be answered by elected officials who are directly responsible to the American people. This is why the Department of Labor rescinded guidance on topics such as independent contractors. This will ensure there is no misconception regarding this Administration's respect for the rule of law and for the individual.

Removal of the administrator interpretation does not change the legal responsibilities of employers under the Fair Labor Standards Act or Migrant and Seasonal Agricultural Worker Protection Act, as reflected in the Department's long-standing regulations and case law. The Department will continue to fully and fairly enforce all laws within its jurisdiction, including the Fair Labor Standards Act and the Migrant and Seasonal Agricultural Worker Protection Act.

EMPLOYER GUIDANCE ON JOINT EMPLOYMENT

The use of staffing agencies, third party management, and other new work arrangements have become more common. Research by two internationally recognized labor economists – Alan Krueger and Larry Katz – shows that between 80-100 percent of net employment growth between 2005 and 2015 are in these types of alternative work arrangements. It is your responsibility as Secretary to make sure that employers comply with the law, such as the basic labor standards of minimum wage and overtime as specified by the Fair Labor Standards Act. And it is the function of the Wage and Hour Division to provide clear guidance to employers on their responsibilities.

Ms. DeLauro: Why did you withdraw guidance that makes it clear to employers their responsibilities under existing law and court opinion in regard to joint employment?

Mr. Acosta: Traditional common law doctrines that have served this nation for centuries have been eroded without passage of any law by Congress and without due process like notice and comment. Such fundamental questions should be answered by elected officials who are directly responsible to the American people. This is why the Department of Labor rescinded guidance on topics such as joint employment. This will ensure there is no misconception regarding this Administration's respect for the rule of law and for the individual.

Removal of the administrator interpretation does not change the legal responsibilities of employers under the Fair Labor Standards Act or Migrant and Seasonal Agricultural Worker Protection Act, as reflected in the Department's long-standing regulations and case law. The Department will continue to fully and fairly enforce all laws within its jurisdiction, including the Fair Labor Standards Act and the Migrant and Seasonal Agricultural Worker Protection Act.

MINIMUM WAGE

It has been a decade since Congress last increased the minimum wage. Tipped workers, in particular, have been left behind—the federal tipped minimum wage has been stuck at \$2.13 an hour for more than 25 years. These policies hurt women, in particular. They make up more than half of the workforce in jobs that pay the minimum wage and two-thirds of jobs in tipped occupations.

At your confirmation hearing, you said, “Whether it is those who are working, those who still seek work, those who are discouraged or underemployed, or those who have retired, if confirmed as Secretary of Labor, I will advocate for them.”

Ms. DeLauro: As a self-proclaimed advocate for workers, do you support legislation to increase the minimum wage and also to eliminate the tipped wage?

Mr. Acosta: As you know, Congress is ultimately responsible for setting the federal minimum wage. The Department of Labor has no authority to act unilaterally. States and localities may also set a minimum wage. I recognize that cost of living and other economic factors vary greatly across the United States and that many states and localities have increased their minimum wage

above the federal floor. The Department is committed to fully and fairly enforcing the minimum wage law at the level set by Congress.

CRIMINAL PROSECUTION FOR WORKER SAFETY VIOLATIONS

During the Bush Administration, the Department of Justice (DOJ) started a worker endangerment initiative to criminally prosecute employers in cases of willful violations resulting in death or injury under the stronger provisions of environmental laws where these laws had also been violated. Under the Obama administration, this initiative was continued and the two departments – Labor and Justice – entered into a formal memorandum of understanding to coordinate efforts on enforcement cases where there were criminal violations of laws. The Don Blankenship conviction for the deaths at Upper Big Branch was one of these cases.

Ms. DeLauro: Will the Department of Labor continue the joint DOL-DOJ criminal enforcement initiatives on worker safety that have been undertaken by the past two administrations so that criminal violations that result in worker deaths and injuries can be effectively prosecuted using the full range of legal authorities available?

Mr. Acosta: As a former United States Attorney, I understand the importance of criminal referrals to the Department of Justice. I will continue to support criminal referrals in appropriate cases.

SUSAN HARWOOD TRAINING GRANTS

Since 1978, over 2.1 million workers in dangerous jobs have received training and education on how to protect themselves on the job through this small, but vital OSHA training grant program. Grants were given to organizations that reached workers in the most dangerous industries with vital safety and health training. This in-depth training reached workers who had never been trained before and the results have been clear: workplaces made changes to increase safety.

As you know, there is no comprehensive OSHA standard requiring basic safety training for all workers, and these workers—landscapers, laborers, loggers, etc.—are in the most dangerous industries.

Ms. DeLauro: If this program is eliminated, how will these workers get the training and education to be able to identify and prevent job hazards?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) is proposing to use alternative methods to develop and deliver training to reach the broadest possible audience. The House Appropriations Committee also eliminated funding for these grants in both Fiscal Years (FY) 2017 and 2018. In the FY 2017 report House language, the Committee specifically noted its concern that these grants are inefficient and ineffective. OSHA has a variety of programs and tools available that provide training, outreach, and assistance to employers and employees. These include Alliances, Strategic Partnerships, On-site Consultation, and numerous targeted outreach events, such as the Fall Stand Down in Construction, which provide information on workplace

safety and health to the public. Training and outreach programs delivered directly by the agency can more efficiently provide the same type of information currently delivered through the training grants to a broader audience. Additionally, many Alliance Program agreements contain a training element, and numerous training and information resources are available on OSHA's website.

OSHA will continue its strong commitment to, and emphasis on, the enforcement of standards and regulations that serve as an effective deterrent to employers who put their workers' lives at risk. OSHA's budget request reflects a commitment to reduce workplace injuries, illnesses and fatalities through a balanced approach of both enforcement and compliance assistance.

Ms. DeLauro: Wouldn't it make sense to continue these small grant programs, as an investment in preventing injuries that cost workers, their families, and the economy billions of dollars every year?

Mr. Acosta: The President's Fiscal Year 2018 Budget includes such an investment. It includes a proposed increase of \$4 million and 20 full-time equivalent employees to provide additional outreach and training to high-risk workers. This includes funds for additional Compliance Assistance Specialists, new training materials, and support for OSHA's Cooperative Programs, Strategic Partnerships, and Alliances to address hazards in high-risk industries. In addition, OSHA uses its National, Regional, and Local Emphasis Programs to target its enforcement activities in industries where fatalities and serious injuries occur.

