

**OVERSIGHT OF THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
SECOND SESSION

—
FEBRUARY 15, 2018
—

Serial No. 115-101



Printed for the use of the Committee on Energy and Commerce
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U.S. GOVERNMENT PUBLISHING OFFICE

30-188 PDF

WASHINGTON : 2018

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OVERSIGHT OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

THURSDAY, FEBRUARY 15, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 12:33 p.m., in room 2123, Rayburn House Office Building, Hon. Michael C. Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Upton, Shimkus, Latta, Lance, Griffith, Bilirakis, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, Luján, Schrader, Kennedy, Cárdenas, Eshoo, DeGette, and Pallone (ex officio).

Also present: Representatives Welch and Tonko.

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Mike Bloomquist, Deputy Staff Director; Adam Buckalew, Professional Staff Member, Health; Kelly Collins, Staff Assistant; Zack Dareshori, Legislative Clerk, Health; Paul Eddatell, Chief Counsel, Health; Adam Fromm, Director of Outreach and Coalitions; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Clerk, Health; Ed Kim, Policy Coordinator, Health; James Paluskiewicz, Professional Staff Member, Health; Mark Ratner, Policy Coordinator; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Counsel, Health; Austin Stonebraker, Press Assistant; Josh Trent, Deputy Chief Health Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jacquelyn Bolen, Minority Professional Staff Member; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Counsel, Health; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Una Lee, Minority Senior Health Counsel; Miles Lichtman, Minority Policy Analyst; Rachel Pryor, Minority Senior Health Policy Advisor; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; C.J. Young, Minority Press Secretary.

Mr. BURGESS. The Subcommittee on Health will now come to order. I ask everyone to please take their seats.

And before we get started, I do want to take a moment to recognize yesterday's devastating events in Florida. We will continue to learn more about how things occurred, and I know my colleagues

and I will keep the victims, the injured, and their loved ones foremost in our minds.

Representative Bilirakis and Representative Castor, we will also be thinking of you, the entire Florida delegation, and the people of Florida during this difficult time.

I would like to recognize myself 5 minutes for the purpose of an opening statement.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

This afternoon, we are honored to have Secretary Alex Azar before the Health Subcommittee to discuss the Department of Health and Human Services' budget for the fiscal year 2019.

First, Secretary Azar, congratulations on your recent confirmation, and we appreciate your willingness to participate today, and I believe this is your third congressional hearing in 24 hours. So we also appreciate your endurance.

Earlier this week, President Trump and his administration released their budget, which provides a blueprint on where Federal investments could be made as well as areas of additional funding and resources and areas of efficiency.

We appreciate the administration sharing its vision for the upcoming fiscal year as all of us on the committee work to solve many of the healthcare issues impacting our respective communities across the country.

Mr. Secretary, you see before you on this dais men and women with a multitude of backgrounds and experience and different political approaches to solving these problems—different political philosophies.

But I can tell you for a fact everyone seated on this dais on either side is committed to seeking solutions and doing the work necessary, and I pledge that we will work with you as we accomplish these goals for the American people.

The Energy and Commerce Committee, specifically this subcommittee, has the broadest jurisdiction in Congress over our Nation's healthcare matters, major policy operations under the Department of Health and Human Services.

These include both private and public health insurance markets, Medicare, Medicaid, Children's Health Insurance, and the Affordable Care Act; biomedical research and developments, particularly those emanating out of the National Institutes of Health; the regulation of food, drugs, and medical devices, as well as cosmetics through the Food and Drug Administration.

We also oversee Federal policies affecting substance abuse and mental health, which demand interagency collaboration, especially with the Substance Abuse and Mental Health Administration; and oversight of not only the Nation's public health but also global health, including the Centers for Disease Control and Prevention.

Again, Members on both sides of this dais on this committee, we do have our differences but I believe we have the mutual goal of delivering for the American people and working together on issues that demand our full attention.

We have got an opiate crisis that demands our attention. We have got to improve the quality and access to healthcare products

and services. We have to harness the scientific and medical technologies of today to advance the healthcare policies of tomorrow.

What this committee has already accomplished under the previous administration and the current administration is indicative of what is certainly possible: passage of the Medicare and CHIP Reauthorization Act to repeal the sustainable growth rate formula; the enactment of the 21st Century Cures Act; the reauthorization of several key user fees at the Food and Drug Administration last year; the reauthorization of Children's Health Insurance and community health centers and other important public health and Medicare extenders just last week.

On this committee, we were able to include 19 Member-led healthcare initiatives in the recent Bipartisan Budget Act that included both Republican and Democrat priorities. The Health Subcommittee still has an extensive list of items to finish before the end of this year. These include holding hearings on legislative policies and developing the proposals to blunt the opioid epidemic, to reauthorize the Pandemic and All-Hazards Preparedness Act and the Animal Drug User Fee, and examining the cost drivers of the Nation's healthcare infrastructure and offering solutions and improvements to programs like 340B drug discount under the Health Resources and Services Administration.

We are also interested in Consumer eHealth in the Office of the National Coordinator for Health Information Technology.

I would like to build upon the work that our subcommittee initiated last year and continue assessing the ways that our current healthcare infrastructure can more positively impact Americans in urban and rural areas where illnesses like Alzheimer's disease and mental health disorders pose challenges for our loved ones and their families.

As a physician who understands the demands and challenges of treating patients while maneuvering through the reporting and other compliance requirements, which can often be barriers to providing better patient care, I want you to know I am committed to relieving the burdens that have been placed on doctors through commonsense market-driven solutions.

Many of the actions the current administration has taken thus far are very encouraging, and it is my hope we can continue to work together on this effort.

Mr. Secretary, I want you to regard this subcommittee as a resource and a partner to you and your agency to fulfill your mission and deliver for America.

Again, I want to welcome you, Secretary Azar, and I want to thank you for being here. I look forward to hearing your vision for the Department of Health and Human Services and exploring opportunities to work together on the many critical health issues on behalf of the American people.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Today, we are honored to have Secretary Alex Azar before the Health Subcommittee to discuss the Department of Health and Human Services' budget for the fiscal year 2019. First, Secretary Azar congratulations on your recent confirmation,

and we appreciate your participation today, which I believe will be your third congressional testimony within the last 24 hours.

Earlier this week, President Trump and his administration released their budget which provides a blueprint on where Federal investments could be made as well as areas of additional funding resources and efficiencies. We appreciate the administration sharing its vision for the upcoming fiscal year as all of us on the committee work to solve many of the healthcare issues impacting our respective communities across the country.

You see before you on the dais, men and women with a multitude of backgrounds and experience and different political philosophic approaches to solving these problems. But I can tell you everyone seated on this committee is committed to seeking solutions—and doing the work necessary.

The Energy and Commerce Committee, specifically this subcommittee, has the broadest jurisdiction in Congress over our Nation's healthcare matters, encompassing the major policies and operations under the Department of Health and Human Services. These issues include both private and public health insurance markets under Medicare, Medicaid, CHIP, and the Affordable Care Act; biomedical research and developments, particularly those emanating out of the National Institutes of Health; the regulation of food, drugs, medical devices, and cosmetics through the Food and Drug Administration; Federal policies affecting substance abuse and mental health, which demand interagency collaboration, especially the Substance Abuse and Mental Health Administration; and oversight of not only the Nation's public health but also global health pandemics, including the Centers for Disease Control and Prevention.

Again, Members on both sides of the dais on this committee do have our differences, I believe that we have the mutual goal of delivering for the American people and working together on issues that demand our full attention, such as combating the opioid crisis, improving the quality and access to healthcare products and services, and harnessing the scientific and medical technologies of today to advance healthcare policies of tomorrow. What this committee has already accomplished under the previous and current administration is indicative of what is certainly possible—the passage of the Medicare and CHIP Reauthorization Act to repeal the SGR; the enactment of the 21st Century Cures Act; the reauthorization of several key user fees at the FDA last year; and the reauthorization of CHIP, community health centers, and other important public health and Medicare extenders last week. Just on this committee, we were able to include 19 Member-led healthcare bills in the recent Bipartisan Budget Act that included both Republican and Democrat priorities.

The Health Subcommittee still has an extensive list of items to finish before the end of this year. These include holding hearings on legislative policies and developing a package of proposals to blunt the opioid epidemic, reauthorizing the Pandemic and All Hazards Preparedness Act and Animal Drug User Fee, and examining the cost drivers of the Nation's healthcare infrastructure and offering solutions, and/or improvements, to programs like 340B drug discount under the Health Resources and Services Administration and Consumer eHealth at the Office of National Coordinator for Health IT.

I would also like to build upon the work our subcommittee initiated last year and continue assessing the ways our current healthcare infrastructure can more positively impact Americans in urban and rural areas, where illnesses like Alzheimer's disease and mental health disorders pose challenges for our loved ones and their families. As a physician who understands the demands and challenges of treating patients while maneuvering through reporting and other compliance requirements—which can often be barriers to providing better patient care—I am committed to relieving the burdens that have been placed on doctors through commonsense, market-driven solutions. Many of the actions the current administration has taken thus far are encouraging and it is my hope we can continue to work together on this effort.

I want you to regard this subcommittee as a resource to you and your agency, and a partner to fulfill your mission and deliver for America. I again want to welcome Secretary Azar and thank him for being here. I look forward to hearing your vision for the Health and Human Services Department and exploring opportunities to work together on the many critical healthcare issues on behalf of the American people.

Mr. BURGESS. At this time, I would like to recognize the ranking member of the Health Subcommittee, Mr. Gene Green of Texas, for 5 minutes, please.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Secretary and Mr. Chairman. Thank you, Mr. Secretary, for being here today, and it is unusual to have two Texans who are ranking and chair of the Health Subcommittee. We wondered about that for most of this session. But somehow it works out.

This week, President Trump released his 2019 budget request. Budgets are more than just numbers on a page. They are statements of priorities.

Unfortunately, I believe the priorities of the administration are out of whack. This budget doubles down policies that would hurt working Americans and jeopardize their health.

It proposes devastating cuts to Medicaid, Medicare, public health programs, and yet again calls for repeal-and-replace of the Affordable Care Act.

This dangerous budget imperils access to care for millions of Americans and puts our Nation's healthcare system at risk.

Three million Americans lost their health insurance this year because of the administration. This budget proposes to take away from millions more.

Proposing to cut Medicaid by \$1.4 trillion is an assault on the working families and would be even crueler than the permanent caps on funds that Trumpcare passed by the House would have imposed.

It would implement harsh barriers to coverage for low-income families altogether. The budget would gut the single largest insurer of children, enact an unprecedented cut on the largest payer for behavioral health, and threaten care for seniors in nursing homes, individuals with disabilities, and working families.

Repealing the ACA and cutting 675 billion in healthcare dollars over a decade would take healthcare away from millions of Americans, raise costs, and destroy Obamacare's protections for people with preexisting conditions.

This budget cut of almost \$500 billion from Medicare shifts costs to seniors and cutting our healthcare safety net. It cuts \$1 billion from the Centers for Disease Control and Prevention at a time when a robust public health infrastructure couldn't be more important.

It is clear they have very different aspirations for this country and what our healthcare system should look like.

The picture of the administration's budget paints a harsh one where more and more Americans join the ranks of the uninsured every day, where seniors face declining quality of care and Medicare due to deep and irrational cuts to pay for the tax cuts for the wealthy, and where working families and people with disabilities can no longer rely on the safety net that is Medicaid.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Thank you, Mr. Chairman, and thank you to Secretary Azar for being here this morning.

This week, President Trump released his 2019 Budget Request.

Budgets are more than a numbers on a page—they are a statement of priorities.

Unfortunately, I believe the priorities of this administration are wildly out of whack.

This budget doubles down policies that will hurt working-class Americans and jeopardize their health.

It proposes devastating cuts to Medicaid, Medicare, and public health programs, and yet again, calls for “repeal and replace” of the Affordable Care Act.

This dangerous budget imperils access to care for millions of Americans and puts our Nation’s healthcare system at risk.

Three million Americans lost their health insurance this year because of this administration, and this budget proposes to take coverage away from millions more.

Proposing to cut Medicaid by \$1.4 trillion is an assault on working families and would be even crueler than the permanent cap on funds than the TrumpCare bill passed by the House would have imposed.

It would implement harsh barriers to coverage for lower-income families and all together, the budget would gut the single largest insurer of children, enact an unprecedented cut on the largest payer for behavioral health, and threaten care for seniors in nursing homes, individuals with disabilities, and working families.

Repealing the ACA and cutting \$675 billion in healthcare dollars over a decade will take healthcare away from millions of Americans, raise costs and destroy Obamacare’s protections for people with pre-existing conditions.

This budget would cut almost \$500 billion from Medicare, shifting costs to seniors and cutting our healthcare safety net.

It cuts more than \$1 billion from the Centers for Disease Control and Prevention, at a time when a robust public health infrastructure couldn’t be more important.

It is clear we have very different aspirations for this country, and what our healthcare system should look like.

The picture the administration’s budget paints is a harsh one- where more and more Americans join the ranks of the uninsured each day; where seniors face a declining quality of care in Medicare due to deep and irrational cuts to pay for tax cuts for the wealthy; and where working families, and people with disabilities can no longer rely on the safety net that is Medicaid.

I appreciate the opportunity to hear from our witness and look forward to answers to our questions.

I yield 1 minute to Congressman Ben Ray Lujan.

I yield 1 minute to Congressman Peter Welch.

Mr. GREEN. I appreciate the opportunity to hear from our witness. I am looking forward to asking questions, and I’d like to yield 1 minute to my California colleague Ms. Matsui.

Ms. MATSUI. Thank you very much, Mr. Green.

I am extremely concerned by the priorities reflected in this President’s budget. This proposal directly and negatively impacts hard-working families who depend on crucial services.

It guts Medicaid by \$1.4 trillion. These cuts mean working single mothers in between jobs, families with a family member who suffers from addiction, and grandparents in long-term care facilities will have less access to care.

And the HHS budget once again declares war on the Affordable Care Act, restricting access to coverage. These are cruel inflictions from an administration who claims to be addressing the opioid crisis.

I am disappointed that HHS, which has a mission to enhance and protect the health and well-being of all Americans, has presented a budget that targets the most vulnerable in our communities—women, children, people with disabilities and mental illness, and the LGBT community.

I sincerely hope that in our conversation today we can address the failings in HHS’ budget vision and how the agency should in fact be working to protect all Americans.

Thank you. I yield back to the ranking member.

[The prepared statement of Ms. Matsui follows:]

PREPARED STATEMENT OF HON. DORIS O. MATSUI

Thank you for yielding. I am extremely concerned by the priorities reflected in this President's budget.

This proposal directly and negatively impacts hard-working families who depend on crucial services.

It guts Medicaid by \$1.4 trillion. These cuts mean working single mothers in-between jobs .. families with a family member who suffers from addiction. and grandparents in long term care facilities. will have less access to care. And, the HHS budget once again declares war on the Affordable Care Act. restricting access to coverage. These are cruel inflictions from an administration who claims to be addressing the opioid crisis.

I am disappointed that HHS, which has a mission to enhance and protect the health and well-being of ALL Americans. has presented a budget that targets the most vulnerable in our communities: women, children, people with disabilities and mental illness, and the LGBT community. I sincerely hope that in our conversation today we can address the failings in HHS' budget vision and how the agency should, in fact, be working to protect all Americans. Thank you, I yield back.

Mr. GREEN. Mr. Chairman, I yield 1 minute to my colleague from Vermont, Congressman Welch.

Mr. WELCH. Thank you very much.

Mr. Secretary, in March of 2017, President Trump invited Congressman Cummings and me to the White House to discuss drug prices.

This committee has got a big concern about that. Mr. Burgess has been very active. And his concern was that the prices are beyond affordability for individuals, for the businesses that are trying to cover their employees, and for taxpayers. He believes they are too high. He's explicit that it's inexcusable and unsustainable. The causes are many. You've got incredible experience in the industry, so you understand it.

And the hope, I think, that the entire committee has is that, when you come back in a year, let's say, we are going to show that the price has stabilized or started to go down.

The status quo is just killing us. And if you have these medications that have great promise but people can't afford them, they are not going to be sustainable.

Mr. GREEN. Mr. Chairman—

Mr. WELCH. And I yield back.

Mr. GREEN. OK. In my last six seconds, I want to also take personal privilege. My staff member Kristen O'Neill, this is her last day with us. She's going to bigger and better things.

She's been in our office doing healthcare for 6 years and, as you know, that's been pretty traumatic for both sides of the aisle. But I'll miss Kristen because she's been a great staff member and made sure I didn't make too much of a fool of myself.

[Applause.]

And I yield back my time.

Mr. BURGESS. Gentleman yields back. The Chair thanks the gentleman.

Chair recognizes the gentleman from Oregon, Mr. Walden, chairman of the full committee, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Well, thank you, Mr. Chairman, and I would also join in I guess congratulating Kristen on her departure. I don't know if that's a good thing or a bad thing.

But you've certainly played a key role on healthcare issues here and done a great job for Gene, and our team has enjoyed working with you as well. So we wish you every success in going forward.

Mr. Secretary, we are delighted to have you here as well. Welcome to the Energy and Commerce Committee.

On behalf of all of us, I'd like to again congratulate you on your confirmation as the Secretary of the Department of Health and Human Services.

Your previous leadership experience at the Department and in the private sector I think gives you a tremendous springboard to do great work for the American people, and we like to work as much as we can around here in a bipartisan way and we know we share a lot of common objectives. We appreciate your appearing before the subcommittee so shortly after your confirmation.

Energy and Commerce has always led the way in delivering meaningful healthcare reforms and policies for the American people, and last year we completed our work to spur new innovation and competition in the life sciences sector through the FDA Reauthorization Act.

Ensuring and strengthening America's leadership role in biotechnology to help consumers will continue to be a priority for our committee.

We also just enacted the longest extension of the Children's Health Insurance Program—as you know, CHIP. We did critical extensions of Medicare extenders that seniors rely upon.

We strengthened public health by providing funding for community health centers—really, really important, especially I know in my part of the world, 240,000 Oregonians get their care through our very important network of community health centers—and we have done a lot of other public health priorities.

We also rolled back the Affordable Care Act's Independent Payment Advisory Board, which threatened to undermine care for our Nation's seniors who rely upon the Medicare program.

We did this all in a fiscally responsible way by doing the hard work of ensuring that new spending was fully paid for with targeted and smart reductions in other spending.

These priorities and others were part of the 19 Energy and Commerce Committee bills that were signed into law by President Trump as part of the Bipartisan Budget Act of 2018. So we got a lot of work teed up through here, and then we are able to put it in that package and the President signed it.

So, Mr. Secretary, we had a chance to talk earlier this week about our shared priorities, and we look forward to partnering with you and the entire Department of Health and Human Services.

This committee has a rich tradition of bipartisan oversight and legislative work, and I see a lot of opportunity for us to continue down that path in the coming weeks and months.

Particularly, I'd like to focus on the issue of opioids and the crisis that is afflicting our country and our citizens. It's a top priority for

me. It's a top priority for Members on every side in this committee. We need to build upon our previous legislative efforts, known as the Comprehensive Addiction Recovery Act, or CARA, and the funding provided in the 21st Century Cures Act.

I would point out that's the most funding the United States Government has ever put directly toward the opioid epidemic, and we intend to do more and we are set up in the budget agreement to do even more, going forward. But we want to make sure it goes to the right places for effective purposes and helps in this effort.

While these laws resulted in record amounts of money being devoted to this fight, more is needed to address this growing crisis, and in last week's budget bill we were able to deliver headroom to provide new resources for both 2018 and 2019. So we look forward to working with our friends in the Appropriations Committee as we work on how that money should be spent.

Last year, we held a Member Day. We solicited solutions to combat the opioid epidemic. We had, I think, something like 50 Members of Congress come before this committee—an unprecedented show of support—with their ideas and their suggestions about what we could do.

We also have had tremendous work being done by our Oversight and Investigations Subcommittee, now led by Chairman Harper, looking at how these drugs got into our communities and the tripwires that didn't trip, or if they did we want to know why somebody didn't take notice.

Given that addressing the opioid epidemic has bipartisan support and President Trump's leadership and commitment to this issue, it is my hope and belief this committee will deliver additional legislation this spring and that we can get into law soon.

The Health Subcommittee also plans to build upon the work of our Oversight and Investigations Subcommittee's report on 340B. This program is important, as it serves our low-income individuals. But it's essentially not been modernized in two decades. So it's our belief that reforms are necessary to both strengthen and secure the program so it can best serve low-income populations and make sure they have access to affordable medications. So we look forward to working with you on that.

Along with finding opportunities to lower costs for consumers across the board and addressing reauthorizations later this year, 2018 will be busy for this subcommittee and, Secretary Azar, we look forward to partnering with you on these initiatives and many more going forward.

And with that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Secretary Azar, welcome to Energy and Commerce. On behalf of all of us, I'd like to congratulate you again on your confirmation as the Secretary of the Department of Health and Human Services. Your previous leadership experience at the Department and in the private sector will give you a tremendous springboard to do great work for the American people.

We appreciate you appearing before the subcommittee today so shortly after your confirmation.

Energy and Commerce has led the way in delivering meaningful healthcare reforms and policies for the American people. Last year, we completed our work to

spur new innovation and competition in the life sciences sector through the FDA Reauthorization Act. Ensuring and strengthening American's leadership role in biotechnology to help consumers will continue to be a priority for this committee.

We also just enacted the longest extension of the Children's Health Insurance Program, critical extensions of Medicare extenders that seniors rely upon, and strengthened public health by providing funding for community health centers and other important public health priorities. We also rolled back the Affordable Care Act's Independent Payment Advisory Board—which threatened to undermine care for our Nation's seniors who rely upon the Medicare program. We did this all in a fiscally responsible way by doing the hard work of ensuring new spending was fully paid for with targeted and smart reductions in health spending.

These priorities and others were part of 19 Energy and Commerce Committee bills that were signed into law by President Trump as part of the Bipartisan Budget Act of 2018.

Secretary Azar, we had a chance to talk earlier this week about our shared priorities and we look forward to partnering with you and the entire Department of Health and Human Services. This committee has a rich tradition of bipartisan oversight and legislative work—and I see a lot of opportunity for us to continue down that path in the coming weeks and months.

Particularly, I see a great opportunity for us to work together to combat the opioid crisis, a top priority for me and for this committee. We need to build upon E&C's previous legislative efforts, namely the Comprehensive Addiction Recovery Act (CARA) and the funding provided in the 21st Century Cures Act. While these laws resulted in record amounts of Federal resources being devoted to this fight, more is needed to address this growing crisis. In last week's budget bill, we were able to deliver headroom to provide new resources to combat the opioid crisis for the rest of FY 2018 and FY 2019. We look forward to working with our friends at the Appropriations Committee on this point.

Last year, we held a Member Day to solicit solutions to help combat the opioid crisis—hearing directly from Members both on and off this committee, Republican and Democrat. Later this month, this subcommittee will launch its review of targeted solutions to help combat the opioid crisis. This work will be done in tandem with our Oversight and Investigations Subcommittee work led by Chairman Harper.

Given that addressing the opioid epidemic has bipartisan interest and with President Trump's leadership and commitment to this issue, it is my hope and belief that this committee will deliver additional legislative solutions that we can move to the full House later this year.

The Health Subcommittee also plans to build upon the work of our Oversight and Investigations work regarding the 340B program. This important program designed to serve low-income individuals has essentially not been modernized in more than two decades. It is my belief that reforms are necessary to strengthen and secure the program so it can best serve low-income populations access affordable medications. We look forward to working with HHS and stakeholders to make sure we get the job done right.

Along with finding opportunities to lower costs for consumers across the board and the addressing reauthorizations later this year, 2018 will be a busy year for this subcommittee.

Secretary Azar, we look forward to partnering with you on these initiatives and working on many of our shared priorities together.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentleman from New Jersey, Mr. Pallone, ranking member of the full committee, 5 minutes, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

To my dismay but not my surprise, President Trump's 2019 budget proposal continues the cruel and complacent perspective of ripping healthcare away from millions of Americans to help pay for the Republicans' tax scam that overwhelmingly benefits the wealthy and corporations.

This budget is an attack on working families, seniors, and life-saving programs. I want to just highlight some of the more egregious issues with the budget.

It doubles down on gutting and capping the Medicaid program, the Nation's largest health insurer, and cuts our Nation's safety net by \$1.4 trillion.

Meanwhile, it builds on the administration's ongoing illegal efforts to kick vulnerable Americans off Medicaid through work requirements, lockouts, and proposed lifetime limits.

Simply put, the Trump administration's vision for our country through this budget is to take coverage away from families living on the brink that depend on Medicaid to make ends meet.

The Trump budget also includes over \$500 billion in cuts to Medicare, jeopardizing healthcare for seniors. Deep cuts to safety net providers, nursing homes, home health agencies, and other providers appear to be based not on any real policy rationale but cutting for the sake of cutting. Essentially, cut healthcare for seniors to pay for that Republican tax cut.

Sadly, the Trump budget continues the same Republican efforts to repeal the Affordable Care Act. As proposed, ACA repeal would leave millions more uninsured, gut protections for preexisting conditions, and result in a \$675 billion cut to our healthcare system.

In addition, ongoing efforts to sabotage the ACA such as cutting off cost-sharing reductions and rolling back consumer protections have already resulted in skyrocketing costs for middle-class families and 3 million more Americans uninsured in 2017.

And now, HHS is sitting by the sidelines while Idaho clearly circumvents the law, and this is simply unacceptable.

Today, we will hear from our newly confirmed Secretary Azar, and Mr. Azar moves into the top leadership position at a very trying time.

The Department has been embroiled in scandal since day one. From former Secretary Tom Price's exorbitant travel expenses, to the use of official resources to lobby in favor of ACA repeal-and-replace, to Brenda Fitzgerald's purchases of tobacco stock while she was the head of CDC, these issues deserve immediate attention.

This morning I sent a letter to you, Mr. Secretary, asking you to conduct a top-down review of the Department and all of its operating divisions to assess the extent to which HHS personnel are abiding by all applicable Federal ethical regulations and policies and whether appropriate safeguards are in place to protect against abuse and conflicts of interest.

I hope we hear today about your plans to faithfully uphold the laws set by Congress, improve transparency, and eliminate conflicts of interest and protect the health of working families.

The American people deserve a commitment to restore the integrity of the Department.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

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Today, we will hear from newly confirmed HHS Secretary Azar. Mr. Azar moves into the top leadership position at a trying time—the Department has been embroiled in scandals since Day 1. From former Secretary Tom Price's exorbitant travel expenses, to the use of official resources to lobby in favor of repeal-and-replace, to Brenda Fitzgerald's purchase of tobacco stock while she was the head of CDC, these issues deserve immediate attention. This morning, I sent a letter to Secretary Azar asking him to conduct a top-down review of the Department and all of its operating divisions, to assess the extent to which HHS personnel are abiding by all applicable Federal ethical regulations and policies, and whether appropriate safeguards are in place to protect against abuse and conflicts of interest. I hope we hear today about his plans to faithfully uphold the laws set by Congress, improve transparency and eliminate conflicts of interest, and protect the health of working families. The American people deserve a commitment to restoring the integrity of the Department.

Thank you.

Mr. PALLONE. I'd like to yield—I don't have exactly 2 minutes, but half my time initially to Mr. Luján and then to Mr. Kennedy. I yield to Mr. Luján at this time.

Mr. LUJÁN. Thank you, Mr. Pallone, and Mr. Secretary, thank you for being here today.

In previous hearings, you told some of my Democratic colleagues that we all shared values on healthcare. I am interested to hear more about how the Trump administration's budget reflects these shared values, or perhaps explore where in fact we are not aligned.

I believe healthcare is a right, not a luxury. I believe healthcare should be affordable no matter your income, accessible no matter where you live, high quality no matter how you're insured.

The President's budget proposal continues the Republican obsession with repealing the Affordable Care Act, which would strip healthcare away from tens of millions of Americans.

Let me be clear. Those are not my values. I believe it's a tragedy that seniors all across this country have to choose between rent and prescription drugs.

I believe it's a tragedy that, before the Affordable Care Act, more Americans filed bankruptcy for medical debt than anything else. I believe it's a tragedy that, before Medicaid expansion, paying for inpatient opioid treatment was out of reach for so many middle-class Americans.