OSHA PRESS RELEASES

Mr. Secretary, since this Administration took office there have been only a limited number of press releases announcing the results of OSHA investigations. Under both President Bush and President Obama, OSHA issued hundreds of press releases every year to highlight significant enforcement cases.

While OSHA issued many more citations—in fact tens of thousands more—the Department selected only those cases above \$100,000 in the Bush Administration and above \$40,000 under the Obama administration to issue press releases. Since OSHA rarely if ever will visit a given workplace, it is often the only way for employers to be reminded that the agency even exists.

Ms. DeLauro: What is your policy for issuing press releases to highlight significant enforcement cases?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) issues press releases for significant cases based on a number of considerations, including cases involving willful citations, workplace fatalities or serious injuries, willful violations related to an area of strategic importance or emphasis, or when employers have engaged in conduct such as falsifying evidence or making false statements to a Compliance Officer, or other action aimed at undermining OSHA's inspection process.

WHISTLEBLOWER ENFORCEMENT

Mr. Secretary, OSHA investigates whistleblower cases under the Occupational Safety and Health Act and 21 other federal laws. Strengthening OSHA's whistleblower program is crucial given the role whistleblowers play in safeguarding occupational health, financial reform, consumer product safety, and air and water supplies. At current funding levels, OSHA is often in violation of statutory deadlines to investigate its whistleblower cases, which stall at the agency for an average of 303 days. The fiscal year 2018 budget would further reduce funding for OSHA's whistleblower programs.

Ms. DeLauro: How would OSHA fulfill its statutory obligations to protect whistleblowers under the proposed funding level?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) remains committed to protecting whistleblowers that raise workplace concerns. OSHA will identify opportunities to streamline processes and procedures while maintaining investigative quality and improving the time it takes to complete an investigation. One area being considered is an expansion of the Alternate Dispute Resolution (ADR) process, which has proven effective in resolving complaint disputes expeditiously.

OSHA will also focus on enhancing its Whistleblower Investigations Manual (WIM) with the goal of streamlining investigative steps and processes in order to more effectively carry out its mission of conducting fair, thorough, and neutral fact-finding investigations. OSHA will continue to focus on improved efficiencies and effectiveness including its ongoing goal of reducing the average age of pending investigations, average age for screening new complaints, and compliance with the prescribed WIM instructions.

Ms. DeLauro: At your proposed funding levels, how many whistleblower investigations would you estimate to complete in fiscal year 2018?

Mr. Acosta: At the proposed funding levels, the Occupational Safety and Health Administration (OSHA) estimates it will complete 2,795 investigations in Fiscal Year 2018.

Ms. DeLauro: At your proposed funding levels, what is the projected average age of pending whistleblower investigations in fiscal year 2018?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) is diligently working to streamline the investigative process without compromising the quality of investigations. As of the second quarter of Fiscal Year (FY) 2017, the average age of pending whistleblower investigations was 296 days and the agency projects maintaining this average in FY 2018.

Ms. DeLauro: At your proposed funding levels, what is the projected processing time for whistleblower investigations in fiscal year 2018?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) is diligently working to streamline the investigative process without compromising the quality of investigations. OSHA's average processing time is 290 days to complete an investigation and OSHA expects this processing time to continue in Fiscal Year 2018.

APPRENTICESHIP PROGRAM BUDGET

I noted your recent comments to your G-20 counterparts that apprenticeship is a priority for you. In March, President Trump said he supported the creation of five million apprenticeships under his watch. I then reviewed the Department's budget proposal and was surprised to see that it cuts Apprenticeship Grants by \$5 million (5 percent).

At the hearing, you noted that there was not enough time to make changes to your budget request after the FY 2017 omnibus was signed into law on May 5th and before the budget was released more than two weeks later on May 23rd. There is no way around it. If your budget request was enacted, it would result in a cut to Apprenticeship Grants. In addition, if the Department's overall funding level was locked in at the time the omnibus became law, then any increases you wanted to sustain in the budget request would come at the expense of other Department of Labor programs.

Ms. DeLauro: What specific programs would you have cut if your intention was to level fund Apprenticeship?

Mr. Acosta: The President's proposed Fiscal Year (FY) 2018 Budget was based on the FY 2017 Continuing Resolution (the Further Continuing Appropriations Act of 2017), the funding law that was enacted when the budget was prepared. Apprenticeships were funded at the 2017 Continuing Resolution level, and the Budget's intent was level funding. Businesses all over the country need skilled workers, and our education and workforce development programs need to be market-responsive. We know that apprenticeships are extremely effective in bridging the skills gap while keeping pace with ever changing business demands. I am committed to increasing high-quality apprenticeships, including expansion into high-growth, emerging sectors. Employers looking for skilled workers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations.

APPRENTICESHIP FINAL RULE

Ms. DeLauro: Not everyone who wishes to pursue an apprenticeship has equal access to this program. This is especially true for certain minority populations and women. That is why the Department of Labor issued its Final Rule effective January 18, 2017 that modernizes the equal opportunity regulations that implement the National Apprenticeship Act of 1937. Please share what guidance will be provided to apprenticeship sponsors who must comply with the Final Regulations that became effective on January 18, 2017.

Mr. Acosta: The Employment and Training Administration's Office of Apprenticeship issued guidance designed to explain the rule and provide compliance assistance to registered

apprenticeship sponsors—including frequently asked questions, fact sheets, implementation timelines, multiple webinars for stakeholders, and other resources. The Department continues to provide individualized compliance assistance to sponsors, states, and other stakeholders upon request.

MIGRANT AND SEASONAL FARMWORKERS ELIMINATION

The Migrant and Seasonal Farmworker program is one of the Department's highest performing – participants are placed into employment 90 percent of the time and wages are increased threefold. It gives workers a ladder they can climb to improve their skills and improve their lives by finding new, higher paying, and more secure employment opportunities. Congress on a bipartisan basis recently came together and reauthorized this program in 2014. At its core, this program is truly a hand-up, not a hand-out, for some of the most vulnerable in our society.

Ms. DeLauro: Given this evidence, why does your budget propose to eliminate this program?

Mr. Acosta: The National Farmworker Jobs Program is a nationally-directed, locally-administered program of services for migrant and seasonal farmworkers—partnering with community organizations and state agencies. Migrant and seasonal farmworkers who are eligible for this program are also eligible for similar services through the core Workforce Innovation and Opportunity Act (WIOA) Titles I and III formula programs, rendering the program duplicative.