This Trump budget dismantles Medicaid and the Affordable Care Act. It represents an attack on working families and lifesaving programs. The Trump budget cuts care for children, families, women, and people with disabilities while once again favoring the wealthy over corporations. Those are certainly not my values.

I yield back.

[The prepared statement of Mr. Luján follows:]

PREPARED STATEMENT OF HON. BEN RAY LUJÁN

Thank you, Secretary Azar, for joining us today.

In previous hearings, you told some of my Democratic colleagues that we all have shared values on healthcare. I'm interested to hear more about how the Trump administration's budget reflects these shared values, or perhaps explore where we in fact are not aligned.

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I believe it's a tragedy that seniors all across this country have to choose between rent and their prescription drugs.

I believe it's a tragedy that before the Affordable Care Act, more American's filed bankruptcy for medical debt than anything else.

I believe it's a tragedy that before Medicaid expansion, paying for in-patient opioid treatment was out of reach for so many middle-class families.

The Affordable Care Act and Medicaid expansion provided a historic step forward in addressing the health disparities have plagued our communities.

A healthcare system that addresses these issues reflect my values.

This Trump budget dismantles Medicaid and the Affordable Care Act. It represents an attack on working families and lifesaving programs.

The Trump budget cuts care for children, families, women, and people with disabilities while once again favoring the wealthy and corporations.

Those are certainly not my values.

Mr. PALLONE. Mr. Kennedy, you got, like, 10 minutes left.

Mr. BURGESS. Ten minutes?

Mr. PALLONE. Ten seconds.

Mr. KENNEDY. I got 6, 7 seconds. So I'll yield back.

Mr. PALLONE. I am sorry. Thank you, Mr. Chairman.

Mr. BURGESS. Gentleman yields back. Chair thanks the gentleman.

This concludes Member opening statements. The Chair would remind Members that, pursuant to committee rules, all Members' opening statements will be made part of the record.

Testifying before our subcommittee today is the Honorable Alex Azar, Secretary of the United States Department of Health and Human Services.

Secretary Azar, you will have an opportunity to give an opening statement followed by questions from Members. We do want to thank you for being here today.

You are now recognized for 5 minutes to summarize your opening statement, please.

**STATEMENT OF ALEX M. AZAR II, SECRETARY, DEPARTMENT
OF HEALTH AND HUMAN SERVICES**

Mr. AZAR. Chairman Burgess, Ranking Member Green, Chairman Walden, and Ranking Member Pallone and members of the committee, thank you for inviting me here today to discuss the President's budget for the Department of Health and Human Services for fiscal year 2019.

I would like to begin by expressing, of course, my sympathies and prayers for the victims and families of the tragedy in Florida. I want to echo the President's comments this morning that this administration is committed to working with States and localities to tackle the issues of serious mental illness.

It's a great honor to be here. It's an honor to serve as Secretary of the Department of Health and Human Services. Our mission is to enhance and protect the health and well-being of all Americans.

It is a vital mission, and the President's budget clearly recognizes that. The budget makes significant strategic investments in HHS' work, boosting discretionary spending at the Department by 11 percent in 2019 to \$95.4 billion.

Among other targeted investments, that is an increase of \$747 million for the National Institutes of Health, a \$473 million increase for the Food and Drug Administration, and a \$157 million increase over 2018 funding for emergency preparedness across the Department.

The President's budget especially supports four particular priorities that we have laid out for the Department, issues that the men and women of HHS are already working hard on: fighting the opioid crisis, increasing the affordability and accessibility of health insurance, tackling the high price of prescription drugs, and using Medicare to move our healthcare system in a value-based direction.

First, the President's budget brings a new level of commitment to fighting the crisis of opioid addiction and overdose that is stealing more than a hundred American lives every single day.

Under President Trump, HHS has already disbursed unprecedented resources to support access to addiction treatment. This committee in particular took a major step in addressing the crisis through creating the 21st Century Cures Act's State-targeted response to the opioid crisis grants.

The budget would take total investment to \$10 billion in a joint allocation to address the opioid epidemic and related mental health challenges.

Second, we are committed to bringing down the skyrocketing cost of health insurance, especially in the individual and small group markets so more Americans can access quality affordable healthcare.

This budget recognizes that this will not be accomplished by one-size-fits-all solutions from Washington. It will require giving States room to experiment with models that work for them and allowing customers to purchase individualized plans that meet their needs.

That's why the budget proposes a historic transfer of resources and authority from the Federal Government back to the States, empowering those who are closest to the people and can best determine their needs.

The budget would also restore balance to the Medicaid program, fixing a structure that has driven runaway costs without a commensurate increase in quality.

Third, prescription drugs cost too much in our country. President Trump recognizes this, I recognize this, and we are doing something about it.

This budget has a raft of proposals to bring down drug prices, especially for America's seniors. We propose a five-part reform plan to further improve the already successful Medicare Part D prescription drug program.

These major changes will straighten out incentives that too often serve program middlemen more than they do our seniors. These changes will save tens of billions of dollars for seniors over the next 10 years, adding to savings we are already generating with reforms the Medicare Part B payments under the 340B drug discount program.

The budget also proposes further reforms in Medicaid and Medicare Part B to save patients money on drugs and provide strong support for FDA's efforts to spur innovation and competition in generic drug markets.

We want programs like Medicare and Medicaid to work for the people they serve. That means empowering patients and providers with the right incentives to pay for health and outcomes rather than procedures and sickness.

Our fourth departmental priority is to use the tremendous powers we have through Medicare as the largest purchaser of medical services in the U.S. to move our whole healthcare system in this direction.

This budget takes steps toward that by, for instance, eliminating price variation based on where post-acute care is delivered, rationalizing payments to physicians and hospital-owned outpatient facilities, supporting investments in telehealth, and advancing the work of accountable care organizations.

The future of Medicare must be driven by value, quality, and outcomes, not the current thicket of opaque, unproductive incentives.

Making our programs work for today's Americans, sustaining them for future generations, and keeping our country safe is a sound vision for the Department of Health and Human Services, and I am proud to support it.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Azar follows:]

Statement by Alex M. Azar II
Secretary, U.S. Department of Health and Human Services
on
The President's Fiscal Year 2019 Budget
before
Committee on Energy & Commerce,
Subcommittee on Health

U.S. House of Representatives
February 15, 2018

The mission of the Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of the American people.

President Trump and all of us at HHS take that charge seriously. So, when programs are not as effective as they can be, or cost more than they ought to, or fail to deliver on their promise, change and reform are necessary.

The President's Fiscal Year (FY) 2019 Budget applies this reform mindset to the work of the Department, making thoughtful and strategic investments to protect the health and well-being of the American people, while addressing the opioid crisis, promoting patient-centered healthcare, strengthening services for American Indians and Alaska Natives, encouraging innovation in America's healthcare future, addressing high drug prices, reforming the Department's regulations, and generally focusing resources toward proven and effective initiatives. The Budget also recognizes the fiscal challenges our country faces today, and the need to focus our investments and update them to meet the needs of a rapidly changing world.

The President's Budget for HHS also reflects proposals to meet the President's comprehensive Government-wide Reform Plan through a Department initiative called *ReImagine HHS*. *ReImagine HHS*, through a range of initiatives, aims to identify opportunities to improve the work HHS does for the American people, in terms of its efficiency, quality, and cost-effectiveness. In particular, *ReImagine HHS* offers a unique opportunity for the experienced career staff of the Department to lead initiatives that will advance the work of the Department and revamp outdated processes and structures.

Across all of HHS's priorities, the Budget makes clear that business-as-usual will not suffice, and that the substantial investments made every year at HHS ought to be allocated with efficiency and toward programs that work.

Tackling the Opioid Epidemic

One of the Department's top priorities is fighting the scourge of opioid addiction facing our country.

Due to skyrocketing numbers of opioid overdoses, deaths by drug overdose have become the leading cause of injury death in the United States. In 2016, 174 Americans died each day from drug overdoses. American life expectancy has dropped for the second year in a row—a tragic development not seen in more than a half century.

The President's Budget recognizes the devastation caused by this crisis in communities across America, by providing a historic new investment of \$10 billion in HHS funding to address the opioid crisis and serious mental illness, and building upon the work started under the 21st Century Cures Act.

The Budget's targeted investments advance the Department's five part strategy, which complements work being done elsewhere in the Administration and covers:

- Access: Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Overdoses: Targeting availability and distribution of overdose-reversing drugs;
- Data: Strengthening our understanding of the epidemic through better public health data and reporting;
- Research: Supporting cutting edge research on pain and addiction; and
- Pain: Advancing better practices for pain management.

The Budget proposes to improve ways in which the Federal Government helps communities respond to the opioid epidemic. As just one example, the Budget directs resources to the Substance Abuse and Mental Health Services Administration to improve access to medication-assisted treatment services, boost state capacity to establish and operate comprehensive prevention systems, and disseminate high-quality resources on best practices for treatment.

The Budget includes a total of \$126 million to support efforts by the Centers for Disease Control and Prevention (CDC) to prevent the abuse and overdose of opioids. This investment supports key public health and surveillance activities at the state level, recognizing that states can best determine their unique needs. CDC will also continue to increase the awareness and adoption of the CDC Guideline for Prescribing Opioids for Chronic Pain. In all of these activities, CDC will endeavor to support and execute programs that have a proven track record of success.

We recognize that government at the Federal, state, and local levels cannot defeat the opioid crisis alone, so HHS will continue to leverage the resources and expertise of the private sector and academia to develop new tools to end the epidemic. This includes a \$500 million investment in a National Institutes of Health (NIH) public-private partnership to accelerate the development of new treatments for pain and addiction.

To help address the drivers of the epidemic, current practices for pain management must also be rethought, including in the work of Federal agencies that prescribe painkillers. The FY 2019 Budget will support the Pain Management Best Practices Inter-Agency Task Force, which will determine whether there are gaps or inconsistencies in pain management best practices among Federal agencies; propose recommendations on addressing gaps or inconsistencies; provide the public with an opportunity to comment on any proposed recommendations; and develop a strategy for disseminating information about these best practices.

Effectively Treating Serious Mental Illness

Serious mental illness, such as a psychotic or major depressive disorder, afflicts nearly 10 million American adults each year, and remains one of the nation's most difficult healthcare challenges. Without treatment, many of these individuals cycle repeatedly among the health, behavioral health, and criminal or juvenile justice systems, with each system insufficiently prepared to meet their needs. According to one report, 10 times as many Americans with serious mental illness are in jail or prison than in inpatient psychiatric treatment, and tragically, Americans with serious mental illness live lives at least 10 years shorter, on average, than others.

The Budget recognizes that there are effective, proven forms of treatment for those struggling with serious mental illness, which have not always received the necessary support. One is "assertive community treatment," which places individuals in the care of a multidisciplinary behavioral health staff to deliver comprehensive services and treatment and has been shown to reduce hospitalization and improve patient satisfaction compared with other interventions of the same cost. The Budget fully funds a new Assertive Community Treatment for Individuals with Serious Mental Illness program, authorized by the 21st Century Cures Act.

Another effective approach to serious mental illness is the Budget's support of Certified Community Behavioral Clinics, funded as part of the new \$10 billion investment to address the opioid epidemic and serious mental illness. The Budget also continues to direct 10 percent of state allocations from the Community Mental Health Services Block Grant to bring care more quickly to those experiencing a first episode of psychosis, a proven intervention.

Advancing Health Reform That Works

A Washington-centric, one-size-fits-all approach to healthcare —especially in insurance markets most affected by Obamacare — is simply not working and must change. The President's Budget proposes a bold plan to redirect a significant amount of healthcare funding back to the states and individuals, where healthcare decisions should be made, while also taking major steps to encourage innovation and better quality of care.

The Budget supports repealing Obamacare and replacing the law with flexibility for states to create a free and open healthcare market tailored to their citizens' needs. The two-part approach is modeled closely after the Graham-Cassidy-Heller-Johnson amendment to H.R. 1628, the

American Health Care Act of 2017, and also includes additional reforms to put healthcare spending on a sustainable fiscal path.

The proposed Market-Based Health Care Grant Program will help states stabilize their insurance markets and provide for a smooth transition away from Obamacare. The Budget would also fix the perverse incentive structures created by Obamacare, by ending the disparity between states that expanded Medicaid to new populations and those that did not and providing states with a choice between a per capita cap and a block grant.

The Budget also proposes reforming our broken medical liability system, to ensure it is not driving excess costs. Finally, the Budget proposes consolidating the byzantine system of graduate medical education funding into a single, direct grant program that will streamline incentives and better serve patients and providers.

Bringing Down Drug Prices

As President Trump has repeatedly made clear, the prices Americans pay for prescription drugs are simply too high. The Budget proposes a range of legislative measures to build on the proven success of the Medicare Part D prescription drug program, including through giving drug plans more tools to negotiate with manufacturers and encourage use of higher value drugs. In addition, the Budget discourages rebate and pricing strategies that increase spending for both beneficiaries and the Government and, for the first time in the program's history, provides beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap for seniors with especially high drug costs.

Sustainable Medicaid and Medicare Reforms

Millions of Americans rely on Medicaid and Medicare to meet their everyday healthcare needs. Together, federal health care programs comprise the largest portion of the Federal budget. The President's Budget proposes several legislative solutions to improve the programs, promote greater efficiencies, advance patient-centered care, and reduce government-imposed burden on providers.

The Administration recognizes that the over-50-year-old structure of the Medicaid program has failed to create a sustainable Federal-state partnership that is capable of controlling costs. In fact, its outdated design incentivizes cost increases without delivering commensurate benefits or allowing for much-needed local health innovation.

Our Budget proposes a new future for Medicaid that will restructure Medicaid financing, provide states with new flexibilities to better serve their communities, improve the state plan and waiver processes, and provide the right incentives to preserve the program for future generations.

Boosting Upward Economic Mobility

There is no more effective anti-poverty program than helping someone find a job. Recognizing this common-sense approach, the President's Budget re-focuses HHS's public assistance programs on helping low-income Americans find gainful employment, providing them with a sense of purpose, personal dignity, and independence.

Importantly, the Budget proposes key reforms to the Temporary Assistance for Needy Families program that reinforce its focus on promoting work as the best pathway to self-sufficiency. Specifically, the Budget strengthens the program's accountability framework related to work requirements and ensures that states allocate sufficient funds to work, education, and training activities.

The Budget also proposes establishing Welfare to Work Projects that will allow states to streamline funding from multiple public assistance programs and redesign service delivery to meet their constituents' specific needs. Importantly, these Welfare to Work Projects would be rigorously evaluated, expanding the evidence base that informs how assistance programs can be most effectively structured to help Americans achieve self-sufficiency.

In January, for the first time in the history of the Medicaid program, the Federal Government indicated openness to state-led innovations that promote work or community engagement activities for working age, able-bodied enrollees. Productive work and community engagement is associated with improved health and well-being, meaning this reform can achieve the goals of the Medicaid program while also supporting independence and economic self-sufficiency for millions of able-bodied adults.

Promoting Efficiency and Innovation in Scientific Work

Supporting and encouraging scientific research is a longstanding Federal priority, one that results in both a growing economy and longer lives. Executing this responsibility demands that the Federal Government regularly consider how to organize such support in the most efficient manner possible.

The administration believes it is a priority to support NIH, a crown jewel of American science, and proposes to do so not just through continued financial investments but also through innovative partnerships with non-federal entities, administrative reforms, and better coordination and planning.

Among other efforts to derive maximum benefit from the substantial Federal investments made in NIH research, the Budget supports expanding public-private partnerships that will challenge private sector partners to match Federal investments; increasing coordination across NIH's Institutes and Centers; focusing grant awards on projects with the highest potential to accrue benefits for public health; assessing new and current strategic investments in research; curtailing

the rate at which high researcher salaries at private institutions are reimbursed with taxpayer dollars; and implementing burden reduction measures to reduce costs for grant recipients.

The Budget also supports administrative reforms for NIH, including efforts to harmonize operational functions and break down silos within the agency. In addition, the Budget proposes to consolidate three other major HHS research institutions in NIH to maximize the effectiveness of their research.

The Food and Drug Administration (FDA) is another crown jewel of American science. But its needs and priorities must change as the face of medical innovation changes, too. The Budget includes investments for FDA to speed the development and approval of new drugs and medical devices, and to increase the quality and safety of next generation manufacturing practices, including approximately \$500 million to strengthen medical product safety development and access.

Investing in Our Biodefense, Preparedness, and Global Health Security Programs

The President's Budget aims to improve our nation's preparedness for, and capabilities to respond to, chemical, biological, radiological, and nuclear threats; pandemic influenza; natural disasters; emerging infectious diseases; and cybersecurity challenges.

In each area, smart investments that empower the private sector and our global partners will help keep our country safe.

Chemical, Biological, Radiological, and Nuclear Threat Preparedness

The Budget includes \$512 million for the Biomedical Advanced Research and Development Authority (BARDA) and \$510 million for Project BioShield, which fund successful public-private partnerships that support the development and procurement of new medical products crucial to defending our country against chemical, biological, radiological, nuclear, and infectious disease threats. Prior HHS investments in these programs have resulted in more than 190 medical countermeasure candidates, 34 FDA-approved products from BARDA, and the procurement of 14 new products for the Strategic National Stockpile. Funding will also be available for exercises to build preparedness for threats such as emerging infectious diseases, natural disasters, and manmade biological, chemical, nuclear, and radiation threats.

The Budget proposes to transfer the Strategic National Stockpile to the Office of the Assistant Secretary for Preparedness and Response, to boost operational efficiencies and streamline development and procurement of medical countermeasures. It also provides \$575 million to maintain and replenish the stockpile, the nation's largest supply of life-saving medical countermeasures that can be deployed in the event of a public health emergency.

Natural Disaster Preparedness

Following the powerful hurricanes and historic wildfires of 2017, HHS remains ready to respond to any and all hazards when disaster strikes. The Budget ensures the Department is able to support essential emergency preparedness activities to refine our disaster responses. In particular, Hospital Preparedness Program resources will continue to be allocated to states and localities according to risk, ensuring communities with more risk have the necessary coordination and resources. The Budget also continues to provide \$50 million to support the National Disaster Medical System. Through this cost-effective and successful program, HHS trains and deploys teams of American healthcare professionals from across the country to provide medical care to our fellow Americans in the event of an emergency.

Global Health Security

One of the most effective ways to protect Americans from the threat of infectious diseases is to enable other countries to follow through on their own commitments to contain and respond to disease threats. Such investments are far less expensive than mounting an international public health response to control an epidemic.

To support this goal, the Budget provides a total of \$409 million for CDC's global health activities, which strengthens CDC's international preparedness and response capabilities. The Budget would also build on substantial progress that has been made toward global health security goals under the Global Health Security Agenda (GHSA), including a \$59 million investment that provides funding for CDC to continue this work into FY 2020.

Cybersecurity

The Budget recognizes that HHS must continue robust operations to meet today's cybersecurity needs and includes \$68 million to ensure the Department is able to protect sensitive and critical information in an ever-changing threat landscape. The Department will also focus on support for and coordination with the healthcare and public health sectors in close coordination with the Department of Homeland Security, to promote information and resource sharing across levels of government and the private sector.

Strengthening the Indian Health Service

Through the Indian Health Service (IHS), HHS is responsible for providing quality healthcare services to more than 2.2 million eligible American Indians and Alaska Natives. The Budget prioritizes funding for this agency, and in particular for direct health services. The Budget also makes significant investments to assist IHS facilities with meeting CMS quality health standards.

Looking forward, and consistent with our statutory authorities, we recognize that how we provide quality healthcare in Indian Country and beyond must change to achieve and ensure the high quality of these services. More Tribes have assumed the responsibilities of providing

healthcare for their members with support from the IHS, and investments in the Budget reflect our support for the growth of tribal self-governance in the provision of healthcare.

* * * * *

The President's 2019 Budget for HHS recognizes the importance of focusing government spending on programs that work and reforming our nation's healthcare programs for a fast-changing world. This Budget recognizes that securing America's future demands sound fiscal management and responsible decisions about our priorities. If we are serious about fulfilling HHS's mission of enhancing and protecting the well-being of all Americans, we must adopt the bold innovation and direction espoused by the President's Budget.

Mr. BURGESS. Mr. Secretary, thank you for your testimony. Thank you for being here today. We will move on to the Member questions portion.

I would like to first recognize the vice chairman of the subcommittee, Mr. Guthrie of Kentucky, 5 minutes, please.

Mr. GUTHRIE. Thank you, Mr. Chairman. I appreciate it.

Mr. Secretary, thank you for being here. I had a meeting earlier today with Workforce on Opioids, and that's something that we are all concerned about, particularly my home State.

And one tool that could be improved to combat the opioid crisis is prescription drug monitoring programs. As you know, PDMPs can help spot potential drug misuse or diversion.

I've heard from stakeholders that integrating PDMP data into the clinical workflow in a timely manner is needed to improve provider and dispenser resources.

Can you please describe how HHS is thinking about leveraging its authorities to encourage best practices within PDMPs?

Mr. AZAR. So thank you, Congressman, for that question.

I look forward to any ideas that you and others may have about ways that we can support States in this critical effort.

One of the proposals in our budget is to require States to monitor high-risk billing activity to identify and remediate abnormal prescribing and utilization patterns that may indicate abuse in the Medicaid system. That may include States with prescription drug monitoring programs as a vehicle to do that.

We also are asking for authority to make sure that, whenever we exclude a provider, it will automatically lead to transmission of that information to DEA to pull the physician's ability to write controlled substances through the DEA.

Mr. GUTHRIE. Thank you.

Second question, on Medicaid rebates. Strengthening and improving the oversight of the Medicaid drug rebate program is something this committee has been working on for several years.

In fact, recently the HHS Office of Inspector General just issued a report on CMS' oversight of the program. In their report, the OIG found that, from 2012 to 2016, Medicaid may have lost \$1.3 billion in base and inflation-adjusted rebates for 10 potentially misclassified drugs, with the highest total reimbursement in 2016. This budget includes a proposal to clarify Medicaid definition of brand and over-the-counter drugs under the Medicaid drug rebate program to prevent inappropriately lower manufacturer rebates.

We are interested in your legislative proposal in this budget, and could you describe it and then have your office provide us with details?

Mr. AZAR. Yes, thank you.

So this is an issue that came up in the last year or last year and a half regarding making sure that manufacturers are clearly understanding and that the rules of the road are very clear—what's a branded drug, what's a generic drug, what's an over-the-counter drug—so that we are getting our proper rebate payments in the Medicaid program, and as you mentioned, that can be an error to the tune of \$1.3 billion of misreporting. So we are asking for language that would clarify that.

In addition, you know, we have got in our budget proposal a plan that we would like authority to grant up to five States the ability to negotiate their own formulary for drugs with drug companies to see if they can do an even better job than we do through our statutory Medicaid drug rebate program to bring down drug costs.

Mr. GUTHRIE. Thank you. I look forward to looking at the details of that.

And one more. I'll go back to my first question on the prescription drug monitoring programs. It's my understanding that prescription drug monitoring programs are not allowed to have data on patients receiving methadone.

On the other hand, buprenorphine prescribed in an office-based setting is typically filled at the pharmacy, and pharmacies can submit dispensing information to the PDMPs.

So methadone dispensing and buprenorphine dispensing are treated unequally when it comes to this prescription drug monitoring. What can the Department and Congress do to improve safety and health outcomes for patients while still protecting patient privacy?

Mr. AZAR. I am glad you mentioned that.

I had not been aware of that issue with methadone reporting into the prescription drug monitoring databases. I'll be happy to look into that. I don't understand why that would be the case. These can be very important vehicles to prevent physician shopping as people try to abuse legal opioids. So I am happy to look into that.

Mr. GUTHRIE. Well, thank you. I look forward to sharing that with you and looking forward to getting the answers.

And I appreciate you being here. I know you've had a couple of long days. And I have about 50 seconds left, so I just want to say I actually drove to Greenbrier, and when I got there everything that had happened, and they were interviewing Dr. Burgess, and the person interviewing Dr. Burgess on the radio kept trying to, well, "Wasn't there fuel—wasn't there whatever—essentially, did you run into a dangerous situation?" Dr. Burgess kept saying—like all the others there, he kept saying, "Well, I didn't think about that. I was just trying to help people."

So I've always known you to be a man of principle, and it's great to verify also you're a man of character. So I appreciate that very much, and I yield back.

Mr. BURGESS. And Dr. Bucshon as well, of course, that day.

Mr. GUTHRIE. Yes—I have 14 seconds—yes, everybody. But I heard you specifically say that. So I appreciate it.

Mr. BURGESS. All right. If you're through praising me, I was going to yield you another 15 minutes.

[Laughter.]

Chair recognizes the gentleman from Texas, 5 minutes for questions.

Mr. GREEN. Mr. Chairman, I'll reserve my time.

Mr. BURGESS. Gentleman reserves—the Chair recognizes the gentleman from New Jersey, 5 minutes for questions, please.

Mr. PALLONE. Thank you, Mr. Chairman.

Secretary, the State of Idaho recently released guidelines that would eviscerate critical protections that are enshrined in Federal law and would potentially destabilize the health insurance market.

Idaho would allow insurers to deny people with preexisting conditions, not cover pediatric dental or vision care, charge older Americans more, and exclude maternity and newborn coverage.

I sent you and Administrator Verma a letter on this issue a few weeks ago, and I asked questions about whether these guidelines are in compliance with Federal law and, if not, what the agency planned to do to enforce the law, and I received what I consider an unacceptable response.

And I quote, it says, "At this time, the Centers for Medicare and Medicaid Services does not have any additional information to share regarding this bulletin. We are committed to fulfilling our obligations under the law while continuing to work with States to provide flexibility where possible and we are happy to keep you informed of any developments."

So Mr. Chairman, I'd like to ask unanimous consent to enter my letter and the response into the record, and I'll give them to you now.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. And, again, this response is inadequate and non-responsive, so I'd like to use my time today to follow up on some of the questions set forth in my letter, and where possible I'd ask you to respond yes or no because we have only got 3½ minutes.

Secretary, are you aware that the Affordable Care Act imposes certain requirements on health insurance coverage offered in the individual market, including, for example, community ratings, coverage of preexisting conditions, and the inclusion of essential health benefits? That, I think, can be a yes or no.

Mr. AZAR. That would be a yes, I am aware.

Mr. PALLONE. All right. Thank you.

Is it your impression that these requirements are optional for States or able to be waived?

Mr. AZAR. I would need to check under 1332 our waiver authority against each of those. I still haven't sat with the attorneys and learned all the parameters of what can be waived or what can't be waived through our waiver—

Mr. PALLONE. All right. Well, I'd ask you, if you could, to get back to me in writing within, like, a week or so about that because I don't think it would be that difficult to respond.

Secretary, are you aware that, under Section 2761 of the Public Health Service Act, as Secretary of the Department you have a legal obligation to enforce the law and take action against any insurers offering noncompliant plans in the State of Idaho?

Mr. AZAR. So we have only—at this point, I've seen what's in the press reports, and I've seen what Idaho has purported to pass, and then just the recent news about the Blues' plan coming in with a plan.

If that gets to the point where it's actually both finalized as well as certified by the State or not certified, where there is final action, we would certainly review that and—a searching review for compliance with the legal obligations that we have in our statutes.

Mr. PALLONE. I mean, I appreciate that. But, you know, in my opinion—and I know you don't agree with me—I think that, you know, these news reports are pretty clear what they are proposing,

and I would think that, you know, if you felt—and I do—that they were in violation of the law, you could initiate and start some kind of investigation now. You wouldn't have to wait until, you know, you see whether they are finalized or not, because what my concern would be, that if we wait until then, you know, they might already have a negative impact on the public.

But explain to the committee—I know you haven't taken any action against the State, you said, or any action against insurers who are clearly in violation. But how long would this take? You said, I have to wait until it's final. I mean, I am concerned that this—you know, that this happens and people are negatively impacted. You want to give me some kind of time line, if you could?

Mr. AZAR. Well, we are certainly not going to let anyone be negatively impacted by noncompliance with the law. What we are going to do, though, is not reach out—I just—I can't reach out to every press report and—

Mr. PALLONE. No, I know. But—

Mr. AZAR [continuing]. Take enforcement action based on information in press reports.

Mr. PALLONE. You see, my concern though—

Mr. AZAR. We are tracking it very closely, though.

Mr. PALLONE. All right. But I just would like to make sure that you complete an evaluation before the plans are approved by Idaho and sold to consumers, which I am told by the news report could happen as soon as April.

So can you at least assure me that your evaluation and decision whether to go after them or not allow it would be made before they approve it and sell it to consumers?

Mr. AZAR. I cannot imagine a circumstance where we would not evaluate it for compliance against the law before offered to consumers.

I do think it's appropriate to wait to see even if the State finds it in compliance with whatever their State laws are. I don't see why we would be reaching in and picking up matters out of press reports.

Mr. PALLONE. All right.

Mr. AZAR. We don't make it a habit of reviewing applications of States.

Mr. PALLONE. Would you at least assure me that you—would you at least assure me that you wouldn't allow them to go ahead and sell these things without doing that evaluation and determining?

Mr. AZAR. I fully expect that we would do so.

Mr. PALLONE. All right.

Mr. AZAR. I fully expect that would be—I can't imagine why we would not.

Mr. PALLONE. All right. I appreciate that.

Thank you, Mr. Chairman.

Mr. BURGESS. Gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Michigan, former chairman of the full committee and the author of the Cures for the 21st Century, Mr. Upton. You're recognized for 5 minutes.

Mr. UPTON. Thank you, Mr. Chairman, and welcome, Mr. Secretary, to our great committee.

I do have a couple questions. The opioid crisis—and I know that this committee looks forward to a bipartisan series of bills in the next number of weeks, moving forward—for me, I have a district that's sort of a blend between rural and urban, and I just want to know what some of your thoughts are providing particularly technical assistance to some of those communities that may not have the resources even though we know that our more populated centers are stressed to the Nth degree as well.

Mr. AZAR. Thank you for asking about that.

I am just really very—I am just gratified, excited that on a bipartisan basis we are able to tackle this opioid crisis and the \$10 billion of funding appears to be in the budget agreement, and we have requested \$3 billion of that for 2019 on top of \$3 billion in 2018 that we are hoping will come through the omnibus.

So significant funding on top of the historically high level of funding through 21st Century Cures that we put out in 2017.

We have one program in particular I wanted to call your attention to for more rural areas. So through HRSA in 2019 we would propose \$150 million for rural substance abuse to actually help those providers in more rural areas and ensure there is adequate capacity there for treatment for addiction and dependence.

We also would be putting \$400 million into quality improvement payments for our community health centers—just, by way of example, some of the steps at the community level.

Mr. UPTON. Yes. I visited a couple of our community health centers, one in particular this week, and they do a really amazing job and, again, one of the things that's certainly been bipartisan as this committee has moved forward.

I don't know if you're familiar with this fire retardant PFAS, which has been in the ground water and particularly in a lot of our military installations from years past.

Our delegation—Michigan delegation—met formally earlier this week, and I know that we on a bipartisan basis are looking to do a letter to the appropriators asking that there may be funding in this omnibus appropriation bill next month for the Centers for Disease—a CDC study looking at how extensive that is. Are you very familiar with this issue?

Mr. AZAR. I am slightly familiar. Obviously, not as much as you are.

I know that CDC is already working on gearing up and preparing for that study work in the event of appropriation.

Mr. UPTON. So, if you could help us on that, that would be appropriate.

As the newly sworn-in Secretary of HHS, you are certainly taking a very important role—oversight role on major Federal and State programs.

There have been a couple of pretty high-profile State budget battles not only—in particular, Illinois, which has had a significant disruption in payments to vendors, which led to hardships for some Medicaid recipients in that State.

I am working on a proposal that, again, I think will be bipartisan to ensure that Medicaid beneficiaries are not impacted by those budget battles by ensuring that managed care plans can, with late payments from the State to third parties in order to maintain a

cash flow and continue paying their front line providers who are, in turn, treating those Medicaid beneficiaries.

I don't know if you're aware of that situation or not.

Mr. AZAR. I am not, but I'd be happy to get back to you on that if you could give more detail, because that's not a situation—I know the Illinois issues on payment in the past, certainly, but I hadn't heard of this particular third-party issue.

Mr. UPTON. Yes, they continue to—we are looking to try and resolve that, particularly for the companies that are in essence eating the—not getting paid for now years because of those Illinois battles.

The last question I have is, in '05 Congress changed the Medicaid—excluding the prompt-pay discounts from the AMP calculation.

I've introduced legislation to fix the prompt-pay loophole in order to treat prompt pay in Medicare the same as in Medicaid, and as most businesses use it as a tool to make markets work more efficiently. It will raise reimbursement for community-based physicians to help improve access in less expensive settings.

Does the administration support applying that same prompt-pay policy in Medicare as well as in Medicaid?

Mr. AZAR. This would be in the ASP+6 methodology—

Mr. UPTON. Correct.

Mr. AZAR [continuing]. And excluding it from ASP. I don't know. That's a new issue to me. I have not heard about the question of prompt pay within ASP submissions. Again, happy to look at that and get back to you on that.

Mr. UPTON. Yes. I may submit a formal question and let you respond in the days ahead.

With that, yield back. Thank you. Thank you, Mr. Secretary.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and thank you, Secretary.

I am very concerned about the skyrocketing costs of and the crushing burden of prescription drug prices. Families around the country are struggling to be able to pay for them, and some people are dying.

Tragically, Shane Patrick Boyle and Alec Raeshawn Smith both died because they could not afford the jacked-up price of insulin during the time that Eli Lilly was under your watch and this occurred.

I think it's completely unacceptable. So you acknowledged in your Senate Health Committee testimony and in your comments today to Senator Sherrod Brown that the list price is part of the problem.

So what I want to know is, what is HHS going to do specifically to deal with the list price? I really don't want to hear about the other ways that you may be under control of the Medicaid negotiation or more generics. If there is nothing, you can just tell me that there's nothing. But I really want to know about the list price set by pharmaceutical companies.

Mr. AZAR. So the list price is a problem, and so we have in the budget proposal, one of the items is in Part B, the physician-administered drugs, to actually have an inflation penalty in there as we do in Medicaid, so that, if a pharma company increases the price above inflation, there would be a reduction in the reimbursement that would be offered by Medicare and that then flows through also to the patient, who pays a share of that at the point of sale or at the doctor's office.

We also are looking at—we proposed five major reforms to the Part D program, several of which we think actually reverse the incentives for high list prices.

Ms. SCHAKOWSKY. OK. Let me interrupt—let me interrupt for just a second.

Again, there are sectoral ways that you might be dealing. So we are dealing with Medicare, dealing with Medicaid.

But in terms of doing something for all consumers of drugs, is there not something that can be done about these list prices that—it's like, in dealing with an avalanche, we are dealing with the middle of the avalanche rather than the top of the avalanche, which is really the issue of the list price.

Mr. AZAR. Well, if—there is only one list price. So if we can use our influence through these Government programs and create incentives towards lower or flatter list prices, it benefits everybody.

So that actually is what we are trying to do, Congresswoman.

Ms. SCHAKOWSKY. So you're saying if, in Medicare Part D, that you would do that—that that would affect the list price for everyone, including people not in Medicare Part D?

Mr. AZAR. It creates a disincentive towards higher list price, and that list price is the same across the entire sector. There is one list price. It's called the wholesale acquisition cost. And so that would impact everybody and benefit everyone if we can do that. What we are trying to do is look for, and I am open to ideas you would have—how do we—every incentive in the system right now is towards higher list prices.

Ms. SCHAKOWSKY. Exactly.

Mr. AZAR. And we create incentive towards lower or flatter list prices that respect—that way it respects innovation, it respects marketplaces, but actually make the finances in the market work to push down list prices.

Ms. SCHAKOWSKY. I would hope so, because otherwise the least insured person is going to be the one that's going to pay that jacked-up price so that the pharmaceutical companies can continue to make their profits if we don't do it across the board.

Mr. AZAR. I agree with you.

Ms. SCHAKOWSKY. So OK. I wanted to, in the time remaining—so last week, as the ranking member of the now-defunct select panel that was dealing with the issue of fetal tissue, I wrote to you with the other Democratic members of that panel raising questions about HHS Office of Civil Rights chief, Chief of Staff March Bell, who I—well, worked with is not quite the right word—who was the chief counsel to Chairman Blackburn on the panel.

Mr. Bell has acknowledged working with David Delaiden, who was indicted for his action in creating the highly edited video that prompted the panel's beginning even in the first place.

And by the way, I ask unanimous consent, Mr. Chairman, to submit that letter that I wrote into the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. SCHAKOWSKY. So these connections pose a serious risk with March Bell's new position at HHS. So I would like to know, yes or no, given the ethical questions surrounding Mr. Bell's conduct during the select panel's investigation, can you commit that March Bell will be recused from any case pending before OCR on fetal tissue or abortion services?

Mr. AZAR. We just received the letter that you sent, and I appreciate your raising these concerns. We will look at them seriously, and we will work with the career-designated agency ethics official and ensure that he and we follow any applicable Government ethics rules on recusal.

Ms. SCHAKOWSKY. And I am happy, and I think other members of the panel—that were members of the panel—would be happy to work with you, as well. We were mistreated, and the connections that he had were really unacceptable.

So I thank you, and I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for questions, please.

Mr. LATTA. Thank you, Mr. Chairman, and thank you very much, Mr. Secretary, for being with us today. And before I begin my questions, I'd like to thank your staff at FDA for all their hard work and collaboration on the OTC monograph reform work that we are doing, and I look forward to working together to get this important legislation across the finish line.

As you mentioned in your testimony, one of the HHS' top priorities is and should be tackling the opioid epidemic, and you've heard from the former full committee chairman about the issues that opioids are having across this country.

The misuse of opioids is taking lives of individuals far too soon, and the crisis is particularly horrific in Ohio. A recent report indicates Ohio's drug overdose deaths rose 39 percent between mid-2016 to 2017.

That's the third-largest increase among States. More importantly, that's 5,232 lives lost in a 12-month span.

This crisis is devastating families and our communities. In December 2017, HHS held a symposium and code-athon to identify and develop data-driven solutions to the opioid epidemic.

It is my understanding the event went well and helped to develop ideas that could become foundational solutions to the problem. It seems the event also highlighted the continued challenge the Federal Government has in leveraging data across departments and agencies, particularly within HHS, given the sensitivity of health data.

Mr. Secretary, what do you need from Congress to enable data sharing within HHS across your own agencies and with other departments in a safe and secure manner that both protects patient privacy and facilitates innovative solutions?

Mr. AZAR. Congressman, I have not had raised to me the issues of any data security or data transfer issues within HHS among our agencies.

So I'd love to check back with our folks and see what they came up with, and if there are authorities that we would need to enable effective transfer of information and collaboration, I certainly agree that we need to be doing that.

Mr. LATTA. OK. Let me go on because, again, especially in Ohio, as I said, this is truly an epidemic.

Continuing with the data discussion, I have a bill, the Indexing Narcotics, Fentanyl, and Opioids Info Act, that seeks to improve how communities respond to the epidemic by putting information on Federal funding, efforts on prevention and treatment data on effective programs, and data on areas hit hardest by opioid abuse all in one place.

In what ways is HHS currently working to make the data surrounding the epidemic more easily accessible to the public, and if I could just be more specific: In my district and when I've been across the State of Ohio, I've heard from departments, agencies. They have a very hard time. They don't have grant writers, and they are trying to get help and they can't find the help really out there, and they also are trying to find where the money is to help facilitate this.

So it's really—does HHS have something out there right now that the communities and law enforcement could be looking at to get some help?

Mr. AZAR. So, if the concern is around sharing best practices, that's actually something that I've spoken with our SAMHSA administrator about—how we can create better vehicles to ensure that what we learn from one State can be taken by others without reinventing the wheel.

In fact, just this week, the President and I separately have spoken with Governor Kasich about the work going on in Ohio and what best practices from there we might be able to take and translate out to others States as having been sitting in the epicenter of the opioid crisis.

Mr. LATTA. OK, because also just—you know, again, to follow up, though—if someone's out there looking for something right now that HHS might have to help them, could they out online and find it right now?

Mr. AZAR. I believe at the SAMHSA.gov Web site but also certainly just letting—calling in into SAMHSA, we would be very happy to point them to available resources that we have.

Mr. LATTA. OK. And because, again, I think maybe just follow up again because, if you could provide the specific steps. So if someone—you say they'd have to go to the SAMHSA website? And again, I want to thank HHS, because they have been in my district at one of our events that we had to get information out to the public from HHS and SAMHSA.

But, again, what I am hearing from the people in my district is that they can't find the information. So, again, that's why I've introduced the legislation, to try to make it more accessible.

You have a one-stop shop, you might say, that you can find this information. So I'd like to work with you all on this as we go for-

ward because, again, this is what we hear from back home, from our departments or agencies or ADAMHS boards. But it's critical for them to get the help, get the information.

Mr. AZAR. Happy to work with you on that.

Mr. LATTA. Thank you.

Mr. Chairman, I yield back.

Mr. BURGESS. Gentleman yields back. Chair thanks the gentleman.

The Chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions, please.

Ms. MATSUI. Thank you, Mr. Chairman, and thank you, Secretary Azar, for being here today with us.

Mr. Azar, you previously stated that one of your top goals as Secretary is to address the opioid epidemic. The President's proposed budget acknowledges the fight that States and local communities are waging against the crisis and proposes increasing some funding for prevention efforts.

I share this goal and appreciate the additional funding, particularly for things like community behavioral health clinics.

However, the massive cuts this budget makes to Medicaid and the repeal of the Affordable Care Act would undo any progress made and, indeed, take a step backwards in our efforts to provide treatment to those suffering from a substance abuse disorder.

To take it a step further, the proposed budget preserves the CMS OPPS rule that is an attack on the 340B drug discount program. The purpose of this program is to allow hospitals and clinics to stretch scarce Federal resources to serve the underserved.

So taking a piece of that away takes away critical resources that these providers are using for things like fighting the opioid epidemic on the ground in our communities.

Giving some of those savings back to the hospitals that have high levels of charity care not only does not make sense administratively, it wrongly indicates that 340B providers are not already serving the vulnerable.

That is the point. In fact, the flexibility allowed by the savings in the program allows hospitals to do things like open new clinics in rural or underserved areas. Why would we want to take that away?

It seems evident that this budget is taking money from the very communities the Trump administration claims to want to help. The 340B program, a crucial player in our fight against opioids, does not cost a dime of taxpayers' money. It should be a program with strong bipartisan support. I cannot comprehend why it is under attack.

As I said, this budget proposes to cut Medicaid by over \$1.4 trillion through block grants and per capita caps. And yet, shoring up Medicaid and strengthening that program is perhaps the single best thing we can do to battle the opioid crisis.

Medicaid covers 4 in 10 nonelderly adults with an opioid addiction and a full 80 percent of treatment for infants with neonatal abstinence syndrome. It is the largest insurer for children and a lifeline for their parents. Often, Medicaid is the only way those with an opioid addiction come into the healthcare system for treatment.

Your rhetoric on the opioid epidemic is not matched by your actions. Cutting the very insurance coverage that treats these people for ideological reasons—the coverage that provides opioid abuse treatment—will not help us address the opioid epidemic.

The President's budget has made it abundantly clear that he's not serious about this epidemic. Secretary Azar, do you agree that Medicaid is a critical tool in the fight against the opioid crisis?

Mr. AZAR. Our Medicaid program is an important tool in providing healthcare to many Americans, but we also have to put it on a stable long-term sustainable footing for it to be there for this and future generations.

That's the challenge that we have, and we want to empower the States so that they have the right incentives to actually deliver quality service, and for the States the opioid crisis is front and center, and so they will design their programs in the best way possible for them to be able—

Ms. MATSUI. We understand that. However, Medicaid has been a success and I really truly feel that eliminating the Medicaid—this is really truly eliminating the Medicaid entitlement, for all intents and purposes, by cutting by \$1.4 trillion.

Now, the Affordable Care Act then only expanded Medicaid to cover those who often had no access to employer-sponsored coverage. It ensured that plans offered actually cover services that people need, from preventive care to inpatient hospital care.

Secretary Azar, do you believe in the value of preventive health services?

Mr. AZAR. I think we all share the goal of preventive health services.

Ms. MATSUI. OK. Do you believe that people are more likely to seek and receive preventive health services when they are free of charge?

Mr. AZAR. People are going to seek—if they are insured and they have the ability to seek out preventive services, they are going to more likely utilize services.

Ms. MATSUI. Right.

Mr. AZAR. Sometimes they may overutilize from free of charge, as opposed to having cost sharing—

Ms. MATSUI. Well, preventive care, though, is really important.

Do you believe people are more likely to seek and receive preventive health and chronic condition management services when they are available locally in the community, whether in person or remotely?

Mr. AZAR. Well, we want to make sure that services are available and are accessible to people through community health centers, through telehealth, through alternative service providers. That's part of our agenda, is to make sure that healthcare is affordable and accessible to people.

Ms. MATSUI. So do you also believe that a person is more likely to seek medical treatment if they have health insurance than if they were uninsured?

Mr. AZAR. We all share the goal of helping to make insurance be affordable and accessible to individuals. The challenge is our current individual system under the Affordable Care Act is not deliv-

ering on that promise for 28 million Americans for whom it's unaffordable.

Ms. MATSUI. Many of the provision in this budget claim to provide choice to patients when really they are just allowing patients to once again be offered less substantial coverage and services.

With that, I yield back. Thank you.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions, please.

Mr. LANCE. Thank you, Mr. Chairman, and good afternoon to you, Mr. Secretary. Congratulations to you on your appointment and your confirmation, and I look forward to working with you.

As you are aware, the administration received additional resources for the FDA—I believe it was \$486 million—as a result of the 2-year budget agreement the President has signed into law.

With these new funds we understand that the FDA will continue to do everything possible to bring safe new therapies to consumers as quickly as possible such as by investing in continuous manufacturing research, and that is research that is being done in part at universities in New Jersey.

The administration worked with this committee on the 21st Century Cures Act 2 years ago and took a major step toward facilitating the further development of this technology.

Mr. Secretary, could you please explain to the committee how this new funding could advance efforts such as these?

Mr. AZAR. Absolutely. Thank you, Congressman.

We appreciate the work of this committee through 21st Century Cures to reinvigorate and strengthen the FDA for the 21st century and the funding that we got through the budget deal.

This enables us actually to increase year-on-year FDA discretionary funding by \$663 million, which allows us to put a huge investment to speed approval of new drugs and devices as well as to invest in our core quality and safety programs.

So we are quite excited about this at FDA and think this will really help us with speeding access to safe, quality medicines for patients.

Mr. LANCE. Thank you, Mr. Secretary.

I am pleased to see that the administration's budget request includes changes to Part D that will help lower costs to senior citizens by passing on negotiated discounts and rebates to beneficiaries.

Would you please update the committee on this proposal, Mr. Secretary?

Mr. AZAR. Thank you so much, Congressman, for asking about that.

We have a five-part proposal with the Part D drug program, with the idea of how do we lower out-of-pocket costs for our senior citizens.

The first thing that we are requesting Congress do is require that the insurers pass at least one-third of the rebates they receive from the drug companies on to the senior citizen when they walk into the pharmacy at the point of sale.

The second is to create, for the first time ever, a genuine out-of-pocket maximum for seniors so that, when they hit catastrophic coverage, they will pay nothing for their drugs.

We would also fix an incentive in the system, where right now these high list prices keep pushing people to catastrophic coverage, where we, the Feds, are on the hook for 80 percent of that. We want to flip that so that the insurance companies are on the hook for 80 percent and we are on the hook for 20, so that they will push back to keep those list prices down.

We also want to give free generics to our low-income seniors who are in the drug program. So free generics throughout for them.

And we want to give the plans more flexibility to negotiate against drug companies, loosening up some of the rules that they have against them.

Mr. LANCE. And, Mr. Secretary, I hope that these plans might be put in place as quickly as possible.

Mr. AZAR. We will need to work with Congress on that. But this collection of efforts, including others I didn't have a chance to mention, could save seniors tens of billions of dollars in out-of-pocket savings on top of the \$3.2 billion of savings President Trump already delivered through the Part B regulation that's been discussed here already, from saving out-of-pocket expense for seniors.

Mr. LANCE. Thank you, Mr. Secretary. I look forward to working with you on that issue as well as others. I have confidence in you based upon your distinguished career in the private sector and in the public sector working with President Bush and also your distinguished tenure with two of the best jurists in the history of the Nation, and I congratulate you on your becoming the Secretary of HHS.

Thank you, and Mr. Chairman, I yield back the balance of my time.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentlelady from Florida, 5 minutes for questions, please.

Ms. CASTOR. Thank you, Chairman Burgess, and welcome, Mr. Secretary. I appreciate your comments at the outset of the hearing regarding the school shooting in Parkland, Florida.

That's now the eighteenth school shooting in America so far this year, and we are here in mid-February. In America, about 96 Americans die every day at the hands of a firearm. That includes domestic violence, incident suicides. More Americans have died from gun violence in America since 1970 than all who lost their lives in every war in the history of our country, and another completely saddening statistic is that more preschoolers die every year because of gun violence than police officers.

So I appreciate your sentiments that we have to do more when it comes to mental health resources. Would you also commit here today that you will act in a proactive fashion to support new efforts for gun violence safety research at the agencies under your purview, including the Centers for Disease Control?

Mr. AZAR. Thank you, Congresswoman. Again, our sympathies to those of you from Florida.

We believe we have got a very important mission with our work with serious mental illness as well as our ability to do research on the causes of violence and causes behind tragedies like this.

So that is a priority for us, at especially at the Centers for Disease Control.

Ms. CASTOR. So specifically on my question—you know, there was a rider that has been added to various appropriations bills over time that has had a chilling effect and, in essence, has acted as a ban on the Centers for Disease Control conducting gun violence safety prevention research just like we do with automobile accidents that has really ended up saving a lot of lives over time.

Would you commit to that specifically, on gun violence prevention safety research?

Mr. AZAR. So my understanding is that the rider does not in any way impede our ability to conduct our research mission. It is simply about advocacy.

Ms. CASTOR. So will you proactively speak out now, knowing we have had our eighteenth school shooting here? We are mid-February, and 96 Americans on average die a day. Will you be proactive on the research initiative?

Mr. AZAR. We certainly will. Our Centers for Disease Control and Prevention—we are in the science business and the evidence-generating business and—

Ms. CASTOR. Thank you.

Mr. AZAR [continuing]. So I will have our agency certainly be working in this field as they do across the broad spectrum of disease control intervention.

Ms. CASTOR. And we are going to hold you to it.

And Chairman Burgess, this is an important topic for our committee. I wonder, would you commit to holding a hearing on specifically just the topic of gun violence prevention research? That's the purview of this committee.

Would you commit today to holding a hearing? The Democrats had a hearing on our own, but we've got to work on a bipartisan way on this. Would you commit to holding a hearing here in the next few months?

Mr. BURGESS. The committee is open to all suggestions, and I think we've shown that track record over the past year and 2 months.

Ms. CASTOR. We haven't had a hearing on this. But thank you, Mr. Chairman. We will hold you to that.

Speaking of the CDC, we are now living through a worse-than-expected flu season. Over the past years, we have had Zika, Ebola, and I am very troubled by the Trump administration's proposal for a \$1 billion cut at the Centers for Disease Control. I mean, this is weakening our public health research, and I heard what you said—that you support science.

Then why is a \$1 billion cut to the CDC a good idea?

Mr. AZAR. Well, that's actually not what's happening. The \$1 billion—most of that is the transfer of the leadership and supervision and budget for the strategic national stockpile—simply a transfer of that function to the Assistant Secretary for Preparedness and Response.

And then the rest is the transfer, again, of the National Institute of Occupational Safety and Health to be within the NIH, where we believe it more accurately fits the research function. So—

Ms. CASTOR. But then you also—you're cutting \$140 million from chronic disease prevention and health promotion programs that will limit our ability to control these very chronic health conditions—cutting \$60 million from emerging infectious disease programs.

I just don't think that's wise in the days of—when we have had Ebola and Zika, and the CDC has such an important mission and prevention is so important.

Mr. AZAR. Actually, what we have done is invest the \$500 million in chronic disease and prevention through the America's Health block grant, \$263 million through our immunization program, and \$137 million in the emerging infectious disease and zoonotic disease—

Ms. CASTOR. Fortunately—

Mr. AZAR [continuing]. And we regularize that now to not be in the prevention fund but actually move it to the discretionary side so it's part of our organic ongoing operations of the CDC that put us on a sounder footing for the future. I think—

Ms. CASTOR. Well, I hope that's the case. We are going to exercise our oversight role aggressively, and fortunately, in a bipartisan way, we beat back significant cuts to the CDC proposed by the Trump administration last year, and I hope we will do so again.

Thank you very much.

Mr. BURGESS. Gentlelady yields back.

The Chair recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions, please.

Mr. BUCSHON. Thank you, Mr. Chairman. Welcome, Mr. Secretary. Thank you for all the work that you will be doing and have done on behalf of the American people.

In June 2015, a GAO report found that, and I quote, "There is a financial incentive at hospitals participating in the 340B program to prescribe more drugs, prescribe more expensive drugs to Medicare beneficiaries." Again, that's a quote. That's not my comment—GAO report, 2015.

A hospital is able to purchase these drugs at a significant discount with no requirement to pass along savings to the patient or Medicare.

Do you believe that additional program requirements, including targeted guardrails and reporting on the use of 340B program savings, would help us reverse this unintended consequence?

Mr. AZAR. Congressman, I think that the Energy and Commerce Committee has done some exceptional work in looking at the 340B program and finding where it's not maybe meeting all of its purposes and where better oversight is needed.

One of the things that we have proposed through the budget is actually enhanced regulatory authority and oversight authority for HRSA and for this important program.

Mr. BUCSHON. OK. Thank you.

And I am also concerned about the increase in cost of healthcare for consumers, and I am interested in ways to address the problem.

Experts and researchers, including some providing testimony in our oversight subcommittee hearing—just yesterday, actually—have expressed concern that the 340B program incentivizes hospital consolidation, and this consolidation can increase costs for patients.

A recent New England Journal of Medicine study funded by HRSA and the Robert Wood Johnson Foundation found that the final hospital outpatient rule from CMS that would—and I am quoting again, “Lower drug reimbursements to hospitals participating in the 340B program could slow hospital-physician consolidation while not adversely affecting care for low-income patients served by general acute hospitals.”

How does this finding from a leading medical journal influence your thinking about potential new policies in 340B?

Mr. AZAR. I think it’s undeniable that 340B has actually led to consolidations, especially hospital acquisition of independent physicians to be able to take advantage of the acquisition of drug cost or physician-administered drugs to be at a lower cost and have that arbitrage.

We have seen that in the practice of oncology. So I think it’s undeniable that that is going on. And so as we look at reforms in 340B to ensure that it serves its purpose of getting medicine as affordable as possible to low-income and uninsured individuals and to support those who do, we need to—we certainly want to examine those guardrails.

Mr. BUCSHON. Yes. I mean, I just want to say for the record I support the 340B program. I think it’s a very important program.

I have a lot of rural hospitals and other hospitals across the State that really need the 340B program. But I also support more oversight within the program, based on the Energy and Commerce Committee’s final report that came out from our O&I Subcommittee oversight hearings on the program.

I am going to make a quick comment, I mean, based on one of my colleagues’ comments—and this is not a question to you, Mr. Secretary—but I want to point out that I was on the Select Committee for Infant Lives, and it has been discussed here about trying to deflect from the findings of that subcommittee.

And I just want to say that what our Select Committee found and sent criminal referrals to the Department of Justice against, organizations that were selling human body parts for profit—the good news is they are not doing it anymore because they are completely shut down. So I just wanted to clarify that deflecting from the subcommittee’s work and our final report, it doesn’t change the fact that some will go to pretty long—well, extensive lengths to protect Planned Parenthood in addition to other organizations that are performing abortions in the United States.

And then, so the FDA Commissioner Gottlieb has also stated publicly that the Congress should take action to clarify the regulation on LDTs—laboratory-developed tests—and Congresswoman Diana DeGette and I have draft legislation, and right now we have submitted to the FDA and CMS for technical assistance and we are waiting for those results.

So I hope we can count on the full cooperation of HHS as we work through this process, because it's really a critical piece of legislation and some critical reforms.