JOB CORPS BUDGET CUTS

I am a strong supporter of Job Corps. While I am certainly open to some reforms that would improve the program's effectiveness, the Trump budget proposes to slash Job Corps funding by \$256 million dollars. This massive cut to an important program will not only deprive thousands of disadvantaged young people with an opportunity to improve their lives and our economy, but it will inevitably lead to closing Job Corps centers.

Ms. DeLauro: Why would you and President Trump want to deprive these young people of the opportunity to get education, skills training, and basic preparation for the workforce?

Mr. Acosta: The Department of Labor is committed to streamlining or eliminating programs based upon a rigorous analysis of available data to assess programmatic effectiveness. The Budget will streamline the Job Corps program by closing low-performing centers and suspending operations at other strategically-selected centers. Strengthening the safety and security of Job Corps students and staff is a priority as the budget seeks to streamline Job Corps to lead to improved effectiveness and efficiency. The Budget also builds off past evaluations of the program by prioritizing the enrollment of youth over 20—the group shown to benefit from the model.

Ms. DeLauro: Thousands of young people will lose these opportunities and the hope of getting good starting jobs. What are these young people expected to do? Where are they going to get the same kind of opportunity?

Mr. Acosta: Work-based education, including high-quality apprenticeships, are effective to help narrow the skills gap—enabling employers to be involved in the education of their future workforce so they can be sure new hires possess the skills needed to do the job. Apprentices receive wages and, just as importantly, skills that enable them to thrive in today’s workforce. They earn while they learn.

JOB CORPS CENTER CLOSURES

Ms. DeLauro: Regarding center closures, how do you propose to close them and how many will be closed?

Mr. Acosta: Job Corps is conducting a programmatic assessment of performance center by center, surveying physical facilities, assessing programmatic sustainability, and considering the job training needs in each state and area served by a Job Corps center. Using this deliberate approach, the Department of Labor will develop recommendations and determinations, which will inform how the program’s Fiscal Year 2018 resources can be appropriately allocated.

Ms. DeLauro: What will happen to the young people being served? Will they have the opportunity to attend another Job Corps center?

Mr. Acosta: The Department of Labor would prioritize current Job Corps participants, allowing them to complete their Job Corps education experience either at their current center or at another center.

Ms. DeLauro: Will centers be given the chance to make changes through a performance improvement plan before being closed?

Mr. Acosta: Job Corps staff already work extensively to improve low-performing centers, and in some cases have had performance improvement plans in place for many years.

SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM ELIMINATION

The Trump budget justification says the goals of the Senior Community Service Employment (SCSEP) program can “continue to be addressed through the Workforce Innovation and Opportunity Act programs.” Yet, the budget proposes to slash those programs by 40 percent. Instead of a “no-wrong-door” approach to worker training, the Department’s budget is advocating a “no-right-door approach” for older workers. They will face one closed door after another—first with the elimination of SCSEP and then with the decimation of the Adult and Dislocated Worker programs.

In addition, the Department’s budget justification includes a performance chart, a few pages after the recommendation to eliminate the program for failing to meet performance goals. The chart lists three workload and performance metrics: Entered Employment Rate, Employment Retention Rate and Six Months Average Earnings. According to the Department’s own chart, SCSEP exceeded its target goals in each of those performance areas.

Ms. DeLauro: How can you justify that this program is not meeting its performance goals when the performance chart shows the program does meet these goals?

Mr. Acosta: The Senior Community Service Employment Program (SCSEP) is designed to be a work-based job education program for older Americans, serving as a bridge to unsubsidized employment opportunities. In Program Year 2015 (the most recent year for which data are available), the SCSEP placed fewer than half of participants in unsubsidized jobs, a percentage that excludes as many as one-third of those individuals who failed to complete the program. We believe the needs of this population are better served through other programs.

EMPLOYMENT SERVICE BUDGET CUTS

Your budget proposal contains nearly a 40 percent cut to the Employment Service State grants – which according to your budget justifications would result in a loss of services for 6.3 million jobseekers. The Employment Service has provided labor exchange services to jobseekers at a fraction of the cost of other programs – just \$46 per participant this year according to your own budget data, while still exceeding its performance goals in helping participants gain and retain employment.

Ms. DeLauro: Why do you propose to cut such a cost effective program?

Mr. Acosta: Federal workforce development programs need to effectively and efficiently work for jobseekers and employers, and the federal government should not be locked into existing siloed programs. The Budget proposes to shift more responsibility for funding these services to states, localities, and employers. The President's Budget is proposed in the context of maximizing flexibility; allowing a greater role for states, local communities, and businesses; and promoting public-private partnerships to implement the programs that work best for their community.

WIOA TITLE I CUTS

At your confirmation hearing before the Senate HELP Committee you said, “We need to make better efforts to align job training with the skills the market demands of its workers, especially as advancing technology changes the types of jobs available in our economy. The Department of Labor, along with local governments, industry, and educational institutions, can partner to have substantial positive impact on American workers. This is the vision of the Workforce Innovation and Opportunity Act (WIOA).” I agree. The Departments of Labor, Education and HHS are critical partners in propelling our nation’s workforce systems. Yet your budget proposes to cut about 40 percent of the Title I funding under WIOA. These are funds meant to serve individuals with barriers to employment who need help getting good jobs.

Ms. DeLauro: Please explain how your budget better aligns job training with the skills the market demands?

Mr. Acosta: The President's Executive Order on Expanding Apprenticeships in America demonstrates this Administration's commitment to workforce development. Businesses need skilled workers and our education and workforce development programs need to be market-responsive. We know that apprenticeships are extremely effective in bridging the skills gap while keeping pace with ever changing business demands. I am committed to increasing high-quality apprenticeships, including expansion into high-growth, emerging sectors. Employers looking for skilled workers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations.

Ms. DeLauro: How many American job centers will be closed as a consequence of these deep cuts in the federal commitment to job training and placement services?

Mr. Acosta: The President's Fiscal Year 2018 Budget is proposed in the context of maximizing flexibility, allowing a greater role for states, local communities, and businesses, and promoting public-private partnerships. Ultimately, states and localities will determine, in partnership with business and other stakeholders, whether there is a need to reshape the service delivery structure at the local level, including by changing the number of American Job Centers.

Ms. DeLauro: In the most recent program year, an estimated 20 million workers received assistance from WIOA funded programs. How many fewer individuals will the WIOA programs be able to serve with these cuts proposed in the President's budget request?

Mr. Acosta: The President's Fiscal Year 2018 Budget is proposed in the context of maximizing flexibility, allowing a greater role for states, local communities, and businesses, and promoting public-private partnerships. The Workforce Innovation and Opportunity Act prioritizes underserved populations, and states and local areas have flexibility to determine service priorities.