Mr. AZAR. We will certainly be happy to continue that technical assistance in that very complex area of lab-developed tests.

Mr. BUCSHON. It is very, very complex. Again, thank you for your service.

Mr. Chairman, I yield back.

Mr. BURGESS. Was the gentleman thanking the chairman for his service?

Mr. BUCSHON. Thanking the Secretary and the chairman, of course, for his service.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. The Chair recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. SARBANES. Thank you, Mr. Chairman. I thank the Secretary for being here.

I want to pick up on the first part of my time where Representative Castor left off in terms of research being conducted by your agency and by the CDC into gun violence.

Yesterday, obviously, another community was forced to make sense of what is really a uniquely American tragedy, which are these school shootings we have seen.

This is at least the 273rd school shooting nationwide since Sandy Hook occurred back in 2012. In those shootings, 439 people have been injured, 121 people have died, and we keep sending our thoughts and prayers to the victimized families. But we really should be sending them laws that put in place commonsense gun safety measures.

Members of Congress, that's our job. I mean, we provide thoughts and prayers. There are others who are in a better position to do that. Our job is to actually change the law to try to address these tragedies.

I just assume—I mean, I know you had testimony yesterday, I think, on the Hill and earlier this morning. So you've not been back in the office since then.

But I got to believe that this would—another tragedy like what we saw yesterday would just be an all-hands-on-deck moment for you and those around you, your team, to look in the agency, figure out how you can assemble some resources and put them behind some serious research into gun violence. Is that something that your team is undertaking now?

Mr. AZAR. Well, as you know, I am with you, so I am not back at the Department at the moment, so I'll have to check and see what's going on in terms of that.

But with any kind of public health emergency or response we, of course, will update the Secretary's emergency operation center to ensure, for instance, with the response situation here, what's the hospital capacity—are we able to care for those who are injured—what is the census of local—

Mr. SARBANES. So I am going to interrupt you, because I am talking about a different kind of response. I get that response. I understand that you want to support the first responders that are on the ground, the hospitals that are taking the victims.

I am talking about a response that says this is a public health crisis and our agency, which is charged with dealing with public health and is the Department of Health and Human Services, is going to have to really ramp up the kind of research—public health research—we do into this crisis of gun violence—an epidemic of gun violence across the country.

So is that a commitment—as Representative Castor asked you, I am asking you again—is that a commitment that the agency and that you, new to the job, are prepared to commit to?

Mr. AZAR. So we will continue to look at it across our range. We have many public health issues and priorities that we have to investigate and conduct research on and what programs there are and studies that are available that are being worked on at the CDC.

So I am happy to look into what is currently going on and get back to you on that. I am just not aware of—I am 14 days there, so I am not aware of every single research program that we have and every study that's being conducted at the moment.

Mr. SARBANES. Well, I hope you'll do that and, Mr. Chairman, I want to echo the request that we have some kind of hearing that addresses this issue of gun violence as a public health crisis.

Real quickly, let me shift gears. I understand that the administration is looking at expanding what are called these short-term limited duration plans, coverage plans which, in a sense, are these kind of skinny junk plans where you don't have the same kind of protections, you can exclude coverage for pregnancy and childbirth if you're an insurer that offers these kinds of things, you can exclude coverage for mental illness or nervous disorders, for alcohol or drug dependence, et cetera—all the kinds of things we were trying to address in the individual market previously.

But now there is this move on the part of the administration, and I assume it's going to be going through your office, to make these skinny plans that don't have the kind of coverage protections in place more widely available.

You cannot believe that that is moving in a positive direction. I wanted to ask you to address that.

Mr. AZAR. Well, as you know, the short-term limited duration plans were supported and available during the entirety of the Obama administration as a vehicle available to individuals in transition and for whom the Affordable Care Act—

Mr. SARBANES. Right, for a short transition period.

Mr. AZAR [continuing]. The individual market for 365 days a year up until October of 2016.

Mr. SARBANES. Right. But going forward, there is a move on the part of the President to expand both the time frame and allow more of these junk coverage provisions to be in place.

I hope that we are not going to start moving in that direction, because it undermines the very principles that were fundamental to the Affordable Care Act and providing a higher level of coverage.

So I hope you'll be vigilant and make sure that those plans don't begin to swallow up the kind of decent coverage that Americans can expect across the country.

Thank you, and I yield back.

Mr. BURGESS. Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the chairman of the full committee, Mr. Walden of Oregon, 5 minutes for questions, please.

Mr. WALDEN. I thank the chairman, and again, Mr. Secretary, thank you for being here.

Our committee is spending a lot of time on the opioids investigation and trying to deal with this killer in our communities.

I know in my State more people die from opioids overdoses than in traffic accidents, and I think that's pretty close to the case across the country. Every day, every hour, people are losing their lives. And so our focus has been and will be continue to be on the opioid epidemic.

Prescription drug monitoring programs, or PDMPs, can be effective in improving the prescribing of controlled substances in addressing the opioid crisis. More and more PDMPs are being used as public health tools. However, current Federal efforts to support PDMPs are not well coordinated.

However, the following programs could support PDMPs: the Harold Rogers PDMP program run out of the Bureau of Justice Assistance; National All-Schedules Prescription Electronic Reporting Act administered by SAMHSA but hasn't been funded since 2010; State demonstration grants for compressive opioid abuse response, which also has not been funded; CDC's Opioid Prevention in States grants, which provide the most supports to the States; are not even authorized in statute; and finally, the Office of the National Coordinator for Health Information Technology supported PDMP integration with health IT, but this effort only lasted from 2011 to 2013.

So what is HHS doing to better coordinate all of these efforts? How can we better assist to address the needs of States to get timely, complete, and accurate information into the hands of providers and dispensers so they are able to make the best clinical decisions for their patients?

What should we do in this space? What can you do in this space?

Mr. AZAR. So these can be—these prescription drug monitoring programs, these registries, can be very important vehicles to assist prescribers and pharmacists with knowing if they are dealing with a patient who is basically prescription shopping, physician shopping, pharmacy shopping, they've been shut down one place, they go somewhere else to get around the system.

In our budget proposal, we actually are asking Congress to require that States have effective programs for this type of risk identification and risk mitigation for prescribers, pharmacists, and patients that are overutilizing, overprescribing, overdispensing.

We don't specifically ask Congress to dictate the vehicle of it through the prescription drug monitoring programs. I am interested in looking more into the issue of interoperability.

States have developed these programs already independently, and so there is a resource and burden question about forcing that interoperability to try to be nationwide. But, say, in Ohio, West Virginia, or Kentucky, where they are bordering and you could ease the abuse, I'd like to look at ways we can certainly encourage them to work towards connecting their systems up for ready interstate checking.

Mr. WALDEN. I border Washington, Idaho, Nevada, and California with my district, and I know this is an issue I've heard about out there, and there is some collaboration and coordination. But it seems to me that part of what happens with people who are addicted, the desire is so high they are going to find every avenue that they can to satisfy it. And so it's something I think is really important.

And, you know, we get a lot of questions about this potential allocation of money available under the CAPs to do work on opioids—you know, Where should it go?

Have you have a chance to give any thought to where you think the money could best be spent and have the most impact?

Mr. AZAR. So, for the initial allocation that we have requested, which is the \$3 billion in 2019, \$1.24 billion of that would go to SAMHSA. One billion of that would go out to States in the State-targeted response grants, and so that's doubling what the 21st Century Cures funding was over the last 2 years.

We have got a very interesting \$150 million new program for rural substance abuse—

Mr. WALDEN. Good.

Mr. AZAR [continuing]. To really support providers in rural areas, a program for \$150 million on infectious disease transmission to help with HIV/AIDS transmission, Hep C, \$74 million to help communities buy naloxone for first responders—

Mr. WALDEN. Good.

Mr. AZAR [continuing]. For overdose, drug court support, pregnant mother support, medically assisted treatment support, investing in all of those.

Seven hundred and fifty million of it, we would be sending to NIH to support next-generation nonopioid pain treatment development and devices as well as the best cutting-edge research on other forms of pain management. CDC, FDA also would receive funding.

So we have got a game plan that we already are articulating there.

Mr. WALDEN. Excellent. Excellent.

All right. We will look forward to working with you on that. Mr. Chairman, my time has expired.

Mr. BURGESS. Gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Massachusetts, Mr. Kennedy, 5 minutes for questions, please.

Mr. KENNEDY. Thank you, Mr. Chairman. Mr. Secretary, thank you for your service. Thank you for appearing before us today.

I've got a couple of minutes. I want to try to get through this quickly. My colleagues have, obviously, already touched on the fact that under your responsibilities resides the—or under your umbrella resides the Centers for Disease Control. They touched on the fact that 17 students went to school yesterday and did not come back. They've touched upon the fact that nearly 100 Americans die every day because of gun violence.

No one needs reminding in this committee or otherwise that this is an epidemic that has infected our schools, our concerts—60 dead, 800 wounded just a few months ago—our churches.

I received an email last night, or early this morning, from a 17-year-old high school student in my district, Mr. Secretary, that said, “I don’t think proper words can address my concerns. These school shootings scare me. I am scared that my school will be next, that my friends will be next, or that I will be next.

“I don’t think it’s selfish to want to be safe in school, is it? Not just for the victims. I imagine losing the people I love in an awful way like that and simply decide not to imagine it. There are kids who lose their best friends every day to this increasingly normal tragedy.”

Something needs to happen here. Mr. Secretary, please, I ask you—and echoes of my colleagues here—to do everything that you can to make sure that a major public health crisis is going to be addressed under your tenure at HHS. Will you reiterate that pledge?

Mr. AZAR. So I will be happy to look, as I mentioned earlier, to look at what we have invested and if we have the right programs and the right level of research in this field and get back to you on that.

Mr. KENNEDY. Thank you, sir.

Shifting gears a bit here onto Medicaid. There has been much written and said over the course of the past couple of months about Medicaid work requirements.

Mr. Secretary, I am under the impression that the mission of your organization is to, quote, “enhance and protect the health and well-being of all Americans.” That’s correct, right?

Mr. AZAR. Absolutely.

Mr. KENNEDY. And am I to then understand that the policy of this administration is that there is a direct link, a causal link, between working and healthier outcomes for Americans?

Mr. AZAR. We actually do believe that there is a causal link between those who are trained, educated, and able to work—for those who are able—and better health outcomes. And so we do believe in supporting that.

Mr. KENNEDY. Mr. Secretary, that’s not the same question, respectfully. That somebody that is better trained, educated, and able to work is healthier is different than a work requirement makes people healthier.

In fact, I believe a recent study put out—might have been today—indicates that the cost per patient in delivery of Medicaid in Kentucky is actually going to go up, not down, with the imposition of the work requirement. Have you seen that study?

Mr. AZAR. I have not seen that study.

Mr. KENNEDY. Oh. Well, we can submit it for the record for you. [The information appears at the conclusion of the hearing.]

Mr. KENNEDY. Shifting gears, as well, not only are there pieces put in place around Medicaid work requirements, there are disturbing reports coming out that at least five States and that CMS is entertaining the possibility of putting on lifetime caps on Medicaid.

I want to try to understand this. Would it be the policy of this administration that it would be recommending that lifetime caps would somehow make a population healthier?

Mr. AZAR. There are requests that are coming in along those lines. We do not have a position on this, and I do not want to speculate on the ruling on a waiver. But that is not something that we have invited in terms of waiver requests, and so we do not have a position on that at this point.

Mr. KENNEDY. And I understand that the administration might not, and I understand that that's going through the process at the moment. But could you, perhaps given—I know you've only been there for a couple weeks, but you've got a lifetime of service in healthcare. You are truly—you're an expert, you were confirmed by the Senate, in a closely divided Senate, to this role. I assume you have some idea as to whether putting a lifetime cap on Medicaid would make a Medicaid population healthier.

Mr. AZAR. I understand the importance of this issue. I do not want to speculate without actually looking at it in the context of the request that we received. But we do not have a view that is supportive of it or against it. We need to look at it. I need to talk to our team as we evaluate any requests that come in on this—on this one.

Mr. KENNEDY. OK. Perhaps then, if I am to understand what a lifetime cap would actually mean, my understanding of the tax code is that there is in fact a taxpayer subsidy that goes to employer-sponsored healthcare. Is that right?

Mr. AZAR. There is, yes.

Mr. KENNEDY. And so what we are basically saying is healthy people can enjoy that taxpayer subsidy for their healthcare, but when it comes to being poor, if you get really sick, we could cut you off. Is that right?

Mr. AZAR. No. Again, I don't—I have not reviewed any of these waivers or requests that some States appear to be making, so I couldn't even speak to what they are asking for at this point. This is quite fresh.

Mr. KENNEDY. Well, there is public reports from The Hill and from the Washington Post indicating that five States are putting that forward. It might be going through your process, but I am trying to get some guidance as to whether the position of this administration is going to be that if you are healthy, you can get taxpayer subsidies, but if you are poor and sick, you don't.

Mr. AZAR. I don't make it a practice to rule on very serious matters based on what's in The Hill.

Mr. KENNEDY. Fair enough. Yield back.

Mr. BURGESS. Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Oklahoma, Mr. Mullin, 5 minutes for questions, please.

Mr. MULLIN. I appreciate, Mr. Secretary, you not making decisions based on The Hill information, although some of it is quite entertaining.

Mr. Secretary, thank you so much for being here. Mr. Chairman, thank you for allowing me to ask some questions. I am going to get right into it.

Mr. Secretary, I was happy to see that HHS is setting aside \$10 billion for the opioid and serious mental health issues. But I was

surprised to see there was no mention about amending the CFR 42 Part 2.

The President's opioid commissioner and former CDC administrator both believe that we need to amend Part 2. I was kind of getting your position. Have you looked at Part 2 to see what your thoughts are on—

Mr. AZAR. I apologize. Could you help educate me what Part 2 is? That's not a provision I am familiar with.

Mr. MULLIN. Well, so—

Mr. AZAR. The substance of it—I don't know the substance.

Mr. MULLIN. Well, we have a bill right now, H.R. 3545, that I'll be happy to work with you on this if you want to. We'd love to educate your office on it. We have literally 4 minutes here, and I don't think I could go through Part 2 enough to get to it.

But this is something that I have taken on that has been extremely important to me so I appreciate your honest answer on that. If you would like to have your office contact us. You guys are shaking your head. Right on. I appreciate that.

Because we have—we feel like we have a fix for this in our office. So if you'll just meet with us. The bill is H.R. 3545.

Mr. AZAR. OK.

Mr. MULLIN. And we have had a hearing on it before in here. But I understand you've only been there two or three weeks, so—and by the way, I really do appreciate the time. You get confirmed and then all of a sudden it goes, "Wow, what did I get myself into," right?

One more thing I want to get into, I also chair the Indian Health Service Task Force, which is very important to me, being Cherokee. The opioid epidemic has unproportionately hit Native Americans.

I have the privilege of representing District 2 of Oklahoma, which has the highest Native American population in the country, and opioid is wrecking our State and many people's States. And we are working extremely hard to try to figure out how we can put, as I say, the genie back in the bottle.

You know, why we keep sending controlled substance that are highly addictive home is beyond me. That's beside the point. But I really do want to work with you on it.

But yesterday, I think my colleague and a member of the task force, Kristi Noem, asked you about your plan to deal with the agencies and with IHS.

You said that you had prioritized it and provided more money than the President's budget, and this was good to hear. But I wanted to know if you had any specifics that you could lead me down the road on that.

Mr. AZAR. So as I mentioned yesterday, in the President's budget with regard to—there are certain facilities that are having trouble with quality and certification from CMS and being able to perform.

Most are Great Plains. We have got one Navajo. I don't know if there is one—I don't remember if there is one in Oklahoma that's been decertified also. I don't think so.

Mr. MULLIN. No.

Mr. AZAR. And so we have got \$58 million that we are proposing to invest in assisting these facilities and achieving their certifi-

cation, retaining it, and maintaining quality service for the people that we serve.

Like I say, we put \$413 million additional dollars in increase for IHS in the budget as well as another \$100 million for IHS around the opioid crisis as part of that \$10 billion funding in 2019.

Mr. MULLIN. Our task force is a very bipartisan task force, and we have left politics completely out of it. One thing we have noticed is there is very little standing operating procedures and there is very little communication between one clinic to the next.

There is a drastic difference between the Great Plains and, say, in Oklahoma where we have maybe a little bit more funding to be able to put into our Indian clinics. I personally am a product of that. I grew up in Hastings Hospital and went there many, many, many, many times, and I found their service being very adequate—very adequate. My kids still use it.

But we do understand there is a difference, and what I would like to do is work with your team. We would love to be able to maybe set something, where we meet you in South Dakota and see what's happening there and the lack of service that is given, and then also show you what's happening in Oklahoma when the Tribes invest in their own back yards and be able to work with you on coming up with standard operating procedures where we can draw the line and have the same quality of care no matter where you go inside the IHS system and where they can access records and quality doctors and quality healthcare.

This is something our task force has taken on as very important to us, and if you would have your office reach out to us, we want to work with you on this. We want to get this solved.

Mr. AZAR. As do we. So we are open for any suggestions how we can improve the performance of IHS in delivering quality, safe services for our beneficiaries.

Mr. MULLIN. We'd love to meet you up there, too, and show you firsthand what's happening.

Mr. Chairman, I am sorry. I went over. I'll yield back. Thank you.

Mr. BURGESS. The Chair forgives the gentleman. The gentleman yields back.

The Chair recognizes the gentlelady from Colorado, 5 minutes for questions, please.

Ms. DEGETTE. Thank you so much, Mr. Chairman. Welcome, Mr. Secretary.

The Washington Post is reporting today that HHS employees threatened to cut Federal funding from the Vera Institute of Justice if the organization's lawyers communicated with their clients about their abortion rights.

Now, as a lawyer myself, this seems like an unacceptable intrusion into the attorney-client relationship to me. I am wondering, Mr. Secretary, did your staff instruct lawyers at the Vera Institute or any other organization not to discuss abortion rights with their clients?

Mr. AZAR. Congresswoman, I actually—I did not see that story. It's the first I am hearing it.

Ms. DEGETTE. Well, OK. I am not asking you about the story. I am asking you, did your staff instruct the lawyers—

Mr. AZAR. It's the first I am even hearing of the issue. I have not heard anything about this.

Ms. DEGETTE. So you don't even—you don't know. Would you think that would be appropriate, if they did instruct lawyers not to advise their clients of those rights?

Mr. AZAR. So I would like to go back and look into this and see. That's a serious claim—

Ms. DEGETTE. So you're not going to answer my—you don't know if it would be appropriate or not?

Mr. AZAR. Again, I don't want to answer hypothetical questions without looking into the facts of the situation.

Ms. DEGETTE. OK. Well, let me ask you this.

There is something that's been around quite a while at HHS, and that is that there has been a pattern of conduct about the Office of Refugee Resettlement under Director Scott Lloyd's leadership, in particular, to disregard the rules in Federal law when it comes to women's reproductive rights and health.

Let me talk to you about a couple things. As well as this report today, we also found out that Mr. Lloyd has attempted to deny access to abortion to at least four immigrant teens in detention, including one who was a victim of rape.

Now, in each of these four cases, the Federal courts declared Director Lloyd's actions unlawful and allowed the girls to access their reproductive healthcare.

Are you aware of those four cases, sir? Yes or no will work.

Mr. AZAR. I am aware of media reports about them.

Ms. DEGETTE. Well, you're—

Mr. AZAR. I've just been at HHS for 14 days, so I haven't—

Ms. DEGETTE. Yes. Yes, you have. So you're not aware within the agency?

OK. Well, I sent a letter to the agency—and you were not there then, in fairness to you—it was dated December 1st—with some other folks asking that Mr. Lloyd end these unlawful ORR policies denying reproductive healthcare to immigrant women and girls in detention.

We have not yet received a response to this letter. Can you commit to me that we will get a response to this letter?

Mr. AZAR. Yes, we will certainly respond to your letter.

Ms. DEGETTE. OK. And Mr. Chairman, I'd ask unanimous consent to put the letter into the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. Now, Mr. Lloyd, as Secretary of HHS, you have the authority to stop Mr. Lloyd and his staff from advising people they can't tell people about their constitutional rights.

Will you commit to me today that you will ask him to please stop doing that?

Mr. AZAR. So we have with regard to these children who come into our custody a very important statutory obligation, which is to look out for the health and welfare of them as well as their unborn children, and it is a solemn obligation. It is a difficult obligation—

Ms. DEGETTE. Well, excuse me.

Mr. AZAR [continuing]. And it is now a matter of pending litigation, and I really can't—I do not know the facts of the situation nor could I comment, because these are pending matters in litigation.

Ms. DEGETTE. OK. Well, good news. Four courts have already said that your Department can't stop them from getting abortions. Are you contesting those court decisions?

Mr. AZAR. I am not aware of the status on the litigation. I've been at the Department for 14 days.

Ms. DEGETTE. OK. Is it the—let me—

Mr. AZAR. I will not comment on potentially pending litigation.

Ms. DEGETTE. OK.

Mr. AZAR. It would be irresponsible for me as Secretary. I am the named party in the litigation.

Ms. DEGETTE. Well, let me—then—excuse me, sir. Perhaps you can comment on HHS policy for me, then. Is it the policy of HHS to tell your contractors that they are not allowed to discuss abortion rights with their clients? Yes or no.

Mr. AZAR. As I told you, I am not aware of any policy either way—

Ms. DEGETTE. No, no. OK.

Mr. AZAR [continuing]. Or the facts of that situation.

Ms. DEGETTE. Well, you're the head guy. Would you support that kind of a policy?

Mr. AZAR. I am not aware of the facts of that situation, nor can I sit here and off of the cuff state a policy position for the Department.

Ms. DEGETTE. If an employee of HHS told the Vera Institute that their Federal grant would be withdrawn if they advised their clients of their rights, would you support withdrawing it?

Mr. AZAR. I am going to repeat that I—it was irresponsible of me to sit here and on the basis of a supposition of facts articulate a policy position—

Ms. DEGETTE. OK. But—

Mr. AZAR [continuing]. Without investigating and looking into it.

Ms. DEGETTE. OK. Great.

Mr. AZAR. You would not expect me to do otherwise.

Ms. DEGETTE. OK. Great. So will you commit—

Mr. AZAR. I need to be a responsible officer.

Ms. DEGETTE. Excuse me. Will you commit to me that you will investigate and look into it?

Mr. AZAR. I will. I already mentioned—

Ms. DEGETTE. And will you also commit to me that you will get me an answer back in writing within 30 days of this hearing?

Mr. AZAR. I will not be able to commit on the time line there because I do not know the nature of the investigation, the facts, or whether it connects to matters of litigation.

Ms. DEGETTE. When do you think it would be appropriate to get back to me?

Mr. AZAR. I will not be able to commit on a date until I know the circumstances here and know whether it connects to a matter of litigation, because this may be a matter that the Justice Department would decide. I don't want to make a false commitment to you on getting back to you by a date certain on something that might be—

Ms. DEGETTE. Will you get back to me?

Mr. AZAR. We certainly will, yes.

Ms. DEGETTE. Great. Thank you.

Mr. BURGESS. Gentlady's time has expired. The Chair thanks the gentlady.

The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chair, and I appreciate your responses to the previous questions, particularly that you'll get back with some information but not a specific answer based on the legalities of everything.

That being said, I also appreciate your answers previously in relationship to the opioid crisis, which is important to so many of us, and I think that my colleagues have covered that extensively, so I am going to move on to some other things. But appreciate working with you on that in the future.

I've got a number of things that I am passionate about and that affect my district. One is I have a very rural district in the southwest corner of Virginia, and I want to ask you about telehealth because it seems me that we have some issues there with reimbursement.

And if the doctor is willing to conduct a telehealth consult, I believe they should not be prevented or discouraged from providing the service because of outdated reimbursement policies, and I would like to work with you and HHS to help find ways to alleviate reimbursement challenges that are in the way of telehealth exploding and bringing medicine to the nooks and crannies of every part of America.

So what policies are you all working on to facilitate the delivery of telehealth, and what policies do we need to change—and I know you may not have an answer after only 2 weeks—but please let us know what do we need to change to help you all allow reimbursement for telehealth services so the people can get services all over the country and all—predominantly rural areas, but I can see applications in other areas, as well.

Mr. AZAR. Thank you for raising that issue. I am a big supporter of telehealth and how we can harness that, especially for underserved areas like our rural communities.

I do suspect there are significant statutory barriers around reimbursement there, given that most of our constructs were set up in the 1960s for our payment regimes.

So we'd love to work with you on that as I go back and we plow through and identify those barriers to see where we might be able to make changes.

I believe in the budget we have one provision that we are recommending regarding Medicare Advantage plans, I think, and supporting greater payment flexibility around telehealth. But I am sure there are many, many more. But I am a big believer in the opportunities that we have there.

Mr. GRIFFITH. I don't think it's a partisan issue. I think you'd find support on both sides of the aisle to change the laws that are keeping you all from doing things that we all want you to do—so I appreciate that—in relationship to telehealth.

Let's talk about neonatal abstinence syndrome. I am encouraged to see that CMS used State plan authority as it did in the case of West Virginia this week with respect to the State's request to allow its Medicaid program to reimburse certain treatment centers that take care of infants with neonatal abstinence syndrome.

This move suggests that CMS and the States can work together to address the distinct needs of each State. If my home State of Virginia or my neighboring State of Tennessee or other States should choose to follow suit and request coverage of similar services through a State plan amendment or waiver, may I get your commitment that your staff at HHS and CMS will work swiftly to allow such a waiver so that we can ensure infants with NAS in Medicaid get the care that they need?

Mr. AZAR. I don't know the particulars on that approval, but we certainly will work with any State that is going to be delivering care in that area within the confines of our waiver and demonstration authority, and we will do that as swiftly as we possibly can. That seems quite noble.

Mr. GRIFFITH. All right. Now here's one more I am going to push you on: durable medical equipment. I know that there have been some issues. But for rural areas the competitive bid reimbursement adjustment has been deadly for durable medical equipment suppliers.

Folks are having—I've got one fellow in particular. He's driving through, you know, up and down mountains to deliver oxygen, et cetera, to people that he considers friends and clients.

He keeps having to lay people off just to make ends meet. So I ask you, there is an interim final rule that's pending at OMB. I've spoken with OMB and Mr. Mulvaney about that. Will you commit to working with Director Mulvaney to ensure this IFR is released expeditiously? It's currently sitting in your hands.

Mr. AZAR. So I can't speak to that particular IFR or that issue because I do believe that's a matter pending in litigation, but I will tell you our budget—I am very concerned about the issue of DME—the competitive DME and rural access, and our budget proposal actually has some I think very important reforms and suggestions for rural access there.

Mr. GRIFFITH. And I appreciate that, because I will tell you that it won't be a whole lot of months before he just has to completely shut down his operation and then I will have constituents who are no longer being served because, you know, when you're a long way from the nearest town, it's hard to drive down there and get your own equipment and drive it back up the mountain.

Mr. WALDEN. Would the gentleman yield a second?

Mr. GRIFFITH. I yield.

Mr. WALDEN. Yes, I just want to double down on that, because I am finding the same thing in rural parts of my district, where all of a sudden in Burns, Oregon, a long way away, getting access to DME, durable medical equipment, is a real problem.

Oxygen is becoming a real problem, and this is something that I hope the administration will act on expeditiously, as well. So I am glad you raised that.

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

Mr. Chairman, I yield back.

Mr. BURGESS. Chair thanks the gentleman. Gentleman yields back.

The Chair recognizes the gentleman from Oregon, Dr. Schrader, 5 minutes for questions, please.

Mr. SCHRADER. Thank you very much, Mr. Chairman, and thank you, Mr. Secretary, for being here.

You talked in your testimony about the need to improve the individual and small group markets, and I think, frankly, I am one of the folks, along with many others, both sides of the aisle that believes that's true.

But very concerned that in the President's budget, it proposes actually repealing more of the Affordable Care Act, which would cause millions to lose coverage, and this is despite the fact that we had this big debate last year and Congress, who is the lawmaking body, decided not to move forward along those lines.

I don't think Americans want to see their health coverage go away. I think they want to see us come together and strengthen and improve that individual marketplace, which is bleeding over to the small group.

I am with a group of bipartisan Members, several of which serve on this committee, called the Problem Solvers, that has a bipartisan proposal—about 25 of us—that have supported this.

We have legislation that's introduced. It includes the CSRs that were included in both the Republican and Democratic budgets. Talks about a stability fund that was in Republican as well as Democratic proposals. It gives the flexibility you alluded to to States, both in the 1332 and 1333 waivers. Rolls back some of the employer mandate and gets rid of the medical device tax.

Would your administration and you personally be interested in promoting that type of proposal to solve the problem?

Mr. AZAR. So, obviously, we have our budget proposal, which is the broader Graham-Cassidy package, but I am also very happy to work with you and learn more about these ideas that you've got.

Our commitment is, we want to make insurance affordable for people in the individual markets.

Mr. SCHRADER. Thank you. Thank you. Well, I appreciate that, because we would like to work with you or the administration, come up with just a commonsense proposal to fix what needs to be fixed at this point in time so Americans have healthcare.

Under the current budget there are huge cuts to Medicaid and the marketplace. Could you give us some idea of the numbers of folks that are going to lose coverage as a result of the proposals you've put forward?

Mr. AZAR. So I don't have a score that does any estimating on that. What we would do is—

Mr. SCHRADER. If I may interrupt. I am sorry. I have only limited time. I apologize.

The CBO does have a score, and they've indicated repeatedly that 23 million Americans would lose coverage if the Affordable Care Act is repealed in its entirety.

Unfortunately, we have already gone through a measure of that with the current tax cut bill that came out. Very, very concerned that if we double down on that, that would be not good for Ameri-

cans, and hope that as Health Secretary the goal would be to get people more healthcare, not less healthcare.

Last piece, if I may—getting back to the proposals coming out of the great State of Idaho. I respect everyone's sovereignty, but I think the goal of the Affordable Care Act isn't just to treat conditions and people as they walk in the door but to make a better healthcare system, to make people healthier so that they don't have to walk through that hospital door quite as often.

And I guess my question to you is, Would you and this administration enforce all the essential health benefits that are currently a requirement of the Affordable Care Act, given that that is the law of the land at this point in time, including prescription health benefits, mental health benefits, maternity, emergency care, ambulatory care, laboratory services, prevention and wellness, pediatric care, hospitalization, and rehabilitation?

Mr. AZAR. So we certainly have a duty to enforce the laws Congress has written and passed and within any flexibilities, of course, that we have under waiver and other authorities. But, obviously, we have to be committed to enforcing the laws that Congress have given us.

Mr. SCHRADER. All right. I appreciate that very much, Mr. Secretary, and look forward to working with you.

Mr. AZAR. Thank you. Same here.

Mr. SCHRADER. Thank you, and I yield back, Mr. Chairman.

Mr. BURGESS. Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Florida, Mr. Carter.

Mr. CARTER. Well, thank you, Mr. Secretary. Congratulations and thank you for being here today. We appreciate your presence.

I want to start by asking you about DIR fees. Are you familiar with DIR fees?

Mr. AZAR. You know, I am somewhat. Are we talking in the context of the specialty pharmacy issues?

Mr. CARTER. No, not necessarily in a specialty pharmacy. This would be in any pharmacy. These are—these are generally just the fees that are price concessions, or maybe even just fees that are imposed by the pharmacy, by the PBMs, and that are recouped sometimes years later, years after the prescription has been dispensed.

And, obviously, the patients are not getting the benefit of this, and therefore it is costing taxpayers more money because in Plan D, as you well know, the higher the drug and the higher the cost to the patient, it's going to push them into the donut hole and then ultimately into the catastrophic part where the taxpayers will be taking up more of those costs.

I've led several letters to your Department, to CMS, regarding this. I hope that you will look at this closely. One of my colleagues, Congressman Griffith, on this committee has a bill right now making it to where DIR fees would have to be recouped at the point of sale and could not be recouped years later.

So I hope you'll look at that very closely. I want to ask you next about abuse deterrent formulations. Are you familiar with that and how it could be used in the way of opioids?

Mr. AZAR. I am somewhat. I am sure not as deeply as you are with your clinical background.

Mr. CARTER. OK. OK.

Well, I hope that you will look at that. I think that is something that could benefit us and certainly, in our fight against the opioid, something I know you're committed to and certainly that we are committed to.

If I may, if you could just hang with me for a second. You were the CEO of Lilly Manufacturing and Lilly Pharmaceuticals.

Mr. AZAR. I was just the president of the—

Mr. CARTER. Just the president.

Mr. AZAR [continuing]. Commercial business in the United States.

Mr. CARTER. But you understand how PBMs work, and you understand that whole scenario. As a practicing pharmacist for over 30 years, I too understand that. And I am just curious.

Let's just take a product that Lilly may have had. Let's take Prozac or Zyprexa, and both of those are available now in generic formulations. But if you wanted to—let's take Prozac, for instance—if you wanted to get Prozac onto a formulary, as the pharmaceutical manufacturer did you have to offer the company, the pharmacy benefit manager who was compiling that—compiling that formulary—did you have to offer them a rebate in order to get it back?

Mr. AZAR. So if I could address this generally.

Mr. CARTER. Please do.

Mr. AZAR. I would not want to speak in the context of my former employer.

Mr. CARTER. I understand.

Mr. AZAR. But yes, generally, almost all brand of products will have to offer rebates to pharmacy benefit managers in order to secure equal or preferred status on a formulary. Otherwise, they will be disadvantaged or even not covered by that PBM in terms of the benefit package. So that's quite standard.

Mr. CARTER. Yes, and I just want to—

Mr. AZAR. It would be the more unusual case where there isn't a rebate that's being paid.

Mr. CARTER. I've always wondered: Where does that rebate go? Do you know?

Mr. AZAR. Where does the rebate go?

Mr. CARTER. Yes, sir.

Mr. AZAR. So I am certain—

Mr. CARTER. I do know one place it does not go. It does not go to the pharmacist. I can assure you of that.

Mr. AZAR. I believe some of it, obviously, goes into the premium and buying that down. Depending on the PBM's business model, some may be retained by the pharmacy benefit manager as their profit or to cover their expenses. Some may be passed on in lower premiums. I think it would depend on each individual PBM how that works.

Mr. CARTER. But you would agree that that rebate is significant?

Mr. AZAR. It can be quite significant. Average commercial rebates approximate about 35 percent.

Mr. CARTER. Just out of curiosity, you know, if that rebate—it's not going to the patient, and it's not going to the pharmacy. The pharmaceutical manufacturer is paying it to the PBM.

You know, I am not opposed to anybody making money. But the mission of a PBM is to control drug prices. If they are controlling drug prices, why is one of the President's initiatives to bring drug prices down?

Mr. AZAR. Why is it? The President wants—

Mr. CARTER. If the PBMs are doing their job, if they are indeed controlling drug prices, why did the President identify a drug price? Why have all these people on this committee here today asked you about prescription drug prices? Why is that one of the primary issues that we discuss up here?

Mr. AZAR. It's actually—so, first, there are pockets of our programs where we don't get as good of a deal as we ought to and can do, and that's what we are working on.

Mr. CARTER. But I am speaking specifically to the—I don't mean to interrupt.

Mr. AZAR. No, no. And I think it really has to do with list prices. Every incentive in our system is towards higher list prices.

Mr. CARTER. If I may, I just remind you that there are three PBMs that control 80 percent of the market and that one of the PBMs, Caremark, had gross revenues in 2016 that exceeded that of Pfizer Pharmaceuticals, of Ford Motor Company, and of McDonald's combined.

Mr. Secretary, we got to do something about this. We need transparency. Sunlight is the best disinfectant out there. We have to have transparency.

I can't see this in the Plan B. You won't let me see it. We need transparency.

Thank you, Mr. Secretary.

Mr. AZAR. And we do support efforts towards greater transparency.

Mr. CARTER. I know you do, and I look forward to working with you. Thank you very much.

Mr. BURGESS. Gentleman's time has expired.

The Chair recognizes the gentleman from New Mexico, Mr. Luján, 5 minutes for questions.

Mr. LUJÁN. Mr. Chairman, thank you very much.

Mr. Secretary, thank you for being here today, as well.

Mr. Secretary, I am going to ask you a yes-or-no question off the top here. There is \$1.4 trillion less in the budget for the Medicaid program, yes or no?

Mr. AZAR. There is a \$1.2 trillion new fund that would replace the Medicaid expansion and the individual subsidy program under the Affordable Care Act.

Mr. LUJÁN. You're talking about Graham-Cassidy?

Mr. AZAR. Yes. Exactly.

Mr. LUJÁN. So would you agree with the CBO's score—that the CBO said at the very least that Graham-Cassidy reduces Medicaid by \$1 trillion? Are you unaware of that?

Mr. AZAR. I don't know the net score on this. You've got the \$1.4 trillion that would come down, but the 1.2 that would actually replace it through the grant program there. So I don't know the ups and downs on the complete CBO scoring with regard to which part is expansion and where the subsidy—the advanceable, refundable tax credits fit into there.

Mr. LUJÁN. So, Mr. Secretary, I mean, there can be a lot of spin around this, in the same way that during the repeal-and-replace effort my Republican colleagues said that they were not cutting Medicaid—that they were giving more flexibility to the States. Is that how you would describe the \$1.2 trillion that you’re describing here?

Mr. AZAR. Well, no. The core Medicaid program—the old—the traditional Medicaid will grow under our budget from about \$400 billion over 10 years to \$453 billion.

The Medicaid expansion does get rescinded as part of the Graham-Cassidy plan and is replaced along with the individual subsidy program with that \$1.2 trillion grant program.

Mr. LUJÁN. Let me ask the question a different way. President Trump, on several occasions, said that he would not cut Social Security, not cut Medicare, not cut Medicaid.

May 7th, 2015, 10:40 a.m., he tweets, “I was the first and only potential GOP candidate to state there will be no cuts to Social Security, Medicare, and Medicaid.”

July 11th, 2015, 3:23 a.m., “Republicans who want to cut Social Security and Medicaid are wrong.”

A quote to Daily Signal: “I am not going to cut Social Security like every other Republican. I am not going to cut Medicare or Medicaid.”

Did the President keep his word in his budget?

Mr. AZAR. You know, with regard to—

Mr. LUJÁN. Yes or no, Mr. Secretary. Did he keep his word?

Mr. AZAR. Well, with regard—with regard to Medicare—

Mr. LUJÁN. Mr. Secretary—

Mr. AZAR [continuing]. What we are proposing there is to actually reduce by \$250 billion over 10. The rate of growth goes from 9.1 percent annual increases to 8.5 percent. It doesn’t take from beneficiaries. It actually continues to grow.

Mr. LUJÁN. Mr. Secretary, did the President keep his word that he would not cut Medicare, Medicaid, and Social Security in his budget?

Mr. AZAR. I can’t speak to Social Security, and then as to the core fundamental—

Mr. LUJÁN. Mr. Secretary, let me ask you the question differently then. Did the President keep his word that he would not cut Medicaid and Medicare?

Mr. AZAR. The President kept his word that we are not taking from beneficiaries in Medicare, and for Medicaid the President—

Mr. LUJÁN. Will the President—Mr.—

Mr. AZAR [continuing]. Has repeatedly been supportive of repealing and replacing Obamacare, and Medicaid expansion is part of that. He was clear from day one in his campaign about that.

Mr. LUJÁN. Mr. Secretary, he didn’t mention beneficiaries here. He said he would not cut Medicare and Medicaid and Social Security. He would not “cut Social Security and Medicare and Medicaid like every other Republican.”

Did the President keep his word that he did not cut Medicare and Medicaid?

Mr. AZAR. The President is keeping his word that we are supporting Medicare. We are making Medicaid sustainable for the long

term for beneficiaries, and we are proposing the repeal-and-replace of Obamacare, which is not delivering for our people.

Mr. LUJÁN. Mr. Secretary, did you have a hand in developing this budget?

Mr. AZAR. I arrived 14 days ago. So no, I did not.

Mr. LUJÁN. You didn't approve what was submitted?

Mr. AZAR. The budget was already at the printer. If the Senate would have confirmed me sooner, I would have been able to be involved but—

Mr. LUJÁN. Let me ask a question.

Mr. AZAR [continuing]. I arrived 14 days ago after—

Mr. LUJÁN. Let me ask you a different—

Mr. AZAR. I can only do what I can do.

Mr. LUJÁN. Let me ask you a different question: Do you support the President's budget?

Mr. AZAR. I do support the President's budget. That's why I am here today.

Mr. LUJÁN. Did you keep your word that you would enforce not cutting Medicaid and Medicare as you answered to Senator Ben Nelson on the January 24th, 2018, Senate Finance Committee—

Mr. AZAR. I never said that I would enforce not cutting. I said the President—

Mr. LUJÁN. Oh.

Mr. AZAR [continuing]. The President does not support—

Mr. LUJÁN. Mr. Secretary—

Mr. AZAR [continuing]. Cutting Medicare and Medicaid.

Mr. LUJÁN [continuing]. Let me read you a quote.

Mr. AZAR. And I support the President's position. I will go along with where the President is on these programs.

Mr. LUJÁN. Mr. Secretary, if I may, there is a great video that's posted. I think C-SPAN has it, CNN has it. And here's what you said when Senator Nelson asked if cutting Medicaid, Medicare, and Social Security should be used to fill this huge budget deficit hole. You believe the President kept his word, and your job as Secretary would be to enforce, not to cut those programs. So I'll stand by that.

Mr. AZAR. As long as that is the President's—

Mr. LUJÁN. Mr. Secretary—

Mr. AZAR [continuing]. I am here to implement Medicare and Medicaid—

Mr. LUJÁN. Last question, if I may, because I am out of time here. Have you collected a check from Dr. Price for his travel on private planes?

Mr. AZAR. I do not know.

Mr. LUJÁN. Have you investigated abuses at HHS with travel?

Mr. AZAR. I've just arrived 14 days ago, so I've been busy getting ready to come here to meet with you today.

Mr. LUJÁN. Mr. Chairman, as my time is expired here, I know that we have talked about oversight hearings in this subcommittee on this issue. They still have not been scheduled.

I look forward to seeing those scheduled so we could get to the bottom of this, and I'll be submitting more questions to the record to find out what's been investigated. This is a serious issue. Mil-

lions of dollars have been squandered, and the American taxpayers deserve—

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

Mr. LUJÁN. Thank you, Mr. Chairman.

Mr. BURGESS. I am certain that Mr. Guthrie will—I mean, Mr. Harper from Mississippi will await your letter.

The Chair now recognizes the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman. I appreciate it, and thank you, Mr. Secretary, for being here. I appreciate it very much. Thanks for your service.

I am on also—in addition to being on this great committee and this subcommittee, I am also vice chairman of the Veterans Affairs Committee.

This gives me a unique opportunity to serve the health needs of various populations. Community health centers—and I was the author of the reauthorization of the community health centers. They do great work.

As a matter of fact, the Administrator of HRSA, Dr. Sigounas, was down in my district recently. We discussed expanding substance abuse services but also mental health services and dental services, as well, and treating even more veterans.

Community health centers already provide quality care to more than 300,000 veterans—as a matter of fact, he told me exactly 330,000 veterans across the country—and are an important source of care for veterans in rural areas, who may not be able to easily access VA facilities.

Can you share with the committee some of the ways in which health centers are working with the VA to address the healthcare needs of our Nation's veterans? What more can we do to improve veterans' access to community health centers, and are you a proponent of community health centers?

Mr. AZAR. So I and we are absolutely proponents of our community health centers, and one of the things that I am very happy about through the budget deal that was reached is that we put the community health centers on secure footing financially and that we also, through our opioid program, we are going to be making significant investments into HRSA and the community health centers. I think \$400 million will go through quality incentive programs to community health centers to assist them on the opioid crisis.

I am not as familiar about veterans issues in connection with HRSA and community health centers and would be very happy to learn more about ways in which we can be supportive and helpful to our veterans through our community health centers.

Mr. BILIRAKIS. Yes, I'd like to work with you on that. So, in other words, the VA people that are in the VA system, we want to make sure that they have an option, a choice, to go to a local community health center, particularly in some of the rural areas where the clinic or the hospital is far away. And I discussed that with Dr. Sigounas, and I have a bill that I'd like to talk to you about.

Again, Mr. Secretary, in the budget submission, you mentioned changing—and again, this is probably—you said that you've only been on the job for two weeks, so it's really not your budget even

though you approved the budget—you mentioned changing the Part D pharmacy lock-in program.

Is your budget proposal trying to reform and centralize the lock-in program inside CMS rather than the Part D plans? Or are you trying to require all plans to initiate a pharmacy lock-in program?

Mr. AZAR. I believe it's just to require the Part D plans to initiate a lock-in program rather than a centralized one. I believe that's the case.

Mr. BILIRAKIS. OK. Very good. Let me get into another issue, because we don't have a lot of time.

Currently, ASPR's disaster medical assistance team is experiencing a staffing shortage. I am sure you're aware of that. As hurricane season is less than four months away, what is being done at HHS to address this serious public health and safety issue?

Mr. AZAR. So we are working—I've actually met with our Assistant Secretary for Preparedness and Response, and we are prioritizing the hiring to ensure that we get our full complement of national disaster medical services individuals for those disaster teams.

You know, one of the important lessons coming out of this unprecedented hurricane season was our need to continue our learning processes for how we can deal with multiple either manmade or naturally occurring disasters and public health threats at one time. That was a really unprecedented episode, and it's a good learning for us.

Mr. BILIRAKIS. Very good. I've got time for one more question, I believe, Mr. Chairman, and thank you for your service, by the way, Mr. Chairman.

Currently, there isn't a clear standard for medication-assisted treatment prescribing, and we have heard reports of an increasing number of rogue actors offering MAT.

In many cases, these pop-up clinics actively recruit vulnerable client population and provide standardized—substandard, in my opinion—services with minimal oversight.

While we support consumer choice, of course, and market competition, we also want to balance this with the consumer safeguards to ensure that this program—the problem improves, not worsens, and that bad actors are not rewarded via Federal dollars.

Additionally, questions have been raised as to whether States are requiring evidence-based practices to be used in the STR grant program.

What is HHS doing to ensure rogue actors are not the recipient of Federal dollars and evidence-based practices are being used so that the funds expended go to providing the best possible treatment in recovery services?

Mr. BURGESS. If the gentleman will suspend. The Chair is going to ask if he would submit that in writing. We do have Members who are—

Mr. BILIRAKIS. Yes, can you please do that? I would appreciate it if you addressed that.

Thank you very much, and I yield back, Mr. Chairman.

Mr. BURGESS. And I thank you for your accommodations.

The Chair recognizes Mr. Cárdenas from California for 5 minutes, please.

Mr. CÁRDENAS. Thank you, Mr. Chairman. Secretary Azar, I am glad you were able to join us today and I look forward to your answering some of my questions.

I'd like to begin by talking about Scott Lloyd, the head of the Health and Human Services Office of Refugees Resettlement. Tremendous responsibility. This is a man who has shown complete disregard for the U.S. Constitution.

He abuses his authority and tries to enforce his personal beliefs on immigrant women in custody over and over again. He has tried to control women's bodies and violate their constitutional rights to have an abortion.

Mr. Chairman, at this time, I'd like to ask unanimous consent to submit for the record a Washington Post article published today that describes an email reporters obtained from an official Federal contractor. The contractor is V-E-R-A.

The email claims that after a conversation with a Federal employee at the Office of Refugee Resettlement at Health and Human Services, they were directed to prevent their lawyers from discussing abortion access even if minors in custody asked for help to understand their legal rights, or else their multimillion-dollar contract with the Department of Health and Human Services would be jeopardized. For the record, please, Mr. Chairman.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. CÁRDENAS. Thank you so much, Mr. Chairman.

Wow, that sounds like a complete violation of the law to me. Scott Lloyd, the Office of Refugee Resettlement chief—his actions have put young women's lives in danger, even considering subjecting the women to unproven medical experiments, and he personally tried to block a rape victim from getting an abortion.

This is in a memo, and I'll quote from that memo. Quote, "Here there is no medical reason for abortion. It will not undo or erase the memory of the violence committed against her, and it may further traumatize her. I conclude it is not her interest," end quote.

To me, it's just ironic that a man would mention the violence committed on this young girl while at the same time violating her rights.

Why does Scott Lloyd still have a job at Health and Human Services?

Mr. AZAR. Well, first, we don't draw conclusions from media reports, but also these are matters in pending litigation. I am not going to be able to speak to them, nor do I know the facts and circumstances. I have not been able to look into them yet at my time at the Department.

Mr. CÁRDENAS. How committed are you to make it a priority to look into the details of this, which you just mentioned that is now there is litigation going on over this matter?

Mr. AZAR. The mission that ORR has for these young children is a very solemn one, to look out for their health and well-being as well as the health and well-being of their unborn children.

That is a very difficult task. It's an unenviable one, and I think they are trying to do the best they can under the circumstances here to protect both the young girls' health as well as the unborn child's health and to make sure they are standing in here under

their statutory obligations to do this, and we will certainly be looking to ensure that our programs are consistent with the law, that the way we administer them is consistent with court cases as they eventually come out.

Beyond that, I am not able to really comment. I don't have the facts.

Mr. CÁRDENAS. Well, I am glad you answered that way. So maybe you can double down on that answer by expressing before this committee, Members of Congress, about the policies that the Department of Health and Human Services, of which you are now the head, when it comes to following the law and also the U.S. Constitution, it appears to me that that consistency would be incumbent upon any department, any public servant.

Mr. AZAR. I would agree. We will always attempt to follow the law and the court constructions of the law and what our obligations are up against that.

Mr. CÁRDENAS. So are you committed to making sure that not only Scott Lloyd but anybody under your Department would actually make sure that their actions and their interactions with the people that they've been charged in their care that they be consistent with following the Constitution of the United States and the laws passed by this Congress and by Presidents past and present?

Mr. AZAR. We all take an oath. You did. I did. Everyone at the Department takes an oath to support and defend the Constitution and laws of the United States.

Mr. CÁRDENAS. OK. So, again, I asked you earlier how committed are you to make sure that you look into the specific situation that Scott Lloyd has been involved with, that he's now under your purview?

Mr. AZAR. So this is a matter in litigation. I am not going to be able to comment about my personal activity connected to that or the nature of any investigations that we would conduct.

These are matters that are being litigated in the courts right now, and we will follow where the courts end up here, and as I am able to, we will look and determine whether our actions are consistent with the law and with case law as it evolves.

Mr. CÁRDENAS. So you mean to tell this committee, Members of Congress, that you cannot give your own personal opinion about your personal commitment to how much you're going to look into this and how quickly, or whether or not you make it a priority?

Mr. AZAR. I am the head of the agency. My name is on the litigation. I am not able to comment on pending litigation matters or actions that'll be taken pursuant to that.

Mr. CÁRDENAS. I am not asking about actions. I am talking about—

Mr. BURGESS. Gentleman's time has expired.

Mr. CÁRDENAS. I yield back.

Mr. BURGESS. The Chair thanks the gentleman, and the Chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman, and thank you—welcome, Secretary Azar, and congratulations on your confirmation.

I am curious. How many hearings have you had this week?

Mr. AZAR. Three in 24 hours.

Mrs. BROOKS. Yes, that's what I thought. I haven't followed them all, but I know that you have been in the hot seat. And so, congratulations. I hope we are your last for the week, I hope.

Mr. AZAR. I believe so.

Mrs. BROOKS. Good. I want to thank you. In your bio, what I am really thrilled about is the fact that you mentioned part of your work when you were Deputy Secretary focused on advancing emergency preparedness and response capabilities.

It's an issue that I think we don't talk enough about in Congress, and I want to—and because at that time you testified actually as Assistant Secretary of Health in '06 that, and I quote, “we'll work to streamline and make more effective the current BioShield inter-agency governance process. We will make this process more transparent and work to educate the public and industry about our priorities and opportunities.”

A decade has passed since that happened. I don't think we are there yet, and as you know the President's budget proposes to transfer the strategic national stockpile to the Assistant Secretary for Preparedness—ASPR, as you've just talked about meeting with—from CDC, and I think you talked about that transfer in funding.

And this move, as I understand it, will consolidate strategic decision making around the development and procurement of medical countermeasures.

First, I want to state my support for it, and I've included this same proposal in the discussion draft of the PAHPA reauthorization that I am working with my colleague and good friend, Representative Eshoo, that we look forward to working with you and your staff on the reauthorization of PAHPA.

But I want to just ensure that you are familiar with the specific proposal and ensure that you are supporting that proposal as it stands.

Mr. AZAR. Absolutely. In fact, when I was general counsel and Deputy Secretary, where we ran strategic national stockpile out of was something that we thought eventually needed to be with the ASPR, but we didn't have yet the developed procurement capabilities there and management. We now have a very sophisticated program there, and so I think the time is now. It integrates the capability on procurement, on threat assessment, as well as deployment in an operational setting. So I think it's absolutely the right thing to do.

Mrs. BROOKS. Outstanding, and we look forward to working with your staff to make sure that we get it right in the PAHPA reauthorization and also learn whether or not there are any other authorities or things that need to be changed.

You talked about implementation and delivery. That's something I actually want to ask about because we often focus on vaccine development, which can often overshadow vaccine delivery when it comes time, and in a pandemic it's my understanding BARDA said that we could need up to 600 million drug delivery devices over a 6-month period, and our current excess capacity in the marketplace, it can take years to produce different devices.

We certainly learned that during the Ebola crisis. Across the country we did not, for instance, have enough gloves. We did not

have enough masks. We did not have enough things like that, but let alone even the devices that would be needed to execute vaccines.

How do we ensure we have enough drug delivery devices to be prepared when we can't rely alone on the excess manufacturing capacity?

Mr. AZAR. I think that's an excellent question, and that's one of the reasons why it's helpful, I believe, to have the strategic national stockpile connected directly into the Assistant Secretary of Preparedness and Response, so that we line up that holistic sense of genuine care delivery in an emergency, thinking of—you know, for want of a nail, a kingdom was lost—that we don't lack a vial and have a vaccine or lack a needle but have plenty of vaccines. So I think that holistic sense is absolutely part of our mission and our assessment for procurement purposes.

Mrs. BROOKS. I want to just wrap up with my minute that I have left.

Our fellow Hoosier, Director of National Intelligence Dan Coats, said just this week when talking about North Korea's nuclear warheads, he also mentioned they are continuing their longstanding chemical and biological warfare programs.

As you know, over a decade Project BioShield's special reserve fund has created the only market for medical countermeasure development and in 2013, while Congress authorized the \$2.8 billion in funding for the SRF, so far only \$1.5 billion has been authorized.

But I understand that in your budget you've requested SRF be advanced funded at \$5 billion over the next 10 years. Can you talk to us about the consequences if we don't do that to national security and if we don't provide that advanced funding?

Mr. AZAR. It is absolutely vital in BARDA, which is about developing and then eventually for us in BioShield procuring countermeasures that only the U.S. Government is likely the purchaser for, that we be a predictable purchaser.

So for us to get entities to develop therapies or countermeasures, we need to be able to show that we have the money and have the backing of the Congress. And so that's where that type of advance appropriations is absolutely vital for us to be able to secure the commitment from our development partners.

Mrs. BROOKS. Thank you. I am very pleased with your background and expertise in this area and raising these issues to the forefront.

Thank you. Look forward to working with you. I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from New York, Mr. Engel, 5 minutes for questions, please.

Mr. ENGEL. Thank you, Mr. Chairman. Welcome, Mr. Secretary. Congratulations on your appointment.

The President, when he was running for office, said that he would never cut Medicaid and we are, of course, very, very unhappy with potential cuts to Medicaid.

A few months ago, we passed—Republicans passed a tax bill that gave massive breaks to big corporations in the top 1 percent and, when that bill passed, there wasn't a doubt in my mind that the

administration would use the hole that their tax bill blew in the deficit to justify gutting programs that support working families.

And lo and behold, the President's budget cuts are \$1.4 trillion to Medicaid, just shy of the tax bill's \$1.5 trillion price tag.

It isn't subtle. It could not be easier to see that the administration has ways to pay for their legislation. Some of us would say handouts to the wealthiest on the backs of Americans who rely on Medicaid for health use and, even if we set aside the cuts themselves, the policies in this budget give us an idea of the kind of Medicaid experiments that this administration might allow States to try.