Ms. DeLauro: How will the individuals who are kicked out of the workforce system as a result of these cuts get the training they need? How many American Job Centers are expected to close?

Mr. Acosta: The President's Fiscal Year 2018 Budget is proposed in the context of maximizing flexibility, allowing a greater role for states, local communities, and businesses, and promoting public-private partnerships. Businesses need skilled workers and our education and workforce development programs need to be market-responsive. We know that apprenticeships are extremely effective in bridging the skills gap while keeping pace with ever changing business demands. I am committed to increasing high-quality apprenticeships, including expansion into high-growth, emerging sectors. Employers looking for skilled workers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations. Ultimately, states and localities will determine, in partnership with business and other stakeholders, whether there is a need to reshape the service delivery structure at the local level, including by changing the number of American Job Centers.

STATE BUDGETS FOR WORKFORCE PROGRAMS

The National Association of State Workforce Agencies expressed concern about your budget proposal, stating: "...However, states have reached their limit in ability to defray federal cuts, including these and others proposed by the administration. Further reductions to the workforce system will severely impact services, leave millions of jobseekers without help to build new skills and leave the skills gap voiced by employers unfilled. State workforce agencies are rebuilding America's workforce by connecting employers and jobseekers through these critical programs." The Administration in its budget claims that this transfer is to "[shift] more responsibility for funding these services to states, localities, and employers..." But the States are already struggling even with the little federal support we give them now. In addition, as I mentioned at the hearing, the Trump budget would slash funding for Medicaid, SNAP, TANF and LIHEAP—to name a few—and shift massive new costs onto States.

Ms. DeLauro: Please provide the share of the current proportion of funding States typically contribute to their workforce programs.

Mr. Acosta: The Department of Labor does not collect data from states that would allow this analysis.

Ms. DeLauro: Please share the analysis on how employers will adjust and contribute more funding to training under the budget request.

Mr. Acosta: The Department of Labor does not collect data from states or employers that would allow this analysis.

Ms. DeLauro: How exactly do you anticipate States will react to the cuts to provide job-training services? Specifically, what impact would it have on State budgets?

Mr. Acosta: The Department of Labor proposed additional flexibilities to help states make decisions on how to best use federal resources. States would be best positioned to speak to their state budgets.

Ms. DeLauro: Did you conduct analysis on which populations your proposed cuts will disproportionately impact? Why or why not? If yes, please share the results. If not, why not?

Mr. Acosta: The Workforce Innovation and Opportunity Act prioritizes underserved populations, and states and local areas have flexibility to determine service priorities. States would be best positioned to conduct this analysis.

ELIMINATING WORKFORCE DATA QUALITY INITIATIVE FUNDING

I have heard you say that we need better alignment of our educational and workforce systems. I believe that WIOA takes great strides towards accomplishing that goal by better aligning workforce and education data systems. But you propose to eliminate funding for the Workforce Data Quality Initiative with no alternative proposal.

Ms. DeLauro: How are you proposing to better align educational and workforce data so that we can get a better sense of how effective the programs are?

Mr. Acosta: The Department of Labor's request to eliminate the Workforce Data Quality Initiative (WDQI) is consistent with the Administration's policy to shift certain functions and responsibilities to states and the states will choose how to enhance the linkages within state data systems. The Workforce Innovation and Opportunity Act (WIOA) requires alignment of workforce performance data through common performance measures and through the reporting requirements for Eligible Training Providers, many of which are educational institutions. The Department will continue to emphasize and support data quality through guidance, reporting requirements, and technical assistance.

WIOA BUDGET CUTS

WIOA made radical changes and required more alignment between education, labor and workforce agencies and programs. This has required a lot of effort and investment at the local, state and federal level. Your proposed funding cuts comes at a time when the workforce system is transitioning and trying work better with educational systems.

Ms. DeLauro: How are you going to better ensure the alignment that has taken place if you're gutting the system?

Mr. Acosta: Work-based education, including high-quality apprenticeships, is effective to help narrow the skills gap—enabling employers to be involved in the education of their future workforce so they can be sure new hires possess the skills needed to do the job. Workers and employers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations.

YOUTH SERVICES BUDGET CUTS

An estimated 4.9 million young people 16 to 24 are both out of school and out of work. Millions more of our children are at risk. Without the proper community supports and training, these young people will fail to get the skills, education, and work experience they need now to fill the jobs of tomorrow. Yet, the Administration's budget makes deep cuts to Youth formula grants under WIOA, about 40 percent below current funding levels. This will leave our local communities, both urban and rural, without the federal investments they need to better serve our young people.

Ms. DeLauro: How does the President justify such drastic cuts to youth training and support services?

Mr. Acosta: The Department of Labor strives to maximize the efficient use of federal resources so that individuals are well-prepared to meet workforce needs—whether after college, after obtaining an associate's degree or other recognized postsecondary credential like a

certification, or after high school, regardless of whether one earned a diploma. There are overlapping programs administered at multiple agencies that deliver employment and education services to youth. The President's Budget would continue to make funds available for programs serving youth and we will continue to invest in those programs that work and that maximize the use of taxpayer dollars.

Ms. DeLauro: How does the President propose we fill the millions of jobs he's promised our nation if our next generation of workers lacks the requisite skills and training to fill them?

Mr. Acosta: Federal workforce development programs should prepare job seekers for high-growth jobs that actually exist. Work-based education, including high quality apprenticeships, are effective to help narrow the skills gap—enabling employers to be involved in the education of their future workforce so they can be sure new hires possess the skills needed to do the job.

TRANSFERS BETWEEN ADULT AND YOUTH SERVICES PROGRAMS

The budget request would allow the transfer of funds between Adult and Youth programs at the local level. In my opinion, this significantly diminishes the purpose of specific, directed funding streams. This almost seems like an attempt at block granting these two programs. Youth and adults can have very different training needs. For example, WIOA requires that the use of the Youth funds be focused on serving out-of-school youth. We are already hearing that more funding is needed to serve these out-of-school youth, but your block grant approach would jeopardize the funding that exists.

Ms. DeLauro: Have you spoken with the organizations that serve youth about this proposal? What do the people on the ground doing the hard work of getting our out-of-school youth on the right path say about this proposal?

Mr. Acosta: This proposal mirrors the existing legislative flexibility of transferring funds between the Adult and Dislocated Worker streams, which is beneficial for states to determine how to best serve their local populations. This proposal supports states' ability to make determinations about where funding should be targeted, based on each state's needs.