If you ask me, those policies are just as distressing as the cuts because the administration to Congress has made very clear that whatever they cannot cut they will so-called reform in ways that will kick people off coverage, and as far as I am concerned, those kinds of reforms are simply cuts by another name.

The administration has already chosen to go against the Medicaid statute by encouraging States to enact work requirements that we know will take health coverage away from Americans who desperately need it, and now the administration is contemplating letting States put in place lifetime limits on Medicaid coverage. That is something that we have fought against for many, many years, and it sends an alarming message, one that I'd like to address right now.

I'd like to quote a parent from my district whose daughter was born with a rare condition, because I think she put it best. This is a quote from what she sent me. She said, "I never thought our family would be in a position to need a safety net—a program like Medicaid. We might not be who you think of when you think of Medicaid. The safety net is there for all Americans."

So let me say, again, Medicaid is not a handout. It's a health insurance program, and it covers nearly one in five adults in my district.

Medicaid is the single largest insurer for America's children, and it is a promise to every American that our country will not forsake them even when the going gets tough.

So I am glad that I welcomed you, because I know you're going to do—it's a hard job you have, but I'd like you to commit to us now that your Department will not approve requests to place lifetime caps on Medicaid health insurance coverage. I know Congressman Kennedy a little before was trying to get you to say that, but I'd feel much better if you can give us that commitment.

Mr. AZAR. So, Congressman, I appreciate your concern there, and I think they are difficult issues, and these are so complex, difficult issues I really cannot here give you an answer on resolving a waiver I have not seen.

We will take that very seriously. We have not stated an invitation or a State Medicaid director approach around that type of issue. And so I really need to work with our teams to see what the issues are, what the legal constraints even are. I don't even know the legal frameworks with regard to any issue of lifetime caps and how that would interact with our waiver or demonstration authorities.

So it would just be entirely premature for me to sit here and give you an answer on that, except to say I would take it very seriously and there has not been a statement of the administration's positions or views with regard to any requests for lifetime caps in Medicaid.

Mr. ENGEL. Well, I hope you will visit this committee many times, and I hope you will listen to what some of us on this side of the aisle are saying. We have some very—as you've heard all afternoon, we have some very serious questions about it.

We don't want any situation where our people are being knocked off of Medicaid—people who really need it, and lifetime caps is something that we have talked about for a long time here, and we were doing the Affordable Care Act when we talked about it.

It comes up quite frequently, and it's really scary. It's scary for people who don't know what they are going to do if this happens.

So I take you at your word. I hope next time you come back, we can have a more thorough discussion on it. But please hear what we are saying today.

Mr. AZAR. I absolutely will, and I appreciate any dialogue that we can have. These are important programs and very difficult issues, and the more minds that we have at bear, the better.

Mr. ENGEL. OK. Thank you. Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman yields back. And the Chair would observe that there was a repeal of the therapy caps in the bill that we passed a week ago, and I hope the gentleman voted for that.

Does the gentleman from Texas continue to reserve?

Mr. GREEN. I want to continue to reserve.

Mr. BURGESS. All subcommittees members haven't been recognized. The Chair will recognize Mr. Welch for 5 minutes. Mine really is 5 minutes, Peter.

Mr. WELCH. Well, I appreciate that and, Mr. Chairman, I thank you, and I thank you for the work you've been doing on prescription drug prices, and that's what I wanted to talk to you about, Mr. Secretary.

You've got incredible experience in the pharmaceutical industry, and that may be something that can be useful. And I start by saying that I think all of us acknowledge that the pharmaceutical industry has done some good things with life-extending and pain-relieving medication. The problem is, they are starting to kill us with the cost.

And if we want to maintain access to healthcare, we have got to really stabilize the cost. I don't care whether we have a Government aid system, employer-based system, or individual-based system. If the price keeps going up way beyond inflation, we are going to be broke.

President Trump has said a lot of tremendous things about price negotiation and about bringing down the cost. You, in your hearing before the Senate, as I understand it, said the core problem is the list prices of the drugs. Am I correct in that?

Mr. AZAR. I'd say actually I think list price is one of the core problems. The other is insuring that, in various parts of our program, we are getting an adequate deal and, for instance, Part B, the physician-administered drugs, is one where it's actually about, are we even getting a good net price. So I'd say—

Mr. WELCH. Right. OK.

Mr. AZAR [continuing]. There are two main parts.

Mr. WELCH. Here's the bottom line. There are a lot of folks on both sides of the aisle who want to bring these costs down, because all of us have consumers that are getting hammered.

There is a real dispute about what role the Government is going to play in taking action to bring these prices down. But sitting on the sidelines, which has essentially been the approach we have taken, is not working.

Two things I want to talk to you about. One is price negotiation, and the other is bringing down the list prices. I mean, just to quote your boss on price negotiation, "We are the largest drug buyer in the world. We don't negotiate. We don't negotiate. You pay practically the same for the country as if you're going into a drug store and buy the drugs individually. If we negotiated the price of drugs, we'd save \$300 billion a year."

Question: Do you, as the Secretary, support what appears to be the position of President Trump to begin price negotiation by Medicare, which is the biggest purchaser of drugs in the world?

Mr. AZAR. So, in fact, in our budget proposal we have a very novel element there. One of the things that I've talked about is, how can we take the techniques that we use to negotiate in Part D and use them in Part B where we do not negotiate—we simply pay a sales price with a markup on it under the statute.

And so we have actually proposed giving me the authority to move drugs from Part B into Part D, where the PBMs can negotiate on our behalf to secure the kind of great deals. We get the best deals of any payer in the commercial marketplace right now in Part D because the PBMs negotiate that for us.

Mr. WELCH. Right. But the Government is the biggest purchaser.

Mr. AZAR. Yes, in Part B, absolutely, and we are not negotiating at all or getting any kind of discounts or deals, and that's why we think it's quite important.

Mr. WELCH. So I just want to understand this. Are you in favor of your agency, essentially, having the authority to negotiate bulk price discounts just like the VA program does, just like many of the State Medicaid programs do?

Mr. AZAR. I think it requires an understanding of how VA is different. VA is actually acquiring medicine as a purchaser, where we're serving as an insurer in Part B and Part D.

Mr. WELCH. Right. Let me interrupt you.

Mr. AZAR. It's a different dynamic and power structure—

Mr. WELCH. I only have 5 minutes. I know it's complicated, and I know you know how to do it. You've got the experience. But there is something that's really simple and elemental that actually was captured by the President's comments.

If you're buying on behalf of the whole country, you ought to get a better price than if you're individually walking into the drug store, per unit, right? That's essentially what he's saying.

Mr. AZAR. And that's why we say in Part B we'd asked for permission for us to use those negotiating techniques in Part D.

Mr. WELCH. Well, the negotiating techniques are bargaining. I mean, you know, Tommy Thompson, who was one of your prede-

cessors, did it when we had the crisis and he had to buy an immense amount of—

Mr. AZAR. Well, that was a procurement. I was actually involved in that.

Mr. WELCH. Well, you guys did a good job.

Mr. AZAR. That was a procurement.

Mr. WELCH. Right.

Mr. AZAR. The difference in Part D, for instance—if that's what you're getting at—is even Peter Orszag, the Democratic head of the Congressional Budget Office and President Obama's OMB Director, has made clear that in Part D the only way one could get better pricing than we do now is if we had a single restrictive, exclusionary national formulary where seniors get—

Mr. WELCH. OK. All right. Let me—this is my last word.

That's right, but what I heard you say to Mr. Carter is that, essentially, the PBMs impose their own formulary by the rebate system they set up, and if you want in, you've got to pay that price.

So they, instead of doctors and pharmacists, are setting a formulary. And in Vermont what we do under Medicaid is, we have got this commission that sets the formulary, but then there is flexibility so that, if a doctor says this particular patient use this particular drug, we do it. So I hope you follow through.

Mr. Chairman, thank you.

Mr. BURGESS. Gentleman's time is expired.

The Chair recognizes the gentleman from North Carolina, Mr. Butterfield, for 5 minutes.

Mr. BUTTERFIELD. Thank you very much, Chairman Burgess, and I apologize for being late for the hearing, and I know you go through this every day. I've been multitasking all day long.

But Chairman Burgess, thank you for holding this hearing. Once again, the administration has shown how out of touch it is with most Americans. It is not surprising that this administration is proposing more changes—yet more changes—to healthcare that will harm the middle class and make it more difficult for our citizens to access quality healthcare.

I am from North Carolina. My constituents want healthcare, plain and simple. People across the country want healthcare.

That is why, despite all the Republican efforts to undermine the ACA, the program is still going. In my opinion it's still going strong, and more than 1 million Americans signed up for the ACA for the first time after President Trump pulled the rug, or attempted to pull the rug, from under the program.

This budget ignores the wishes of our constituents who flooded our offices with calls, asking us to protect the ACA and protect Medicaid from Republican efforts to gut these programs.

It also ignores the bipartisan will of Congress. They just approved a 2-year budget with increased funding for important health programs like the National Institutes of Health. This budget would take healthcare away from my constituents, and I strongly oppose it. I voted for the Budget Deal Act last week.

Since the Affordable Care Act was first implemented, the uninsured rates steadily declined year after year. From 2010 to 2016, 20 million Americans gained health insurance. Unfortunately, this

administration has done everything it can to reverse that, in my opinion.

Since President Trump took office, the Department of Health and Human Services has done its best—in my opinion, again—to sabotage health coverage for individuals, make it harder for people to get covered.

As a result, for the first time since the ACA was implemented—and it was this committee that implemented the ACA, I was part of it—the uninsured rate actually increased for the first time.

According to Gallup, 3 million more Americans were uninsured in 2017 compared to the previous year. It was also the largest single-year increase that has been observed since Gallup began collecting this data. Quite an accomplishment, after years of seeing the uninsured rate go down.

Now, Mr. Secretary, I understand from my staff you've been on the job for 14 days, so I won't be brutal with you, even though I have some very strong feelings. I understand when you're new to something, you have to get acclimated.

But yes or no, please: Do you agree or disagree, sir, that 3 million more uninsured does not reflect—well, first of all, do you agree with the 3 million number? Is that accurate?

Mr. AZAR. I don't know that that's accurate. I just—I don't know. I don't have the current, up-to-date uninsured numbers after the enrollment period that came out of the Affordable Care Act enrollments.

We were slightly off this year from the previous year. I don't know the aggregate change on the uninsured.

Mr. BUTTERFIELD. I think all of the stakeholders generally agree there was a tick down.

Mr. AZAR. Slightly.

Mr. BUTTERFIELD. Now, how sharp it was, I don't know—I don't know that answer for sure. But that's not success. Anytime the uninsured rate goes down, that is not a measure of success. Would you agree or disagree?

Mr. AZAR. I think it reflects the problems that we have with the Affordable Care Act on that individual market program. That's why we want to work together to try to change it, to create a program that actually will work and deliver for those 28-plus million Americans for whom this program is not giving them affordable access to insurance.

So we want to work together to try to solve that for those forgotten men and women. We talk so much about the 10 million who are in the individual market there that we are buying insurance for, subsidized, and we forget the ones who have been priced out of that marketplace that we really have to come up with solutions for.

Mr. BUTTERFIELD. But you certainly agree that it's a legitimate goal for all of us as leaders to try to make sure that the population has access to healthcare? That goes without saying.

Mr. AZAR. We all share that goal, yes.

Mr. BUTTERFIELD. OK. And do you make a commitment to us that you will work with us to the extent that you can to make that happen?

Mr. AZAR. Absolutely.

Mr. BUTTERFIELD. According to HHS, minorities are less likely to receive diagnosis and treatment for their mental illness, have less access to it, availability of mental health services, often receive poor quality of mental healthcare.

To address these disparities, Congress just authorized a minority fellowship in 21st Century Cures. We are very proud of that program. This program has been supported for many years to improve healthcare outcomes for racial and ethnic populations by growing the number of culturally competent professionals to serve the underserved.

Last question—yes or no, please: Is HHS proposing to eliminate this program in fiscal year 2019?

Mr. AZAR. I do not recall that program in our budget. I'd be happy to get back to you in writing on that.

Mr. BUTTERFIELD. Get back to me. Get back to me, please.

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

Mr. BUTTERFIELD. That is very important. Thank you for your patience, Mr. Chairman.

Mr. BURGESS. Does the gentleman from Texas continue to reserve?

Mr. BUTTERFIELD. I am not from Texas. Oh. Oh. Oh. I am sorry.

Mr. GREEN. We will be glad for you to come to Texas, George.

Mr. BURGESS. I recognize the gentleman from New York for 5 minutes.

Mr. BUTTERFIELD. He cut me off so sharply, I thought he was coming back at me.

Mr. BURGESS. Five minutes.

Mr. BUTTERFIELD. All right. There is always a little tolerance when Members are winding down, Mr. Chairman. But thank you.

Mr. BURGESS. Mr. Tonko is recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair, and Secretary Azar, first, let me thank you for coming before this committee.

It is my fervent hope that in the days to come we can find ways to work together to make progress on important healthcare priorities for our Nation.

Unfortunately, today you are here to defend what I believe is a mean budget that would take us backwards—backwards with this budget on opioids, backwards on mental health, and certainly backwards on providing affordable, high-quality healthcare for all.

It's often said that a budget is a statement of our values, and after reading this year's budget, the values of the Trump administration couldn't be clearer.

The overreaching, overarching message that I hear is, you're on your own. If you are an individual who has struggled with opioid addiction and you have put yourself on the path to recovery with the help of treatment provided by Medicaid coverage, too bad. You're on your own, and Medicaid has been cut by \$1.4 trillion.

If you are a senior who paid into Medicare all your life and believed this President when he promised over and over again that there would be no cuts to Medicare, too bad—you're on your own to the tune of \$554 billion over the next decade.

If you are a single mom working two jobs to put a roof over your head and using your SNAP benefits to help put nutritious food on

the table, you're on your own. But don't worry, we will send you a box of peanut butter and some Wheaties.

I could go on and on. But simply put, this budget is not reflective of who we are and of our needs, and of our values that I hear about when I am home in New York.

Many of my colleagues have already spoken about the devastating cuts to Medicaid, Medicare, and the Affordable Care Act this budget contains, and I would like very much to associate myself with their remarks.

It cannot be said enough, but you simply can't put forward a legitimate proposal for addressing the opioid epidemic at the same time that you are proposing more than a trillion dollars in cuts to Medicaid. It just doesn't pass the smell test.

Medicaid is the largest payer for behavioral health services in our country and remains our single best tool to address the opioid crisis. The continued partisan attacks on this safety net program put lives in jeopardy and needs to stop now.

Now, even after this administration has talked a big game about prioritizing the opioid crisis, I'd like to dig a little deeper into some specific cuts that I have seen in this budget that will send us backwards in this fight.

First, I'd like to ask about SAMHSA's strategic prevention framework initiative. As the name implies, the flexible funding is used to support State-based strategies to prevent youth substance abuse.

SAMHSA's own data show that States and communities receiving funding from this program have made improvements in reducing the impact of substance abuse.

Secretary Azar, your budget request would cut \$60 million from the strategic prevention framework initiative, which would reduce funding by more than one half. In your budget rationale, you state that this cut is made to prioritize other high-need programs.

So, Mr. Secretary, when we have 174 individuals a day dying of overdoses, what is more high need than continuing investments in proven substance abuse prevention strategies that are very much critical to the inclusive formula for success?

Mr. AZAR. So we actually are investing new money into SAMHSA—\$1.24 billion for opioids. So I believe we have demonstrated a clear and deep—

Mr. TONKO. But you're cutting the prevention program, and prevention treatment and recovery are all important.

Mr. AZAR. I'd want to investigate more about that particular program, but we actually are adding many new programs. I do not know the particulars on that program. I apologize. But the—

Mr. TONKO. But it's the point I am making. You're adding new programs and at the same time drastically reducing standard programs that have really been proven to be successful, and I am trying to figure out the rationale and then the outcome—the final line in terms of the statistics that I shared—174 individuals dying per day.

Mr. AZAR. I'd be happy to get back to you on that particular program. I can just tell you our commitment around the opioid crisis and the SAMHSA's role in it is deep and broad, as evidenced by the \$1.24 billion commitment there just in the 1 year.

Mr. TONKO. OK. I appreciate that and look forward to your response.

Another program that is targeted for cuts is SAMHSA's Screening, Brief Intervention, and Referral to Treatment program, also known as SBIRT, an evidence-based practice that helps screen for potential substance use problems in individuals.

Funding provided by this program helps medical professionals implement SBIRT in their practices and has resulted in at least 2.7 million individuals being screened as of 2016.

The fiscal year '19 budget eliminates all funding for the SBIRT program, claiming that this successful demonstration that has been taken up across the country can be paid for by public and third-party insurance.

I found this rationale extremely odd because one of the things I hear from advocates all the time is the need for better screening and early intervention.

Mr. BURGESS. The gentleman's time has expired. The Chair would ask if he will submit that question in writing. I am certain the Secretary will be happy to respond to it.

Mr. TONKO. I thank the Chair.

Mr. BURGESS. The Chair recognizes the gentleman from Texas for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, and Mr. Secretary, thank you for your patience today and being here, and you've heard from the folks on our side of the aisle, and I share the values.

And I think I've never met a doctor who didn't just want to treat their patients and to make them well. It's hard for us, though, to have that goal of making someone well when you start talking about lifetime caps, for example.

In an earlier career here, I remember we had "death panels," and if you have a lifetime cap and someone runs out of their Medicaid—so those are issues that need to be worked out on the elected level.

I have the concern about the President's budget because, again, we all heard there's not going to be any cuts in Medicare or Medicaid during the campaign, but today we see substantial cuts in Medicaid and Medicare. Cutting \$500 billion in Medicare and more than \$1.4 trillion in Medicaid is just not what I think a Health and Human Services Agency ought to be doing.

We need to figure out ways we can do it, and my goal is not to have rationed care, and I think that's probably the goal all of us ought to share as Americans, because my goal has been to expand access.

I represent a very urban district in Houston, and until the Affordable Care Act, 44 percent of the people who worked in my district did not get insurance through their employer. And now they have that option—in fact, that requirement. We took away the requirement, but their employers still need it, so there have been some good things.

Mr. Secretary, particularly in light of the ongoing opioid epidemic, does the administration not comprehend the danger of cutting these health insurance programs, and do you agree that people have access to needed healthcare services through that service covered by their insurance?

Mr. AZAR. So we absolutely share the commitment around substance abuse treatment for individuals who are suffering in the opioid crisis and, again, we share the goal. We just have different tactics to get there. We actually believe that our approaches will lead to more people having access to affordable insurance. Reasonable minds can differ about this, but the goal is the same.

We just differ on what we think would get there, and we do believe that it's better for more people to have insurance. We think right now the system is locking so many people out of that in terms of affordability. But we want them to have that access.

Mr. GREEN. Well, the affordability—I would hope that the administration would not cut the subsidies that some of my working poor who, you know, make too much money to get Medicaid but they also don't make enough money to pay for an insurance without the subsidies.

But let me go back to the Medicaid program. Medicaid is the largest single payer of behavioral health in the United States, and financing more than 25 percent of all treatment. But the administration's budget cuts Medicaid by more than 25 percent.

So with cuts like these, it seems like if you cut Medicaid and we still say we want to deal with people with behavioral or opioid addictions, you can't do it. It's like me going to Aetna or Blue Cross and say, "I want insurance, but I am not going to pay for it." That just doesn't work.

The administration continues to pursue repeal and replacement of the Affordable Care Act. But that's a congressional decision, both the House and the Senate, and I would hope the agency would not make decisions on it before it gets guidance from Congress, because that's what the law is.

Can you commit to stopping undermining or sabotaging our health insurance markets and take urgent action to reverse the increase of the uninsured rate?

Mr. AZAR. So we believe in ensuring that our programs help deliver affordable insurance and choice to individuals, and the steps that we take are about trying to create stable markets, stable risk pools. The challenge that we are having on declining enrollment is that our offering is not good. People are being shut out by these radically increasing premiums from the way the market was designed. So we want to make insurance to work for folks.

Mr. GREEN. Let me—I only have 45 seconds left, and I am next to the last for you, so you'll be out of here soon.

But we did that bill in this committee, and we didn't get everything we wanted on the House version. We ended up with the Senate version. But I think we share that. I don't want people paying huge premiums or even subsidizing, but there are ways we can do it. There needs to be a partnership between the administration and the Members of Congress.

I appreciate that you believe we share the goals. With all due respect, it's clear that the budget proposal—we fundamentally do not share the same goals. The picture the administration budget paints is a harsh one where more and more Americans join the ranks of the uninsured every day and, again, in an urban area like I have—not a wealthy area—this would be devastating to folks who are barely on the edge.

And Mr. Chairman, I know I am out of time, and I yield back what I don't have.

Mr. BURGESS. Chair thanks the gentleman. The gentleman yields back and I'll recognize myself for the balance of the time, however much time I may consume, right?

Mr. GREEN. Well, then I'll ask for more time.

Mr. BURGESS. And you have been very generous with us today, and we appreciate it, and historically you've been generous with your time, and I appreciate that, as well.

We did hear a lot today about—and, of course, all of us have been here on the dais all afternoon, so we haven't kept up with any of the news—but, as we kept up with it yesterday and this morning, it did seem, as you listen to those stories, that there perhaps were some significant cues or clues that were missed somewhere along the way.

While some of that will involve other agencies and municipal agencies and not the Department of Health and Human Services, I hope to the extent that there were cues missed to the mental health space that you will work with us in this committee.

We did pass a pretty big mental health title in the Cures bill, and if there is something that you can tighten up administratively or something where you need legislative direction, I just want you to know the committee is prepared to stand by you with that.

I'd also make the observation—and this is information that is readily available on open source—many of the individuals who are involved in this type of crime actually do have some type of psychotropic drug in their system, and that is not to impugn or disparage the use of these medications. But it means that these individuals have intersected with a mental health professional at some point, because these are not compounds that are available over the counter, not frequently something that's bought on the street.

So it does seem that there has been an opportunity, at least, to intersect with a mental health professional, and anything we can do from the agency perspective or legislatively to tighten that up, I'd certainly commit to you that I am willing to work with you on that.

Your predecessor was a colleague of mine, someone who I thought very highly of, and I will tell you from a doctor's perspective, across the country there was a lot of anticipation when Dr. Price was selected as the Secretary of Health and Human Services.

To the extent, going forward, that we can be cognizant—you at the agency and us legislatively—cognizant of things we can do to reduce the burden on physicians and people who actually provide the care—insurance, yes, that's one thing. But if you haven't got someone there to provide the care, the darn insurance card doesn't do you a bit of good. And I do worry that we have put a lot of burden on our men and women who practice medicine in this country.

The electronic health records have been a significant burden. I know there is some concern as we go through some of the Medicare structural reforms. Just for the record, it was important to get rid of the sustainable growth rate formula. We did that. I did think it was going to take longer than 5 years for whatever came next. I lost that argument, and it is to be done under a 5-year time interval.

However, I think you can see from last Friday's vote that the Congress, the legislature is willing to provide, if there is legislative relief that is needed as far as the time line or as far as the flexibility, we are prepared to provide that for you.

Remember that this bill, the Medicare Access and CHIP Reauthorization Act, passed with 393 House votes, 93 Senate votes—big bipartisan majority. A lot of us have a lot of equity and ownership of this, and we want it to be done correctly. That's probably the most important thing.

We have had a number of hearings already. We are going to have another one as MACRA affects small practices, and certainly work closely with Administrator Seema Verma over at CMS. And, again, I just commit to you that we want to do what we can to alleviate that burden.

You had mentioned the interplay between prescription drug monitoring programs and electronic health records. That, I guess, would be one of those opportunities to reduce the burden on practicing physicians, if there is a way to seamlessly integrate that. I don't know if you can do it as far as the privacy concerns. but I think it's something worthwhile to look at.

What I would also say—and I think you've touched on this—there is a lot of data that the Center for Medicare and Medicaid Services has and, to the extent that you can identify a practitioner who is writing an inordinate number of prescriptions, a pharmacy that's filling an inordinate number of prescriptions, a pharmacy that's taking delivery of an inordinate amount of product, these are things that are actually knowable within the data that's locked up in the Center for Medicare and Medicaid Services.

So, again, I hope you will work with us as far as trying—I think too often we will point to our physician community and say, “You guys have got to tighten this up, because we have got an opiate crisis in this country.” And yet, there are places where, from the agency perspective, we could tighten things up and perhaps drill down on where some of those problems actually occur.

You've been very generous with us today. There are going to be questions coming to you in writing. I have several that I will send you.

With that, the subcommittee stands adjourned and, again, thank you, Mr. Secretary.

[Whereupon, at 3:24 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

FEB -9 2018

Administrator
Washington, DC 20201

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pallone:

Thank you for your letter regarding the bulletin recently released by the Idaho Department of Insurance regarding potential state-based health benefit plans. We appreciate your attention to this important issue, and we share your goal of ensuring all Americans have access to choices for affordable health insurance that meets their family's needs.

At this time, the Centers for Medicare & Medicaid Services (CMS) does not have any additional information to share regarding this bulletin. We are committed to fulfilling our obligations under the law while continuing to work with states to provide flexibility where possible, and we are happy to keep you informed of any developments.

Again, thank you for your letter and input on this issue. If you have any further questions, please contact the CMS Office of Legislation. I will share this response with the co-signers of your letter.

Sincerely,

Seema Verma

Congress of the United States
Washington, DC 20515

January 31, 2018

The Honorable Alex M. Azar
 Secretary
 U.S. Department of Health and Human Services
 200 Independence Avenue, SW
 Washington, DC 20201

The Honorable Seema Verma
 Administrator
 Centers for Medicare & Medicaid Services
 7500 Security Boulevard
 Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

We write to you with concerns regarding guidelines issued by the Idaho Department of Insurance that will allow insurers to offer “state-based plans” that do not satisfy consumer protections required of individual market insurance coverage under the Affordable Care Act (ACA).¹ These protections guarantee that families can get the care they need, without anyone—like people with pre-existing conditions, pregnant women, or older patients—falling through the cracks. We seek to understand how the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) worked or plan to work with the State of Idaho to ensure that plans comply with Federal law so that consumers in Idaho benefit from the same protections as consumers in every other state.

According to reports, the State of Idaho will allow insurers to offer plans that deny coverage for pre-existing conditions for up to 12 months if the consumer did not maintain continuous prior coverage.² Additionally, under Idaho’s new guidelines, insurers will no longer be required to cover pediatric dental or vision care and may exclude maternity and newborn coverage, so long as they offer at least one plan that covers these benefits.³ Furthermore, under the new guidelines, insurers will be able to charge consumers more based on their health history and age than is currently permitted under Federal law.⁴ There has been no public confirmation that the State of Idaho received Federal approval prior to releasing these guidelines.⁵

The State of Idaho’s new guidelines eviscerate critical protections that are enshrined in Federal law and have the potential to destabilize the health insurance market and raise premiums for thousands of consumers and families in the State of Idaho. Consumers in so-called “state-based plans” will lose access to coverage for critical services, and these plans will drive up costs for people who purchase insurance that satisfies Federal consumer protections, harming those who need health care most. We have questions regarding the extent of HHS’s and CMS’s engagement with the State of Idaho to ensure compliance with Federal law. We request the following documents and a response to the following questions by February 20, 2018.

¹ Bulletin from Dean Cameron, Director, State of Idaho Department of Insurance, to Health Insurance Carriers in Idaho’s Individual Market on Provisions for Health Carriers Submitting State-Based Health Benefit Plans (Jan. 24, 2018).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Idaho says no Obamacare needed for some new insurance plans*, Associated Press (Jan. 24, 2018).