IMPACT OF CUTS TO YOUTH SERVICES PROGRAMS

Research shows that when young people aren't trained and able to find work, it costs the government more in public expenditures, including health care, public assistance and incarceration. To be blunt, we pay one way or another.

Ms. DeLauro: Does the President's budget contemplate increased spending for Medicaid, TANF, or federal prisons as a result of gutting youth services and thereby taking away employment opportunities for young people?

Mr. Acosta: Those matters are beyond the purview of the Department of Labor. I would refer you to the Office of Management and Budget and other federal departments for specific questions regarding their budgets.

The Trump budget's deep cuts to youth training programs will make it very difficult, if not impossible, for many cities and rural communities to launch summer jobs programs for disadvantaged young people in their communities. These programs are essential to help kids stay out of trouble during the summer, but also to give them their first work experience and set them on the right path to be productive citizens. Simply, summer jobs can change young people's lives.

Ms. DeLauro: Can you tell us how many disadvantaged young people will not have summer jobs as a consequence of the Trump budget's deep cuts to youth programs?

Mr. Acosta: Data from the most recent complete program year show that 18.5 percent of Workforce Innovation and Opportunity Act youth participants typically participate in summer employment. However, as the budget provides additional flexibility to allow states choose how to best use the resources, states would be best positioned to provide that information.

WIOA WAIVERS

Ms. DeLauro: Do you commit to publish all WIOA waivers – including those related to eligible training provider reporting requirements on outcomes on all students in a program of study and percentage requirements on disconnected youth funds—on the Department's website? Please explain why or why not.

Mr. Acosta: The Department of Labor intends to make the waiver responses public.

COMMUNITY COLLEGES

Community colleges are very important providers of workforce development programs in just about every state in the country. Community colleges are central to economic development in many regions, and they provide both credentials and degrees to hundreds of thousands of adults and college-age young people seeking to find and secure their places in the middle class.

The Trump budget, by cutting more than \$2 billion out of employment and training programs, will inevitably have a severely negative effect on community colleges.

Ms. DeLauro: Have you spoken with community college leaders about the devastating effects of these cuts, and can you tell us what they have told you?

Mr. Acosta: The Department of Labor has heard from community colleges about the important role they play in economic and workforce development in their communities. One of the key goals in the President's recent Executive Order on Expanding Apprenticeship in America is to better align businesses and institutions of higher education. Community colleges are an important partner in this work.

Ms. DeLauro: Will we see workforce development programs in community colleges closing down because of these cuts?

Mr. Acosta: States will determine how funds for employment and education programs are distributed.

Ms. DeLauro: And have you spoken with employers who depend upon their local community colleges to provide local workers with the skills the employers need to succeed?

Mr. Acosta: The Department of Labor has heard from employers and community colleges about the important role they play in economic and workforce development in their communities. One of the key goals in the President's recent Executive Order on Expanding Apprenticeship in America is to better align businesses and institutions of higher education, including aligning businesses with community colleges.

H-2B VISA INCREASES

Under section 543 of division F of the Consolidated Appropriations Act, 2017 the Department of Homeland Security (DHS) Secretary must first consult with the Secretary of Labor before exercising his discretion to increase the number of available H-2B visas for the remainder of fiscal year 2017.

Earlier this month, the Education and the Workforce Committee Ranking Member Bobby Scott led a letter expressing deep concern about adding nearly 70,000 more H-2B visas before the end of the fiscal year, given weaknesses and loopholes in the H-2B program that depress wages for U.S. workers and expose H-2B workers to abuse and exploitation. The letter requests that you provide Congress with and make public a detailed description of the methodology you will use to make recommendations to the DHS Secretary.

Ms. DeLauro: According to recent statements from DHS, they have not met with officials from the Department of Labor to discuss potential increases. Is this accurate?

Mr. Acosta: The Department of Homeland Security consulted with the Department of Labor to provide additional H-2B visas during Fiscal Year 2017.

Ms. DeLauro: What methodology or processes is the Department of Labor using or planning to use to make a recommendation regarding potential increases in the number of H-2B visas for the remainder of the fiscal year?

Mr. Acosta: On July 19, 2017, the Federal Register published a final rule from the Departments of Homeland Security and Labor to increase the numerical limitation on H-2B nonimmigrant visas to up to an additional 15,000 through the end of Fiscal Year 2017. Detailed information regarding that rule can be found on the Federal Register's website at: <https://www.federalregister.gov/documents/2017/07/19/2017-15208/exercise-of-time-limited-authority-to-increase-the-fiscal-year-2017-numerical-limitation-for-the>

Ms. DeLauro: Will DOL rely on BLS hiring and vacancy data and patterns of wage and employment, especially in geographic areas and industries with high numbers of H-2B workers?

Mr. Acosta: The final rule from the Departments of Homeland Security and Labor cites several statistics from the Bureau of Labor Statistics.

Ms. DeLauro: Will DOL allow for public comment before and/or after it has developed its recommendation?

Mr. Acosta: The rule was issued with an immediate effective date pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b) and (d).

VETERANS EMPLOYMENT AND TRAINING SERVICE BUDGET

According to the Bureau of Labor Statistics, Post-9/11 veterans have a higher unemployment rate than the national average. BLS also tells us that one in three veterans with a service-connected disability and one in five veterans without a service-connected disability are employed in public service. So, the President's hiring freeze and his plans to dramatically downsize the federal workforce have disproportionately hurt veterans, making it more difficult to bring down their unemployment rate.

The Trump budget proposes \$174.7 million – a reduction of \$333,000 – for the Jobs for Veterans State Grant program, which supports Disabled Veterans Outreach Program representatives (DVOPs) and Local Veterans Employment Representatives (LVERs) across the United States. With the effects of inflation and cost-of-living adjustments, this proposal results in a further reduction in real funding for these programs.

Ms. DeLauro: How many fewer DVOPs and LVERs will serve veterans if the Trump budget is enacted?

Mr. Acosta: The President's proposed Fiscal Year (FY) 2018 Budget was based on the FY 2017 Continuing Resolution (the Further Continuing Appropriations Act of 2017), the funding law that was enacted when the budget was prepared. The Budget assumed no change in the number of Disabled Veterans' Outreach Program (DVOP) specialists and Local Veterans' Employment Representatives (LVER) from the 2017 CR. However, distribution of these funds is ultimately left to the discretion of each state

Ms. DeLauro: And how many veterans who would have been provided with employment and training services will not be served?

Mr. Acosta: The Detailed Workload and Performance Table in the Veterans' Employment and Training Service (VETS) budget showed no change in the number of participants served from the 2017 CR level.

BUREAU OF LABOR STATISTICS - EMPLOYMENT SITUATION

Mr. Secretary, in recent years Donald Trump frequently expressed doubt about the validity of the Bureau of Labor Statistics' (BLS) monthly Employment Situation. He called the numbers "a

complete fraud" (2012); "false numbers" (2013); "a totally phone number" (2014); and "one of the biggest hoaxes in modern politics" (2016).

Ms. DeLauro: Do you believe that BLS' monthly employment data are "false numbers"?

Mr. Acosta: The Bureau of Labor Statistics (BLS) and other government statistical agencies serve an incredibly important role. These agencies have protections and standards that are provided by the Office of Management and Budget to ensure the integrity of the information maintained and disseminated by BLS. These protections are important because the data they produce is used over time to set policy, including employment data. Each month, the *Employment Situation* release provides employment, hours, and earnings estimates based on data collected from employers through the Current Employment Statistics program, as well as six measures of labor underutilization, including the headline official unemployment rate, based on data provided by households through the Current Population Survey (CPS). Each of the six rates of labor underutilization measures what it is intended to measure based on the specific definition of underutilization that applies to each rate. The concepts behind the official unemployment rate largely have been the same for nearly 80 years. While each of the six measures of labor underutilization measures what it is intended to measure, that measure may not be what is being discussed.

Ms. DeLauro: Do you believe that BLS' monthly employment data are "a complete fraud"?

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Ms. DeLauro: Is there any reason to doubt the validity of BLS's monthly employment data?

Mr. Acosta: There is no reason to doubt the validity of BLS's monthly employment data. I note that the *Employment Situation* release provides six measures of labor underutilization, one of which, the U-3, is the official unemployment rate. The concepts behind the official unemployment rate largely have been the same for nearly 80 years.

PATHWAYS EMPLOYEES AT BLS

The Department recently terminated the employment of the majority of BLS Pathways employees. The Pathways program is an apprentice-style program to train employees for highly technical jobs and then convert them to permanent positions if they perform well.

Ms. DeLauro: Why did the Department terminate the employment of so many BLS Pathways employees?

Mr. Acosta: Positions under the Pathways Program at the Department of Labor are temporary excepted service appointments. As a condition of employment, the appointment expires at the end of the one-year service period, at which time the employee may or may not be converted into a permanent position. In accordance with the government-wide hiring freeze enacted in January, the Department has a process in place to evaluate all hiring activities, including conversions of Pathways individuals. Since January 20, 2017, the Department has converted 44 Pathways Recent Graduates, of which 35 were from the Bureau of Labor Statistics (BLS). BLS constitutes 15.5 percent of the DOL workforce and 79.5 percent of the Pathways Recent Graduates (converted since January 20, 2017) work at BLS.

Ms. DeLauro: Given the Department's emphasis on apprenticeship programs, why are you undermining the apprenticeship program that trains skilled staff at BLS?

Mr. Acosta: Positions under the Pathways Program at the Department of Labor are temporary excepted service appointments. As a condition of employment, the appointment expires at the end of the one-year service period, at which time the employee may or may not be converted into a permanent position. In accordance with the government-wide hiring freeze enacted in January, the Department has a process in place to evaluate all hiring activities, including conversions of Pathways individuals. Since January 20, 2017, the Department has converted 44 Pathways Recent Graduates, of which 35 were from the Bureau of Labor Statistics (BLS). BLS constitutes 15.5 percent of the DOL workforce and 79.5 percent of the Pathways Recent Graduates (converted since January 20, 2017) work at BLS.

Ms. DeLauro: What was the level of full-time equivalents (FTE) at BLS on June 1, 2017? And what was the level of FTE at BLS on June 1, 2016?

Mr. Acosta: On June 1, 2016, the Bureau of Labor Statistics (BLS) had 2,304 full-time equivalents (FTE). On June 1, 2017, BLS had 2,295 FTE.

BLS FUNDING LEVELS

BLS has a sizeable amount of built-in costs to support existing personnel—and yet, your fiscal year 2018 budget request is below the funding levels for fiscal years 2016 and 2017.

Ms. DeLauro: Under your budget proposal for BLS, would you be able to continue all surveys and data series that were supported in fiscal years 2016?

Mr. Acosta: At the proposed budget funding level, no surveys are planned for elimination.

Ms. DeLauro: Would you be forced to eliminate any surveys or data series?

Mr. Acosta: At the proposed budget funding level, no surveys are planned for elimination.

Ms. DeLauro: Would you be forced to reduce the frequency of any surveys or data series?

Mr. Acosta: At the proposed budget funding level, there may be non-permanent changes to some programs in order to reallocate funding to the production of core data series that may temporarily reduce the frequency of surveys or data series.

Ms. DeLauro: Would you continue to support the American Time Use Survey?

Mr. Acosta: The President's Fiscal Year 2018 budget request provides funding for the American Time Use Survey.

Ms. DeLauro: Would you continue to support the Job Openings and Labor Turnover Survey?

Mr. Acosta: The President's Fiscal Year 2018 budget request provides funding for the Job Openings and Labor Turnover Survey.

Questions for the Record from Mr. Pocan**EMPLOYEE MISCLASSIFICATION**

Mr. Pocan: Do you think that misclassification is a serious problem?

Mr. Acosta: An important role of the Department of Labor is to ensure that employers who want to do the right thing have clear compliance guidance from the Department. The use of independent contractors is a legal and valuable business practice. However, in some circumstances, when an employer incorrectly labels a worker as an independent contractor instead of an employee, the employer may not be abiding by their responsibilities to compensate the worker according to the requirements of the law. Employees incorrectly classified as independent contractors may be denied access to critical benefits and protections they are entitled to by law. This incorrect classification may also generate losses to the federal government and state governments in the form of lower tax revenues, as well as to state unemployment insurance and workers' compensation funds. Employers who deliberately misclassify workers undercut law-abiding employers who are making contributions to these systems and paying their workers properly.

Mr. Pocan: Do you agree that states lose millions from it misclassifying workers as independent contractors that undermine workers compensation, unemployment insurance, and state payroll taxes?

Mr. Acosta: Employees incorrectly classified as independent contractors may be denied access to critical benefits and protections they are entitled to by law. This incorrect classification may also generate losses to the federal government and state governments in the form of lower tax revenues, as well as to state unemployment insurance and workers' compensation funds. Employers who deliberately misclassify workers undercut law-abiding employers who are making contributions to these systems and paying their workers properly.