The Honorable Alex M. Azar
The Honorable Seema Verma
January 31, 2018
Page 2

1. Idaho's guidelines appear to violate Federal law that requires policies sold on individual insurance markets comply with certain consumer protections, such as the prohibition of discrimination against individuals with pre-existing conditions.
 - a. If HHS and/or CMS believes that the guidelines are in full compliance with Federal law, please provide any documents that demonstrate the legal justification HHS and/or CMS is relying upon to draw that conclusion.
 - b. If HHS and/or CMS have concluded that any or all provisions of the Idaho guidelines are in violation of Federal law, please provide a copy of any documentation of this conclusion.
 - c. If HHS and/or CMS have concluded that any or all provisions of the Idaho guidelines are in violation of Federal law, please provide a written explanation of the Department and/or Agency's plan to enforce the law, including potential engagement with state regulators and insurers.
2. Please provide all communications between HHS and/or CMS officials and officials from the Idaho Department of Insurance, the Idaho Department of Health and Welfare, the Office of the Governor of Idaho, other state employees, and/or affiliated consultants in which the new guidelines were discussed or mentioned. Such communications should include, but not be limited to, emails, letters, faxes and any other written materials, as well as a list of any meetings, calls or other oral communications that took place between the aforementioned parties. In the case of meetings, calls, and other oral communications, please include the date, time, and location at which such communications took place, as well as a list of individuals who participated.
3. Please provide any analysis HHS and/or CMS has performed to evaluate the effects that the Idaho Department of Insurance's new guidelines would have on coverage and market stability in the State of Idaho. Please also provide any analysis the State of Idaho performed to evaluate the effects of the Idaho Department of Insurance's new guidelines that was submitted to HHS and/or CMS.
4. Are these "state-based plans" risk-adjustment covered plans? If so, how will they comply, given that they do not meet other program rules (e.g., offer all essential health benefits, have actuarial value in a metal tier, etc.)? If not, under what authority and when did HHS and/or CMS exempt them?

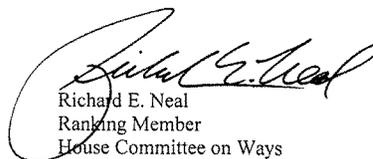
The Honorable Alex M. Azar
The Honorable Seema Verma
January 31, 2018
Page 3

Thank you for your prompt attention to this matter. Should you have any questions, please contact Miles Lichtman of the House Energy and Commerce Committee's minority staff at (202) 225-3641, Melanie Egorin of the House Ways and Means Committee's minority staff at (202) 225-4021, Elizabeth Letter of the Senate HELP Committee's minority staff at (202) 224-6403, or Peter Gartrell of the Senate Finance Committee's minority staff at (202) 224-4515.

Sincerely,



Frank Pallone, Jr.
Ranking Member
House Committee on Energy
and Commerce



Richard E. Neal
Ranking Member
House Committee on Ways
and Means



Patty Murray
Ranking Member
Senate Committee on Health, Education,
Labor, and Pensions



Ron Wyden
Ranking Member
Senate Committee on Finance

Congress of the United States
Washington, D.C. 20515

February 8, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

As you begin your tenure as the Secretary for the Department of Health and Human Services (HHS), we are encouraged by steps you have already taken to address potential conflicts of interest and to ensure that all HHS employees fulfill their critical responsibilities in an impartial and fair manner. For that reason, we want to bring to your attention our serious concerns about the current Chief of Staff to the Office of Civil Rights (OCR), March Bell. Mr. Bell previously served as Staff Director and Chief Counsel for the Select Investigative Panel of the House Energy and Commerce Committee (“the Select Panel”). As members of that Panel, we were concerned about Mr. Bell’s service at the time, we are deeply disturbed about evidence we learned about later that Mr. Bell may have acted improperly during that investigation by secretly coordinating with outside groups. Mr. Bell’s reported statements and actions call into question his conduct, judgment, and ability to meet professional standards of impartiality and fairness.

The Select Panel was created in the wake of highly-edited and fraudulent videos created by David Daleiden and the Center for Medical Progress that targeted reproductive health care providers. At many points during the investigation, the Democratic Members of the Panel raised concerns about the possibility that Majority staff and Members were improperly receiving documents and other information from David Daleiden and his associates, and that those documents were never shared with Democrats. We voiced those concerns in letters to Select Panel Chairman Marsha Blackburn, which are attached here, and which went unanswered by Chairman Blackburn.¹ In addition, after the Select Panel’s hearing on April 20, 2016, Chairman Blackburn stated that she did not believe any of the documents in the Panel’s possession were provided by David Daleiden, instead contending that the documents were from “whistleblowers” and were obtained through other investigative means.

In fact, during a discussion at the Law of Life Summit held in January 2017, Mr. Bell allegedly stated that the Panel Republican’s investigation relied on “lots of phone calls with David Daleiden,” and also noted that he spoke with Troy Newman of Operation Rescue and Mark Crutcher of Life Dynamics during the Select Panel’s investigation.² Mr. Newman and Mr. Crutcher are well known anti-abortion advocates who worked closely with Mr. Daleiden to release

¹ April 7, 2016, Letter to Chair Blackburn from Ranking Member Schakowsky and Select Panel Members.

² <http://www.rightwingwatch.org/post/at-anti-choice-event-hope-that-planned-parenthood-clinics-will-fall-like-dominos/>

the fraudulent videos. Mr. Newman was a founding board member of the Center for Medical Progress, and his organization, Operation Rescue, has led targeted campaigns against reproductive health care providers for many years. Moreover, Democratic Members of the Select Panel specifically called for David Daleiden to testify under oath in our investigative plan, but yet again, the Chairman refused to meet with us to discuss the scope and rules governing the investigation and never responded to our request that Mr. Daleiden be brought in to testify³. Mr. Daleiden is currently under indictment in the State of California, where he has been charged with fifteen felonies for illegally recording confidential communications and committing a conspiracy.⁴ Finally, in his comments at the Law of Life Summit, Mr. Bell reportedly said that the ultimate goal of the Select Panel was to weaken Planned Parenthood, despite claims made by Republicans regarding the purpose of this investigation⁵.

The Select Panel's investigation was wrought with improprieties, procedural abuses, and unprofessional conduct.⁶ However, if it is true that Mr. Bell spoke with those individuals throughout the investigation, it calls into question any remaining legitimacy of the Panel as well as Mr. Bell's professional integrity. Given the ethical questions surrounding Mr. Bell's conduct and actions during the Select Panel's investigation, we respectfully request that, at the very least, Mr. Bell be recused from any case pending before OCR pertaining to fetal tissue or abortion services. It is clear that Mr. Bell is not an impartial investigator on those topics, and we do not believe he can be trusted to fairly adjudicate any related cases.

Thank you for your prompt attention to our concerns. We look forward to receiving your response.

Sincerely,

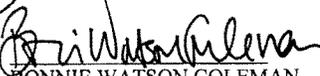

 JAN SCHAKOWSKY
 Member of Congress


 DIANA DEGETTE
 Member of Congress


 SUZAN K. DELBENE
 Member of Congress


 JERROLD NADLER
 Member of Congress


 JACKIE SPEIER
 Member of Congress


 BONNIE WATSON COLEMAN
 Member of Congress

³ November 2, 2016, Letter to Chair Blackburn from Ranking Member Schakowsky.

⁴ https://oag.ca.gov/system/files/attachments/press_releases/Complaint%20Affidavit_SF.PDF?

⁵ <http://www.rightwingwatch.org/post/at-anti-choice-event-hope-that-planned-parenthood-clinics-will-fall-like-dominos/>

⁶ Report of the Democratic Members. *Setting the Record Straight: The Unjustifiable Attack on Women's Health Care and Life-Saving Research, Section IV*, December 2016.

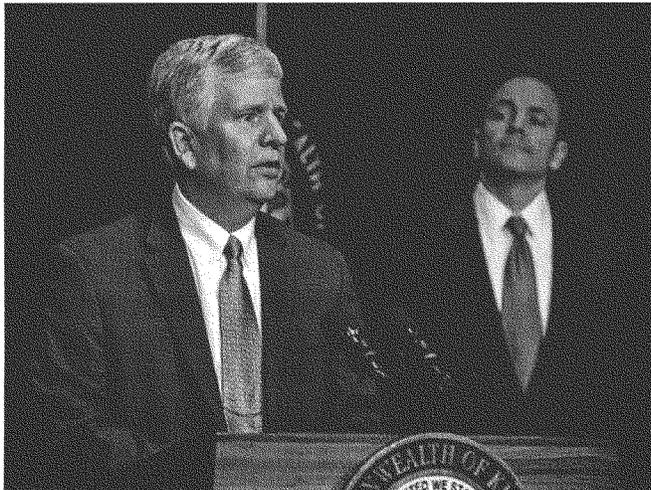
<https://www.courier-journal.com/story/news/politics/2018/02/14/kentucky-medicaid-changes-bevin-work-requirements/319384002/>

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Bevin's Medicaid changes actually mean Kentucky will pay more to provide health care

Deborah Yetter, Louisville Courier Journal Published 10:46 a.m. ET Feb. 14, 2018

Under Gov. Matt Bevin's Medicaid plan, it actually will cost Kentucky more to provide health coverage to people affected by the Medicaid changes than if the state did nothing. Mary Ann Gerth/Courier Journal



(Photo: By Michael Clevenger, The Courier-Journal)

Within Gov. Matt Bevin's complex plan to reshape the state Medicaid program to cut costs and hold people accountable is this fact that may surprise some Kentuckians:

Under Bevin's plan, it actually will cost Kentucky *more* to provide health coverage to people affected by the Medicaid changes than if the state did nothing.

Cost savings come from the assumption that nearly 100,000 people will drop out of Medicaid by the end of the five-year project recently approved by the federal government. For those who remain, the monthly cost of care increases faster than it would have had the state made no changes, according to the administration's projections.

"You're spending more money to cover fewer people," said Dustin Pugel, a policy analyst for the Kentucky Center for Economic Policy in Berea and a critic of the Bevin plan. "I'm not crazy about the idea of us spending more money to cover fewer people."

Meanwhile, Kentucky plans to spend close to \$374 million over the next two years — most of it in federal money — to launch the plan starting July 1.

It has added \$186 million to the current budget and proposes \$187 million in the next budget year starting July 1 for administrative costs, most of the money associated with the Medicaid changes. Part of the administrative costs added to this year's budget would go toward creating a Medicaid computer system required by the federal government.

Much of the money will go to adding technology to track compliance with new rules that require some people on Medicaid to work, train for jobs or volunteer at least 20 hours a week and pay monthly premiums. Those changes are expected to affect fewer than 200,000 people out of the 1.4 million Kentuckians enrolled in the federal-state health plan.

Critics of the plan argue that's a lot of money for a plan aimed at a small fraction of the Medicaid population.

"The math, so far as we know it, doesn't seem to support all the effort that's going into this," said Bill Wagner, CEO of Louisville's Family Health Centers, a network of community health clinics that serves about 40,000 individuals a year, more than half covered by Medicaid.

But the goal isn't just to save money. Rather, it's to get more people into jobs that provide health coverage, Tim Feeley, the deputy secretary of the Cabinet for Health and Family Services, recently told a legislative panel.

"The goal here is to get people working and off Medicaid and into private insurance, to improve their health and give them the satisfaction of working," said Feeley, whose cabinet administers Medicaid.

Bevin has said he wants to provide more Kentuckians with the "dignity" of work.

"This is a program that will allow people to rise up out of poverty," Bevin said last month as he announced that federal officials had accepted Kentucky's Medicaid changes, making it the first state to win federal approval for work requirements for some enrollees.

Advocates argue the majority of those in Kentucky affected by the changes already work at low-wage or part-time jobs with no health coverage.

The changes are aimed largely at the "expansion population" of about 480,000 adults added to Medicaid under the Affordable Care Act, or Obamacare, which allowed states to add anyone up to 138 percent of the federal poverty level, an annual income of about \$16,400 for an individual. But they apply only to "able-bodied" adults, exempting those such as pregnant women, a parent caring for a child, disabled people or those considered "medically frail."

That leaves roughly 200,000 individuals covered by Medicaid who would have to meet the new requirements or lose benefits, Scott Brinkman, Bevin's cabinet secretary, told a legislative panel in July.

What Bevin says are his next steps are if his proposed overhaul of the federal-state health plan should be struck down in court. Mary Ann Gerth/Louisville Courier Journal

Administration officials say the changes will result in cost savings to the state's \$11.5 billion Medicaid program, which gets about 80 percent of its money from the federal government.

But Kentucky Medicaid Commissioner Stephen Miller told the legislative human services budget subcommittee last week that the state will see no savings from the changes in the next two budget years.

But in budget years "three, four and five," Kentucky expects to see savings of \$2.4 billion, about \$300 million of that in state funds and the rest, federal.

State officials acknowledge costs will increase to cover adults affected by the changes over the five-year life of the plan known as a "waiver."

That's because the administration assumes that the healthiest Medicaid enrollees are the most likely to get better jobs with health insurance or improve their incomes under "community engagement" rules that require activities including employment, job training or volunteering 20 hours a week, said Doug Hogan, a spokesman for the Cabinet for Health and Family Services, which runs Medicaid.

That will allow them to leave Medicaid while sicker, higher cost individuals such as the "medically frail" remain enrolled, resulting in higher individual costs, Hogan said.

Medicaid calculates costs on an average "per member per month" basis, and state projections show such costs rising faster for people under the waiver than they would had the state not enacted the waiver.

State Rep. Joni Jenkins, a Louisville Democrat, said she wonders if it's all worth it.

"It seems like we're going through a lot of gyrations at the end of the day to save not that much money," she said.

"But it's all about dignity," Jenkins said in a reference to the governor's comment. "What price can you put on dignity."

Health advocates are skeptical people will leave Medicaid because they get better jobs. Rather, they say, the complexity of the program, its increased demands that people report work or volunteer hours and monthly premium payments are more likely to cause people to lose coverage.

"More than anything we are concerned about the complexity of the program even for those who are working," Wagner said. "There are so many more opportunities for people to lose coverage."

People who don't meet requirements could have benefits cut or be locked out of coverage for six months.

The waiver includes what the administration terms "on ramps" to regain coverage, such as taking a "financial literacy" class. But Wagner said he's doubtful.

"They talk about on ramps for people to get back on," he said. "The off ramps have many more lanes."

Jenkins said she was surprised to learn the state plans to spend \$187.5 million next year — \$170 million of that from the federal government — to build a computer system in part to track work hours of Medicaid enrollees, many of whom already are working.

"I was a little amazed to hear it was \$187 million," she said. "It looks like we're going to spend a whole lot of money to track the working poor to make sure they are compliant with the work requirements."

"It looks like we're going to spend a whole lot of money to track the working poor to make sure they are compliant with the work requirements."

State Rep. Joni Jenkins, D-Louisville

Health advocates including Wagner also are worried about the aggressive timetable for the changes.

Wagner said health providers and patients need detailed information soon about how the new program will work and how patients and providers can comply with the rules.

Miller, the Medicaid commissioner, told the legislative committee last week that such information is coming, probably by mid-March.

"There is a detailed communication plan that will be rolled out," Miller said. "That has to happen, and it will happen."

Meanwhile, the state has a big job to expand its benefit computer system known as Benefind, which it has said it plans to use to track most of the Medicaid changes such as billing and collecting premiums and tracking work or volunteer hours, policy analyst Pugel said.

"They currently have no systems in place to do any of this," he said. "At least not publicly."

Miller has said the state will rely on Deloitte, the contractor who designed the Benefind system, to implement much of the technology.

Wagner said he hopes it doesn't encounter the same problems Benefind did when the Bevin administration launched it in early 2016. The system caused massive problems for people and disrupted essential health, food assistance and other benefits for thousands of Kentuckians.

The problems took months to straighten out and prompted inquiries from lawmakers bombarded with phone calls from desperate constituents.

"It was a nightmare," Wagner said. "This is much more complex."

Deborah Yetter: 502-582-4228; dyetter@courier-journal.com. Support strong local journalism by subscribing today: www.courier-journal.com/deborahy.

Congress of the United States
Washington, DC 20515

December 1, 2017

Eric Hargan
 Acting Secretary
 U.S. Department of Health and Human Services
 200 Independence Ave SW
 Washington, DC 20201

Dear Acting Secretary Hargan:

As Members of Congress, we are gravely concerned about the treatment of young, undocumented women under the control of the Office of Refugee Resettlement (ORR) in the Department of Health and Human Services (HHS). These young women are being systematically denied access to their rights in violation of the Constitution. The recent case of Jane Doe litigated in *Garza v. Hargan*, has highlighted the extreme lengths to which this administration will go to deny a young woman her constitutional right to access an abortion. While Jane Doe's rights were finally honored, we know that last month there were more than 40 unaccompanied pregnant minors in ORR custody. We fear there are many more Jane Does being denied their rights by ORR and, in particular, by ORR Director Scott Lloyd.

Despite your repeated claims to the press, the case of Jane Doe had nothing to do with enforcing the Hyde Amendment, which restricts federal funding for abortion.¹ Jane Doe secured private funds and private transportation to access care.² Rather, the case, and others like it, was a matter of constitutional rights and the rule of law, both of which your agency has routinely ignored in its myopic crusade against abortion.

The Constitution guarantees women the right to access abortion and prohibits the government from putting an undue burden on that right. Despite this clear-cut constitutional protection, you and your office have wielded an arbitrary veto over young women's decisions to have abortions, including victims of rape. In Jane Doe's case, ORR held her hostage; the agency barred her from leaving her shelter to access care, a clear violation of her Fifth Amendment rights, because it disagreed with her health care choice to have an abortion.

That action, and the arguments the government offered to defend them in court, fly in the face of the rule of law. You claimed the government had "strong and constitutionally legitimate interests in promoting childbirth," an argument that reads more like an excerpt from *The Handmaid's Tale* instead of a valid legal claim.³

For more than a century, courts have held that constitutional protections extend to anyone living in this country, including Jane Doe and others like her, regardless of immigration status. Your argument that

¹ North, Anna. "A detained 17-year-old immigrant wants an abortion. The government went to court to stop her." Vox.com, October 24, 2017. <https://www.vox.com/identities/2017/10/19/16500166/texas-abortion-teenager-undocumented-immigration> (North)

² Complaint for Injunctive Relief and Damages at 9, *Garza v. Hargan*, No. 1:17-cv-02122. (D.D.C. 2017) (*Garza* Complaint)

³ Emergency Motion for Stay Pending Appeal as 12, *Garza v. Hargan*, No. 17-5236 (D.C.C 2017) (*Garza* Motion).

somehow Jane Doe has lost these protections because she seeks an abortion is absurd and has no basis in law. That claim is not only untrue but may create a dangerous precedent that women in this country only maintain their constitutional rights when it complies with the administration's political beliefs. We were relieved to see the D.C. Circuit Court of Appeals stand up for the rights of Jane Doe.

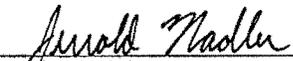
But we know Jane Doe is not alone, and we fear that many other young women's rights are being denied by Director Lloyd and ORR. We have heard deeply concerning reports that HHS now enforces an unconstitutional policy of systematically counseling young women against accessing abortion.⁴ Young women are being forced to visit so-called "crisis pregnancy centers" where they are coerced into revealing their health and sexual history to strangers, often required to undergo invasive and medically unnecessary sonograms, and proselytized by religiously-affiliated counselors.⁵ The government has forced women to inform their families or sponsors of their pregnancies and choice to have an abortion, and even gone so far as to call women's family members themselves.⁶ These actions are a clear violation of these women's First and Fifth Amendment rights.

These grave violations are part of a new, systematic policy of denying women access to abortion at any cost. We have heard that Scott Lloyd himself and other senior HHS officials have personally visited and counseled young women against abortion, threatened punitive action against any shelter that allowed a woman to access abortion, and denied women who request an abortion access to their attorneys.⁷ Further, your agency requested that shelters and grantees provide "immediate and continuing information" to Director Lloyd about detained young women seeking abortion. Your agency has even gone so far as to interfere in a medical abortion by sending a young woman to the emergency room after she had begun her course of treatment.⁸ If these reports are accurate, this policy represents a gross abuse of power. Intimidating and threatening young women over whom you have complete physical and legal control is abusive behavior that goes far beyond any authority granted to you by the federal government and violates your obligation to uphold the Constitution.

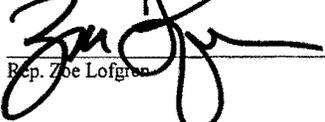
We demand that Director Lloyd immediately cease this policy of intimidation and coercion and comply with the rule of law. Allow young women currently in your custody to access the health care they need, including abortion. Stop denying these women their constitutional rights.

Sincerely,


Rep. Diana DeGette


Rep. Jerrold Nadler


Rep. Louise M. Slaughter


Rep. Zoe Lofgren

⁴ Rayasam, Renuka. "Trump official halts abortion among pregnant teens." *Politico*. October 16, 2017. <http://www.politico.com/story/2017/10/16/undocumented-pregnant-girl-trump-abortion-texas-243844>

⁵ *Garza Complaint* at p 10

⁶ Rayasam

⁷ *Ibid*

⁸ *Garza Complaint* at p 9

Beto O'Rourke
Rep. Beto O'Rourke

Bill Foster
Rep. Bill Foster

Raúl M. Grijalva
Rep. Raúl M. Grijalva

Raja Krishnamoorthi
Rep. Raja Krishnamoorthi

David Scott
Rep. David Scott

Niki Tsongas
Rep. Niki Tsongas

Donald S. Beyer Jr.
Rep. Donald S. Beyer Jr.

Brian Higgins
Rep. Brian Higgins

Judy Chu
Rep. Judy Chu

Salud O. Carbajal
Rep. Salud O. Carbajal

Lois Frankel
Rep. Lois Frankel

Eleanor Holmes Norton
Rep. Eleanor Holmes Norton

Keith Ellison
Rep. Keith Ellison

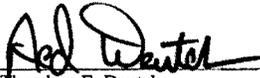
Jan Schakowsky
Rep. Jan Schakowsky

Seth Moulton
Rep. Seth Moulton

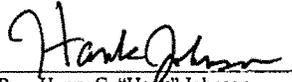
Barbara Lee
Rep. Barbara Lee

Earl Blumenauer
Rep. Earl Blumenauer

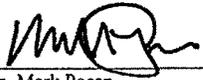
Steve Cohen
Rep. Steve Cohen

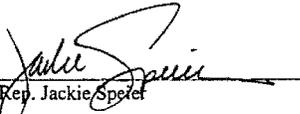

Rep. Theodore E. Deutch


Rep. Adriano Espaillat

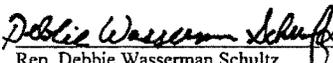

Rep. Henry C. "Hank" Johnson

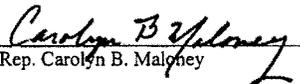

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Rep. Mark Pocan


Rep. Jackie Speier

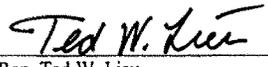

Rep. Mark Takano

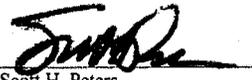

Rep. Debbie Wasserman Schultz


Rep. Carolyn B. Maloney

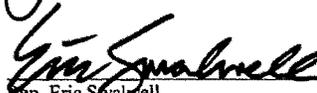

Rep. Keith Ellison

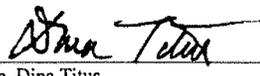

Rep. Marcia L. Fudge

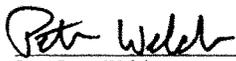

Rep. Ted W. Lieu

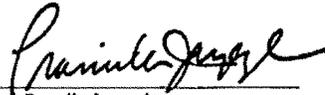

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Rep. Jamie Raskin


Rep. Eric Swalwell


Rep. Dina Titus


Rep. Peter Welch


Rep. Pramila Jayapal

Doris Matsui

Rep. Doris Matsui

John Yarmuth

Rep. John Yarmuth

Suzanne Bonamici

Rep. Suzanne Bonamici

 The Washington Post

Immigration

Immigrant rights group in email says it was warned not to mention abortion to teens

By Ann E. Marimow and Maria Sacchetti February 15 at 4:25 PM

A major legal services group for immigrant children told its lawyers nationwide not to discuss abortion access, even if minors in custody ask for help understanding their legal rights, for fear it would jeopardize a multimillion-dollar contract with the Department of Health and Human Services.

The constraints on what government-funded lawyers can say to young detainees was contained in an email from the nonprofit Vera Institute of Justice, which said it acted after a phone call with an HHS employee. Vera's instruction to lawyers comes as the Trump administration has tried in court to block access to abortion procedures for undocumented teens in federal custody.

"We know for a fact that there is a very real risk to the entire legal services program for children in [Office of Refugee Resettlement] custody if issues other than immigration are addressed in consultations or representation, the abortion issue in particular," a Vera official cautioned in a Feb. 2 email obtained by The Washington Post.

The government pays \$57 million a year under a five-year contract to Vera, which works with 38 organizations in six regions to provide legal help to minors who have crossed the border illegally and without their parents.

In the email, Vera official Anne Marie Mulcahy said she was sending it after a conversation with the government analyst who manages the program within the Office of Refugee Resettlement (ORR) at HHS.

During the call, the employee "directed us to ensure that Vera's legal services providers are not talking to children in HHS custody about abortion," wrote Mulcahy, who is the director of Vera's unaccompanied minors program.

Mulcahy instructed lawyers to immediately strip references to abortion from "Know Your Rights" legal pamphlets and said lawyers could refer children with abortion-related questions to other attorneys.

An HHS spokesman declined to make the employee available for an interview, and independent attempts to reach her were not successful. Mulcahy did not respond to phone and email messages seeking comment.

In a statement, the HHS spokesman said the department “has not issued a new directive on the matter of abortion” to Vera, which it said is under contract “to provide immigration expertise” to unaccompanied minors.

Vera said it routinely is given oral instructions from the ORR.

The department declined to say whether the contract is in jeopardy if lawyers answer questions about or mention abortion rights to the minors and said Vera has not provided it with a copy of the email.

In response to questions about the email, Vera said in a statement: “When given this latest instruction, we issued an email to our legal service provider subcontractors to do two things: protect the program that serves 50,000 children a year, and provide alternative pathways to ensure that children receive the information they need for their health and well-being, including pertinent information about their reproductive rights.”

Immigrants — including children — are not entitled to government-appointed lawyers in immigration court. Federal money for programs like Vera’s is a main avenue for legal advice for unaccompanied children in custody. The group’s lawyers provide one-on-one legal screenings and presentations to advise minors of their rights.

The Vera Institute email directs its lawyers’ attention to how important the abortion issue is to the new head of the ORR.

The office is responsible for the care of approximately 7,700 minors in custody, nearly 70 percent of whom are boys, according to HHS. The minors are facing possible deportation to countries such as El Salvador and Honduras that are ravaged by gang violence and have some of the world’s highest homicide rates.

Mulcahy wrote, “I recognize that this limitation will be concerning to many of you. At the same time, this is a highly sensitive issue right now, and one of utmost import to ORR’s director.”

The ORR chief, E. Scott Lloyd, has refused to “facilitate” abortion procedures for pregnant minors in custody, even at their own expense, triggering a pending lawsuit from the American Civil Liberties Union and a national debate over the constitutional rights of undocumented teens to access abortion services. Since October, four pregnant teens in custody have asked a judge in Washington to force the administration to stop blocking access to abortion services.

Robert Carey, who was ORR director until January 2017, said that under past administrations, Republican and Democratic, the agency did not interfere with the right to obtain abortions.

The federal agency did not pay for the procedures, except in the case of rape, incest or if the teen’s life was in jeopardy, he said. But the agency did not attempt to prevent minors from obtaining abortions through other means nor did it restrict lawyers’ discussions with minors in custody.

Legal experts said the new limitations put lawyers in a bind if they are prohibited from telling teens in custody, for instance, that there is a constitutional right to an abortion.

By reining in what information is provided, they said, the order threatens the role of a lawyer as an independent advocate.

Kari Hong, an immigration law expert who runs a pro-bono program for noncitizens, called the order “very disconcerting.”

“It’s hard to overstate what a breach this is into the communications lawyers are supposed to be providing,” said Hong, who is also a Boston College law professor.

The Supreme Court has upheld restrictions on federally funded family planning clinics prohibiting discussions with patients about abortion. But Hong said that “with gag orders on doctors, the patient is free to walk down the hall or find another hospital.” Children in custody have limited access to lawyers, and she said it’s unrealistic that the minors could find or afford another attorney.

In the email, Vera said its attorneys could refer children to other lawyers not funded by the federal government. “My understanding from ORR is that the referred attorney can then contact the facility and request to meet with the child,” the email says.

Vera said this week that it later followed up with a phone call to legal services providers to say the emailed instructions “do not apply to those cases where lawyers are providing representation to a child, which is covered by many legal and ethical protections.”