Mr. Pocan: And do you agree that misclassification hurts responsible employers who correctly classify their workforce?

Mr. Acosta: Employers who deliberately misclassify workers undercut law-abiding employers who are making contributions to these systems and paying their workers properly.

Mr. Pocan: Then why did you withdraw guidance that simply makes it clear to employers their responsibilities under existing law and court opinion on their responsibilities?

Mr. Acosta: Traditional common law doctrines that have served this nation for centuries have been eroded without passage of any law by Congress and without due process like notice and comment. Such fundamental questions should be answered by elected officials who are directly responsible to the American people. This is why the Department of Labor rescinded guidance on topics such as independent contractors. This will ensure there is no misconception regarding this Administration's respect for the rule of law and for the individual.

Removal of the administrator interpretation does not change the legal responsibilities of employers under the Fair Labor Standards Act or Migrant and Seasonal Agricultural Worker Protection Act, as reflected in the Department's long-standing regulations and case law. The Department will continue to fully and fairly enforce all laws within its jurisdiction, including the Fair Labor Standards Act and the Migrant and Seasonal Agricultural Worker Protection Act.

JOINT EMPLOYMENT

Mr. Pocan: Do you acknowledge that the use of staffing agencies, third party management, and other new work arrangement have become more common?

Mr. Acosta: Regardless of the manner in which a business chooses to operate, the Department of Labor will fairly and fully enforce the law and provide employers with the information and resources they need to comply with the law so that they can focus on creating good, safe jobs and growing their businesses.

Mr. Pocan: Are you aware of research by two internationally recognized labor economists, Alan Krueger (Princeton) and Larry Katz (Harvard) that shows that between 80-100 percent of net employment growth between 2005 and 2015 are in these kind of alternative work arrangements?

Mr. Acosta: A number of studies have sought to capture the changing economy. Regardless of the changes, the Department of Labor is committed to fairly and fully enforcing the law and providing employers with the information and resources they need to comply with the law so that they can focus on creating good jobs and growing their businesses.

COMPLIANCE GUIDANCE

Mr. Pocan: Do you think that it is your responsibility as Secretary to make sure that employers comply with the law, such as the basic labor standards of minimum wage and overtime as specified by the FLSA?

Mr. Acosta: The Department of Labor enforces the laws in its jurisdiction fully and fairly, including the Fair Labor Standards Act.

Mr. Pocan: Do you think that it is the function of an agency like the Wage and Hour Division to provide clear guidance to employers on their responsibilities?

Mr. Acosta: The Department of Labor is committed to providing employers with the tools they need to operate in compliance with the labor laws enforced by the Department and offers a number of useful compliance resources intended to provide employers with readily accessible, easy-to-understand information relevant to both their rights and to their responsibilities under the law. Further, I recently directed the Wage and Hour Division (WHD) to reinstate the opinion letter process to help employers and employees clearly understand their labor responsibilities so employers can concentrate on doing what they do best—growing their businesses and creating jobs.

Mr. Pocan: Then why did you withdraw guidance that simply makes it clear to employers their responsibilities under existing law and court opinion on their responsibilities about joint employment?

Mr. Acosta: Traditional common law doctrines that have served this nation for centuries have been eroded without passage of any law by Congress and without due process like notice and comment. Such fundamental questions should be answered by elected officials who are directly responsible to the American people. This is why the Department of Labor rescinded guidance on topics such as joint employment. This will ensure there is no misconception regarding this Administration's respect for the rule of law and for the individual.

Removal of the administrator interpretation does not change the legal responsibilities of employers under the Fair Labor Standards Act or Migrant and Seasonal Agricultural Worker Protection Act, as reflected in the Department's long-standing regulations and case law. The Department will continue to fully and fairly enforce all laws within its jurisdiction, including the Fair Labor Standards Act and the Migrant and Seasonal Agricultural Worker Protection Act.

OVERTIME FOR LOW WAGE WORKERS

Mr. Pocan: What do you think DOL should prioritize in order to help low wage workers?

Mr. Acosta: All of the laws the Department of Labor enforces seek to fulfil the Department's mission to "foster, promote, and develop the welfare of the wage earners, job seekers, and retirees of the United States; improve working conditions; advance opportunities for profitable employment; and assure work-related benefits and rights." Certainly wage and hour laws provide a level of economic security to the nation's workers. The economic security of the nation's workforce also supports America's businesses and economy as a whole. To protect fair and vigorous competition, the Department's Wage and Hour Division (WHD) addresses compliance issues systematically and deters violations through compliance assistance to reach a broader audience. The Fair Labor Standards Act (FLSA), the Migrant and Seasonal Agricultural Protection Act (MSPA), and the immigration programs administered and enforced by the Department establish standards to protect the wages and the safety and health of vulnerable workers and to ensure that U.S. workers are not displaced by lower paid foreign labor.

Mr. Pocan: Do you think workers making \$24,000 should have to work more than 40 hours without additional compensation, right?

Mr. Acosta: On July 26, 2017, the Department of Labor published a Request for Information (RFI) regarding the overtime rule in the Federal Register. The RFI offers the public the opportunity to comment on a broad range of questions and issues related to the 2016 overtime rule.

SILICA DUST STANDARD

Mr. Pocan: Will you commit to defend, maintain and fully implement the silica standard to finally keep Secretary of Labor Frances Perkins' pledge to "Stop Silicosis" and protect more than 2 million workers from deadly silica dust?

Mr. Acosta: In a statement issued April 6, 2017, the Occupational Safety and Health Administration (OSHA) announced that it would delay enforcing the Construction Industry standard until September 23, 2017. Enforcement of the General Industry and Maritime standards is not scheduled to begin until June 2018. In addition, several industry and labor parties filed challenges to the standard, which are currently pending in the U.S. Court of Appeals for the District of Columbia Circuit. Oral argument is scheduled for September 26, 2017. The Department is currently preparing for oral argument and will comply with any order issued by the court.

SUSAN HARWOOD GRANT PROGRAM ELIMINATION

The President's FY 2018 proposed budget zeroes out funding for OSHA Susan Harwood Training and education grant program. This program has provided approximately \$10.5 million in funding to non-profit employer and worker groups to provide training and education to workers in high-risk industries, with a focus on low wage vulnerable workers who are at increased risk of injury and death. It is the only program that OSHA has that focuses on outreach to workers.

Mr. Pocan: Why is the Trump administration eliminating the only OSHA outreach program that is directed to workers? Why isn't training high risk workers about safety and health hazards and control measures a priority for this administration?

Mr. Acosta: The Occupational Safety and Health Administration (OSHA) is proposing to use alternative methods to develop and deliver training to reach the broadest possible audience. The House Appropriations Committee also eliminated funding for these grants in both Fiscal Years (FY) 2017 and 2018. In the FY 2017 report House language, the Committee specifically noted its concern that these grants are inefficient and ineffective. OSHA has a variety of programs and tools available that provide training, outreach, and assistance to employers and employees. These include Alliances, Strategic Partnerships, On-site Consultation, and numerous targeted outreach events, such as the Fall Stand Down in Construction, which provide information on workplace safety and health to the public. Training and outreach programs delivered directly by the agency can more efficiently provide the same type of information currently delivered through the training grants to a broader audience. Additionally, many Alliance Program agreements contain a training element, and numerous training and information resources are available on OSHA's website.

The President's Fiscal Year 2018 Budget includes a proposed increase of \$4 million and 20 full-time equivalent employees to provide additional outreach and training to high-risk workers. This includes funds for additional Compliance Assistance Specialists, new training materials,

and support for OSHA's Cooperative Programs, Strategic Partnerships, and Alliances to address hazards in high-risk industries.

CUTS TO WIOA BUDGET

The budget calls for significant reductions in funding for key workforce programs under WIOA, which was reauthorized in a bipartisan effort by Congress in 2014. Overall, the cuts represent about a 40 percent reduction from current funding levels, which would have devastating impacts on states and local communities seeking to address the skill needs of businesses and jobseekers.

Mr. Pocan: Is workforce development not a priority for this administration?

Mr. Acosta: Americans want good and safe jobs. The Department of Labor is here to support Americans' desire to gain and hold these jobs. We are going to focus the Department of Labor on its core mission by making smart investments in programs that work.

The President's Executive Order on Expanding Apprenticeships in America demonstrates this Administration's commitment to workforce development. Businesses need skilled workers and our education and workforce development programs need to be market-responsive. We know that apprenticeships are extremely effective in bridging the skills gap while keeping pace with ever changing business demands. I am committed to increasing high-quality apprenticeships, including expansion into high-growth, emerging sectors. Employers looking for skilled workers are best served by a streamlined and efficient workforce system that partners with trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations.

APPRENTICESHIP PROGRAM BUDGET CUTS

A lot of us were surprised that after your trip to Germany where you held up apprenticeship as a model for workforce development, shortly after you got back your budget cut \$5M from apprenticeship grants in just the third year of the program.

Mr. Pocan: Do you intend to maintain the Department's Advisory Committee on Apprenticeships?

Mr. Acosta: The President's proposed Fiscal Year (FY) 2018 Budget was based on the FY 2017 Continuing Resolution (the Further Continuing Appropriations Act of 2017), the funding law that was enacted when the budget was prepared. Apprenticeships were funded at the 2017 Continuing Resolution level. The President's Executive Order on Expanding Apprenticeships in America promotes the development of apprenticeship programs by third parties, including trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations. The Advisory Committee on Apprenticeship remains a valuable resource for the Department of Labor.

CUTS TO ILAB BUDGET

Mr. Pocan: Based on campaign rhetoric, I was under the impression the President understands how worker conditions in countries we have strong trade relationships with impact workers here; why then does your budget cut \$68M from Bureau of International Labor Affairs (ILAB,) and eliminates ILAB extramural grants?

Mr. Acosta: I share the President's commitment to ensuring that our trade policies benefit workers and businesses in the United States. We recognize that our trading partners receive an unfair subsidy when they fail to comply with their trade-related labor commitments, putting workers and businesses in the United States at a competitive disadvantage. The Bureau of International Labor Affairs (ILAB) will use its expertise to address these issues and ensure that U.S. workers and businesses are able to compete on a fair global playing field. At the same time, we should hold our trading partners accountable and ask them to do their share by investing their own resources to effectively enforce their labor laws and fund initiatives to combat child labor and modern slavery.

ILAB will provide direct technical support to our trading partners to improve laws and enforcement and will use its existing technical assistance portfolio to combat forced labor and child labor and improve labor enforcement and working conditions around the world. As part of our continued technical assistance, we intend to ask our trading partners to invest more of their own resources to enforce their labor laws and fund initiatives to combat child labor and forced labor. ILAB will also improve its impact by strengthening partnerships with other U.S. government agencies, such as the Office of the U.S. Trade Representative and Department of Homeland Security, as well as with private sector stakeholders to prevent the importation of goods made with forced labor and make trade fairer for workers and businesses in the United States.

JUSTIFICATION FOR INCREASING H-2B VISAS

The FY 2017 appropriations act gave the Secretary of Homeland Security, in consultation with the Secretary of Labor, the ability to issue H-2B guest worker visas past the 66,000 annual cap. Every year there are thousands of H-2B workers used in the construction industry, despite a national unemployment rate currently over 5% in construction. The program designed for temporary and seasonal jobs in sectors like landscaping, seafood, and hospitality, but for years we have seen steadily increasing usage of H-2B workers in the construction industry, which is not seasonal.

Mr. Pocan: What is the justification for allowing construction employers in particular to bring in foreign workers when there are Americans ready to get to work? And why should even more visas be issued this year in light of the program's clearly insufficient labor protections and wage determinations?

Mr. Acosta: On July 19, 2017, the Federal Register published a final rule from the Departments of Homeland Security and Labor to increase the numerical limitation on H-2B nonimmigrant visas to up to an additional 15,000 through the end of Fiscal Year 2017. The rule

states, “[t]hese additional visas are available only for those American businesses that attest to a level of need such that, if they do not receive all of the workers under the cap increase, they are likely to suffer irreparable harm, *i.e.*, suffer a permanent and severe financial loss.”

The Department of Labor’s regulations require employers to recruit American workers for the job for which they are seeking foreign workers. If, during the recruitment period and up to three weeks before the start of the job, any qualified American worker applies for the specific job, the employer is required to hire that American worker. If qualified American workers do not avail themselves of the opportunity to apply, the Department cannot make a determination that there are qualified and available U.S. workers for that job.

Detailed information regarding that rule can be found on the Federal Register’s website at: <https://www.federalregister.gov/documents/2017/07/19/2017-15208/exercise-of-time-limited-authority-to-increase-the-fiscal-year-2017-numerical-limitation-for-the>

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