The warning to legal services providers drew swift rebuke from members of Congress and from lawyers involved in the broader court challenge to the administration policy related to abortion procedures.

Brigitte Amiri, a lawyer for the American Civil Liberties Union who last year filed the court challenges on behalf of teens in custody seeking abortions, said the instruction to lawyers is “part of Scott Lloyd’s campaign to restrict access to abortion for these young people and it’s deeply troubling.”

She said the ACLU is “investigating the issue and assessing the legality.”

Rep. Jerrold Nadler (D-N.Y.) said the ORR instructions to Vera are a “gross violation of legal ethics.” Rep. Zoe Lofgren (D-Calif.) said Lloyd has “interfered in the constitutionally protected rights of young women who have been placed under his protection” and is “unfit for office.”

Julie Tate and Magda Jean-Louis contributed to this report.

Read more:

He was brought to Virginia as a toddler, deported at 19. He died in an overheated tractor trailer trying to return.

The life sentence he got as a teen came with a chance at parole. But is it a real chance?

Trump election fraud commission bought Texas election data flagging Hispanic voters.

'We will lose practically everything': Salvadorans devastated by TPS decision

 **98 Comments**

Ann Marimow covers legal affairs for The Washington Post. She joined The Post in 2005 and has covered state government and politics in California, New Hampshire and Maryland.  Follow @amarimow

Maria Sacchetti covers immigration for The Washington Post. She previously reported for the Boston Globe.  Follow @mariasacchetti

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Minority (202) 225-3641

March 7, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

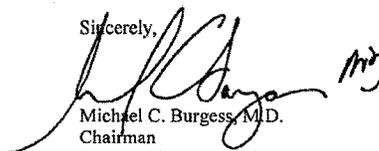
Dear Secretary Azar:

Thank you for appearing before the Subcommittee on Health on February 15, 2018, to testify at the hearing entitled "Oversight of the Department of Health and Human Services."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on March 21, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Questions for the Record

Oversight of the Department of Health and Human Services

Health and Human Services Secretary Alex M. Azar II

February 15, 2018

United States House Committee on Energy and Commerce

Representative Shimkus

Question: I want to alert you to something that will be coming to CMS in the near future that is important to my state and my constituents. The Illinois Hospital Assessment Program expires on June 30 and the State has been working with bi-partisan legislative leaders, and the hospital community on a new plan to update and modernize the program. Bi-partisan legislation will be finalized soon in Springfield, and I look forward to working with you and CMS to ensure it is approved quickly. This program is critical to ensuring patient access to care in my district.

Response: CMS looks forward to reviewing information submitted by the state and working with you however appropriate.

Question: Mr. Secretary, last year each Agency established a Regulatory Reform Task Force and, in September, FDA sent out a request for information on regulations that hurt job creation, are ineffective or impose costs that exceed their associated benefits.

I have heard from employers in my state that the "Intentional Adulteration Rule" which seeks to protect the food supply from those who may intentionally attempt to cause harm to public health.

There is no higher priority for our nation's food companies than a safe food supply, but there is concern that the rule, as drafted, misses the mark. Would you consider speaking to your team about amending the rule to ensure the requirements will indeed do what are intended?

Response: I know that there has been continuing interest in contaminating the food supply by those who wish to do harm to Americans. While this risk is low, it is not zero. As with other forms of terrorism, we must be prepared for this possibility. Many companies have taken steps to protect their products from intentional adulteration. The Intentional Adulteration rule, which is a requirement of the FDA Food Safety Modernization Act, is designed to build upon those efforts.

We have heard concerns about both the cost and flexibility of the Intentional Adulteration rule, particularly around vulnerability assessments. FDA has been working closely with industry on addressing those concerns where appropriate. FDA is also working on a guidance document to help clarify expectations for industry, to identify options for implementing the rule, and to address many of the cost and flexibility concerns that industry has expressed. We anticipate this draft guidance document will be issued soon.

We believe there are some misconceptions about the requirements of the Intentional Adulteration rule. We are committed to an ongoing dialogue with industry to work toward a common understanding of expectations for implementation of the Intentional Adulteration rule, including provisions relating to vulnerability assessments. FDA has collaborated with industry, academia, and government partners on food defense vulnerability assessments for more than a decade, and will continue to do so.

Question: Mr. Secretary, according to some estimates:

- Annual Federal and state government smoking-caused Medicaid payments: \$39.6 billion [Federal share: \$22.6 billion per year. States' share: \$17.0 billion]
- Federal government smoking-caused Medicare expenditures each year: \$45.0 billion
- Other federal government tobacco-caused health care costs (e.g. through VA health care): \$23.8 billion

Do you agree with those numbers or do you have a better data?

Given the high cost to the federal government of smoking-related health care and the potential public health benefits to children who we hope never start smoking, can you describe more thoroughly FDA's plan and timetable to lower the amount of nicotine in cigarettes to minimally or non-addictive levels? Has FDA appropriately prioritized implementation of its plan?

Response: Protecting children from the harms of tobacco use is indeed a high priority. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth in the United States smoke their first cigarette every day, lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit more easily.

The Federal Food, Drug, and Cosmetic (FD&C) Act provides FDA with the authority to establish tobacco product standards. This includes the authority to adopt a tobacco product standard if the Agency finds that it is appropriate for the protection of the public health. In making such a finding, the Agency must consider scientific evidence concerning: (1) The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

To begin the process, FDA has initiated a public dialogue about lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels. FDA has issued an advanced notice of proposed rulemaking (ANPRM) to obtain information regarding the issues FDA would need to address in a tobacco product standard regulation to regulate nicotine levels in combustible cigarettes and render them minimally or non-addictive using the best available science to determine a level that is appropriate for the protection of the public health. The public docket for this ANPRM will be open for ninety days, and comments must be submitted on or before June 14, 2018, via regulations.gov. Reviewing the science and hearing from stakeholders will help FDA form the basis for regulatory action.

If FDA determines that a rule establishing a maximum nicotine level is appropriate for the protection of the public health, among the next steps would be for FDA to issue a proposed rule and obtain public comment. Then, after consideration of comments from stakeholders, FDA could publish a final rule establishing a maximum nicotine level in cigarettes.

Question: A variety of programs within the Department of Health and Human Services (HHS) have been an essential resource for antibiotic research and development (R&D) and additional efforts to combat antimicrobial resistance (AMR). Despite modest but important progress, the antibiotic pipeline remains very fragile. Many of the influenza deaths we're seeing this season are actually due to secondary bacterial infections like pneumonia, which are extremely difficult to treat due to antibiotic resistance. This would

be far worse in a true pandemic. Are there additional tools or resources that would strengthen HHS's work to spur antibiotic R&D and combat AMR? What more could and should be done in this area?

Response: The Department of Health and Human Services (HHS) is an active participant in implementing the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB).

HHS is creating important new tools and collaborations to understand the mechanisms of antimicrobial resistance and facilitate the development of diagnostics, vaccines, and therapeutics to address antibiotic-resistant bacteria.

NIH, CDC, and FDA are collaborating to develop the National Database of Resistant Pathogens. This Database will serve as a global repository for genomic data on drug-resistant pathogens. The National Institute of Allergy and Infectious Diseases (NIAID) at the NIH is sequencing high-priority reference strains for the Database to facilitate research on drug resistance mechanisms, and to advance the development of new diagnostics, therapeutics, vaccines, and other antimicrobial strategies. NIH scientists also are working with colleagues from CDC and other institutions to improve our understanding of gram-negative bacteria responsible for bloodstream infections that are among the most deadly and difficult to treat. In addition, NIAID supports the Antibacterial Resistance Leadership Group, which oversees clinical research to reduce the public health threat of antibacterial resistance.

NIH, through NIAID, is partnering with BARDA on multiple efforts to enhance the pipeline of antimicrobial products that could be used to diagnose, treat, or prevent antimicrobial-resistant infections. NIH and BARDA participate in the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X. CARB-X is an international public-private partnership for the early discovery and development of novel diagnostics, antibiotics, and vaccines that can be used to address the problem of antibiotic resistance. NIAID provides preclinical services and technical support to CARB-X awardees. NIH also has partnered with BARDA to launch the Antimicrobial Resistance Diagnostic Challenge competition to solicit innovative, rapid, point-of-need in vitro diagnostic tests to combat the emergence and spread of drug-resistant pathogens. CDC and FDA are providing additional technical and regulatory expertise for the Challenge. The Challenge competition may award up to \$20 million in prizes. Final awards following the three phases of the Challenge are expected in 2020.

Representative Burgess

Question: Mr. Secretary, the HHS budget proposal suggests requiring doctors who receive Federal funding and are enrolling in Medicare, Medicaid, or CHIP to use centralized CMS screening. Current regulations allow State Medicaid Agencies to rely on CMS screening, but doctors may still be subject to duplicative screening because of other screening programs (such as other state and Federal programs and managed care plans). I am interested in this idea, because some GAO and OIG work suggests states have struggled to successfully implement timely, efficient provider enrollment requirements. Could you please share your thoughts about ensuring this proposal would not just federalize the challenges and create a bigger headache for CMS who has also struggled?

Response: As you note, the budget proposes requiring providers who receive Federal funding and who are enrolling in Medicare, Medicaid, or CHIP to use centralized CMS screening as necessary under Federal law. Regulations currently allow State Medicaid Agencies to rely on CMS screening, but providers are still subject to duplicative screening in many instances as multiple state and Federal programs and managed care plans may screen a single provider.

This proposal significantly reduces the administrative cost and burden associated with provider screening for Medicare Administrative Contractors, Medicare Advantage plans, State Medicaid Agencies, and Medicaid Managed Care plans and limits their exposure to making improper payments, especially for states that may not have the resources to fully comply with existing screening requirements, such as fingerprint-based criminal background checks. We note that screening is not equivalent to enrollment; however, CMS would provide all federally required screenings necessary for enrollment eligibility.

This proposal utilizes already established centralized screening procedures to bring consistency and accuracy to fraud, waste and abuse prevention across all federally funded healthcare programs. CMS has the infrastructure in place to efficiently and effectively conduct all federally mandated screening requirements. For example, CMS has implemented the Advanced Provider Screening (APS) system, which has the capability to continuously monitor all providers that receive Federal direct/indirect funding for licensure status, criminal history, death master file, and OIG exclusions in an automated manner. Federally funded healthcare programs would also be able to leverage CMS's existing fingerprint and site visit verification operations. Screening information would be easily accessible via the Provider Enrollment, Chain, and Ownership System (PECOS), CMS's centralized repository of provider screening and enrollment information. State Medicaid Agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening.

Question: The budget requests Congress clarify the authority for the Healthcare Fraud Prevention Partnership created under President Obama. If Congress were to provide this public-private partnership between CMS and health plans with explicit authority, the Partnership will be able to clearly define the rules and responsibilities of its members and expand the scope of allowable activities to address the full spectrum of fraud and abuse in the healthcare sector, particularly efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse. I suspect this kind of idea would have strong bipartisan support in this Committee. So, would you commit to your staff getting us the specifics you think would help strengthen this program integrity effort in a timely manner?

Response: HHS staff would be happy to work with your staff to provide additional information on this proposal. Currently, the Healthcare Fraud Prevention Partnership operates under the authority established for the Health Care Fraud and Abuse Control Program, which allows for data sharing to address fraud and abuse in health insurance. By providing explicit authority, the Partnership will be able to clearly define the rules and responsibilities of its members and expand the scope of allowable activities, to address the full spectrum of fraud and abuse in the healthcare sector, such as efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse.

Question: Mr. Secretary, I'm concerned about the significant impact the application of the sequester on Medicare Part B drug payments, specifically those used in the treatment of cancer and other serious diseases. Couple years ago, I joined a letter with 123 bipartisan House members to CMS inquiring about their authority to apply the sequester to Part B drugs payments – as the reimbursement rate of those drugs (ASP+6) is already defined in statute. Yesterday, our Oversight and Investigations Subcommittee held a hearing entitled "Examining the Impact of Health Care Consolidation". The application of the sequester is having a negative impact on patients by fueling consolidation of their providers into more costlier settings, such as hospitals. Is this an issue we can continue to work on and where our offices can be engaged?

Response: I am happy to work with your office to learn more about this issue. HHS is committed to enacting reforms to ensure our healthcare programs work for the American people, provide Americans with access to care that meets their needs, increase options for patients and providers, and build financial stability and responsibility.

Question: Mr. Secretary, Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) enacted broad reforms to the Medicare Clinical Laboratory Fee Schedule (CLFS), so that Medicare rates for clinical laboratory services would be reflective of the private market rates of all laboratories. The goal of CLFS reform is to create fair and accurate reimbursement so that the Medicare program realizes savings and that Medicare beneficiaries have sustainable and robust access to life-saving clinical laboratory diagnostic services. However, the Committee has heard significant concern from both stakeholders and Members of Congress that the data collected by the Centers for Medicare & Medicaid Services (CMS) does not accurately reflect private market prices of the full laboratory market of independent laboratories, hospital laboratories and physician office laboratories, and the CLFS rate reductions that began on January 1 of this year will threaten Medicare beneficiary access. Due to our concerns with PAMA implementation and artificially low reimbursement rates for laboratory tests, Energy & Commerce Committee has been working diligently with our counterparts on the House Ways & Means Committee and Senate Finance Committee to determine if legislative intervention is required. Staff from the three committees have made a bipartisan and bicameral request to CMS for technical assistance (TA) comments on potential legislative options to amend PAMA and ensure the intent of CLFS reform is realized. Do we have your commitment to engage with CMS and this Committee on our oversight of PAMA and possible legislation?

Response: We are committed to accurate implementation of PAMA. In the Medicare Physician Fee Schedule proposed rule for calendar year 2018 (82 FR 34089), CMS solicited comments to better understand applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods in order to inform us of potential refinements to the private payor rate-based CLFS for future data collection and reporting periods. In response to the solicitation, we received approximately 40 comments with specific recommendations such as improving the accessibility of the CMS data reporting system by removing certain security measures and changing the requirement that applicable laboratories must report data from claims that require manual remittance processes (82 FR 53181). CMS will consider the comments for potential future rulemaking. I understand that my staff have been in touch with the Committee staff to offer technical assistance on legislative options that you may be considering.

Question: Mr. Secretary, I would like to compliment your Department for taking steps to improve the ability of consumers to enroll in health insurance coverage through a private health insurance exchange. There seems to be continued redundancy which comes at the expense of American taxpayers. Could you please share your thoughts on what other positive steps HHS can take to improve the ability of consumers to get coverage under the current market?

Response: The status quo is not working for millions of Americans – whether it is those who are in the insurance market or those who have been left out of it. I look forward to continuing to work to create a health insurance system that is more affordable and responsive to the needs of individuals and their families, so that we have a healthcare system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them, including association health plans and the expanded options for short-term limited-duration insurance.

Short-term, limited-duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other

forms of insurance, or who are otherwise priced out of the unaffordable ACA insurance markets. Americans need more insurance options, and they need less Federal micromanagement of their insurance options.

Question: Mr. Secretary, the National Clinical Care Commission Act (PL 115-80) was enacted on November 2, 2017. The law establishes within the Department of HHS the National Clinical Care Commission that is tasked with evaluating and recommending solutions on how federal programs can better coordinate and support care for people with diabetes and related metabolic syndromes and disorders. Would you be able to provide a status on when the National Clinical Care Commission will be composed?

Response: We look forward to implementing the National Clinical Care Commission Act and setting up this Commission. The National Clinical Care Commission (NCCC) will ideally be composed by late spring or early summer. The Department looks forward to working with the many stakeholders engaged in these issues.

Representative McMorris-Rodgers

Question: I have sponsored legislation in the past to address Medication Therapy Management (MTM) services that a licensed pharmacist can provide to a patient. As you know, patients who are not taking their medications as prescribed cost our healthcare system approximately \$290 billion annually.

As Congress continues its focus on health care reform, do you see an opportunity to further promote MTM services, through legislation or a CMS regulatory pathway or a combination of both?

Response: Thank you Representative McMorris-Rodgers for raising this important issue. I agree that MTM services are a crucial tool we have available to help fight the opioid scourge. In 2017, CMS began testing the Part D Enhanced Medication Therapy Management (Enhanced MTM) Model, in which stand-alone basic Prescription Drug Plans (PDPs) in selected regions can offer innovative MTM programs, aimed at improving the quality of care while also reducing costs. CMS and accepted participants are testing changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and developing innovative MTM targeting and interventions. The objectives for this model are for stand-alone basic PDP sponsors to learn how to “right-size” their investment in MTM services and identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen healthcare system linkages.

Evidence suggests that the MTM services currently offered by Part D plans fall short of their potential to improve quality and reduce unnecessary medical expenditures, most likely due to misaligned financial incentives and regulatory constraints. Competitive market dynamics and Part D program requirements and metrics may incentivize investment in these activities only at a level necessary to meet the minimum compliance standards. Currently, Part D statutory and regulatory MTM provisions require uniform service offerings to enrollees who meet the plan’s program criteria, based on numbers of medications, and chronic conditions and expected annual prescription drug costs. The result is that Part D MTM programs may not include the level of resources nor the type of activities that could have the greatest positive effect on beneficiary outcomes. This model tests the impact of granting stand-alone basic PDP sponsors a limited waiver of existing MTM, benefit uniformity, and other related regulatory and statutory requirements to encourage Part D plans to offer more targeted and effective MTM services.

CMS is using an independent contractor to conduct an evaluation of this model and we look forward to the evaluator's findings.

Question: On November 16, 2017, CMS released the proposed rule entitled "Contract Year 2019, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," where CMS proposed to create a further incentive for plans to utilize MTM programs. Under current requirements, Part D plan sponsors and Medicare Advantage plans are required to meet a medical loss ratio of 85 percent, meaning the plan must not spend more than 15 percent on administrative functions.

The goal is to incentivize plans to spend more on patient care and on items such as quality improving activities (QIA). There has been confusion as to whether the services provided in the Part D MTM program are considered an administrative function or a QIA. CMS is proposing to clarify that Part D MTM programs will fall under the QIA side of the formula.

Do you see this proposal as part of the final rule? Also, classifying MTM program to fall under the QIA side of the formula a first and complimentary step in advancing MTM?

Response: CMS is reviewing the comments received on the proposed rule, and will consider all feedback as we finalize policies for inclusion in the final rule.

***Addendum:* Under the final rule,¹ CMS clarified that qualified MTM programs offered by Medicare Part D plans finalized on April 16, 2018, are allowed to be included as QIA in the calculation of the Medicare medical loss ratio (MLR). We believe this will encourage sponsors to ensure that MTM is better utilized.**

Question: The Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) October 3, 2016 announcement of the participants for the Part D Enhanced Medication Therapy Model is an opportunity to test additional incentives and flexibilities to Part D sponsors. I believe in better health outcomes for patients through proper medication adherence, at the same time we should achieve taxpayer savings, through reduced costs to the government. However, the design, limited geographical regions and duration of the Enhanced MTM Model are a concern and I believe the agency should reconsider aspects of the current model in order to attain more meaningful representation of retail pharmacy participation across the United States, where pharmacists are providing care and services to their patients.

Is there a possibility for CMS to expand the model in order to incorporate more retail pharmacy participation?

Response: That said, the provision of Enhanced MTM items or services may not be tied to use of specific network pharmacies for dispensing of Part D drugs. The model does not waive Part D network access requirements or any other Part D requirement not specifically listed in the Enhanced MTM Request for Applications. For the purposes of this project, CMS has indicated that a successful participant in this model will design an MTM program that effectively engages enrollees at risk for medication-related issues "where they are" as opposed to requiring the enrollee to come to the plan or plan preferred providers for assistance in overcoming a barrier to improved medication use.

¹ <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

Representative Guthrie

Question: On January 19, 2017, the FDA issued a proposed rule on smokeless tobacco products. I understand that the Agency is currently reviewing the more than 10,000 comments to this proposed rule, including comments from the Department of Agriculture.

- a. How has your office incorporated USDA's economic analysis on the proposed rule? If the department has not already reviewed this report, will your commit to reviewing and giving full consideration to the report's findings as you move forward?

Response: FDA received almost 8,000 comments on the notice of proposed rulemaking on smokeless tobacco products and is currently reviewing and carefully evaluating all comments, including the Department of Agriculture's comment, to determine appropriate next steps. As always, we will give full consideration to the comments provided to us by our counterparts in the administration and from industry, stakeholders, and elected representatives.

Representative Bilirakis

Question: Socio-economic status is one factor that drives health costs. We can see some of that data from Medicare Advantage Special Need Plans where they deal with the dual eligible population. How can we better engage with these patient populations to achieve better outcomes?

Response: The Department shares your concern about the impact of socioeconomic factors on healthcare costs and patient outcomes, and is committed to working with stakeholders to address these important issues. There is growing recognition that social risk factors – such as income, education, race and ethnicity, employment, community resources, and social support – play a major role in health, and significant gaps remain in health and in life expectancy based on income, race, ethnicity, and community environment. As you know, the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (P.L. 113-185) required the Secretary to conduct research on issues related to socioeconomic status (SES) in Medicare's value-based payment programs. As required by the Act, in December 2016 the Assistant Secretary for Planning and Evaluation (ASPE) published a Report to Congress that provided a study examining the effect of individuals' social risk factors on quality measures, resource use, and other measures under the Medicare program, as well as analyses of the impact of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. In addition, in Medicare Advantage, CMS implemented an interim response to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability status that was revealed in our comprehensive research conducted over multiple years by creating the Categorical Adjustment Index (CAI). We also note that CMS is implementing multiple model tests focused specifically on populations with social risk factors, such as the Medicare-Medicaid Financial Alignment Initiative.

Question: There is an interim final rule pending at OMB that would address some of the immediate needs of the home medical equipment industry under competitive bidding by maintaining the transition rates in the 21st Century Cures law. This will be a good first step to addressing some of the real crises in the home medical equipment community and addressing access needs for Medicare beneficiaries. Can you help free this rule at OMB and get it published?

Response: This regulation is under review by the Administration. I share your interest in this issue and should note that access to durable medical equipment for Medicare beneficiaries is a priority for the Department.

Question: The 21st Century Cures legislation signed into law in 2016 makes an important first step in addressing some regulatory hurdles for life-saving treatments by codifying a breakthrough pathway process at FDA to encourage more timely review of innovative medical technology. This provision had FDA's support. However, a similar effort is currently lacking within CMS to create a more efficient coverage and reimbursement process for FDA-approved breakthrough technologies. How will you improve the current process for getting breakthrough products covered in Medicare?

Response: We support the goal of improving the process for approval and coverage of innovative products and reducing the time between FDA marketing approval or FDA's granting of a de novo request and Medicare coverage decisions through CMS's National Coverage Determination (NCD) process. Under the FDA-CMS Parallel Review Program, the agencies concurrently review medical devices to help reduce the time between the FDA's approval of a device and Medicare coverage. This voluntary program is open to certain premarket approval applications for devices with new technologies and to medical devices that fall within the scope of a Part A or Part B Medicare-benefit category and have not been subject to a national coverage determination.

Question: Currently there isn't a clear standard for medication-assisted treatment (or MAT) prescribing, and we've heard reports of an increasing number of rogue actors offering MAT. In many cases these "pop up clinics" actively recruit vulnerable client populations and provide substandard services with minimal oversight. While we support consumer choice and market competition, we also want to balance this with consumer safeguards to ensure that this problem improves, not worsens, and that bad actors are not rewarded via federal dollars. Additionally, questions have been raised as to whether states are requiring evidence-based practices be used in the STR grant program. What is HHS doing to ensure rogue actors are not the recipient of federal dollars and evidence-based practices are being used so that funds expended go to providing the best possible treatment and recovery services?

Response: SAMHSA regulates Opioid Treatment Programs through an initial certification process and ongoing accreditation oversight. SAMHSA also manages the DATA 2000 waiver program for physicians, physician assistants, and nurse practitioners that provide office-based prescribing of certain FDA-approved medications for opioid use disorder. In addition to management and oversight of STR Grantees, SAMHSA is providing ongoing technical assistance (TA) to all grantees using conferences, webinars, learning collaboratives, and the Opioid State Targeted Response TA program. Evidence-based MAT prescribing, supported by a variety of SAMHSA tools and resources, is an essential aspect of this TA.

SAMHSA required states to identify the evidence-based practice that they intended to use in their initial application for STR funds and in their strategic plans submitted in August of 2017. Grant project officers have monthly calls with each state to discuss progress on implementation of their plans and any concerns that either the state or SAMHSA has with progress. Grant project officers are also making site visits to states to meet with state staff and providers and patients to understand the implementation process on the ground. States are required to report twice a year on a set of questions including the numbers of people that received specific services. Additionally, the program is being evaluated by an external evaluator. The evaluation includes an assessment of use of evidence-based practices.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides

other supports in addition to treatment. The fact sheet is on SAMHSA's website:
<https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf>.

Question: The 21st Century Cures Act included additional enforcement and implementation authorities to ensure consumers can access the benefits afforded to them under the Mental Health Parity and Addiction Equity Act. Additionally, Congress directed the Agencies to release a parity compliance document, additional guidance on nonquantitative treatment limitations and disclosure and report on federal investigations within the previous 12 months by December of last year. Can you please advise the Committee on when these materials will be released?

Response: HHS is working collaboratively with the Departments of Labor and the Treasury to implement the provisions of Title XIII of the 21st Century Cures Act (P.L. 114-255). On April 23, 2018, the Departments published the parity compliance program guidance document required by section 13001 (a) the 21st Century Cures Act (the Act). On that date, the Departments also issued the parity documents required by section 13001(b) of the Act, which includes guidance regarding both non-quantitative treatment limitations as well as disclosure and other guidance provided in the form of proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Act, and, finally, a re-proposed model disclosure form. On January 11, 2017, the Employee Benefits Security Administration (EBSA) released its annual MHPAEA Enforcement Fact Sheet summarizing the agency's closed federal MHPAEA investigations and findings in fiscal year 2016. EBSA recently released its Fiscal Year 2017 MHPAEA Enforcement Fact Sheet, which reports its closed investigations and findings of violations for Fiscal Year 2017. All of these documents can be found on the EBSA website, <https://www.dol.gov/agencies/ebsa>.

In December 2017, HHS posted a Mental Health Parity and Addiction Equity Act Enforcement Report. That report is available here: <https://www.cms.gov/CCHIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf>

Question: Puerto Rico has the highest Medicare Advantage penetration in the nation, with 98% of MA-eligible duals and 50% of dialysis patients in a Plan. Unfortunately, due to data anomalies in the reimbursement "formula," Puerto Rico MA programs are severely underwater, with the Island's rates at 43% below the US average, and 39% below the lowest state. The CMS reimbursement for Puerto Rico is even 26% below the US Virgin Islands. Payments for services to dialysis patients are equally 42% below Florida and 28% below the USVI. While I understand that the MA Plans have been in to see CMS and presented extensive data to improve the reimbursement, in its latest proposal for 2019 CMS proposed no meaningful changes to mitigate this harmful and persistent gap. Would you be willing to exercise your administrative discretion to find ways to meaningfully improve the MA programs in Puerto Rico?

Response: As you know, in order to increase benchmarks in Puerto Rico as a percentage of FFS costs, a statutory change would be necessary. The policies proposed in the 2019 Advance Notice and Draft Call Letter will provide stability for the Medicare Advantage program in the Commonwealth and to Puerto Ricans enrolled in MA plans. These policies include basing the Medicare Advantage county rates on only the relatively higher costs of beneficiaries in Fee-For-Service Medicare who have both Medicare Parts A and B, interpreting the criteria used to determine which counties qualify for an increased quality bonus adjusted benchmark in a way that permits certain Puerto Rican counties to qualify, and applying an adjustment to Puerto Rico FFS costs to reflect the nationwide propensity of beneficiaries with zero claims. In addition, in recognition of the impact that recent natural disasters might have on the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, CMS is proposing a variety of strategies to address Star Ratings issues related to plan contracts impacted

by extreme and uncontrollable circumstances, in Puerto Rico and elsewhere. This includes adjusting the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the 2017 performance period, such as Hurricanes Harvey, Irma, and Maria, and the wildfires in California. We remain committed to working together with you to maintain a strong, sustainable MA and Part D program for Puerto Rico and our nation's Medicare beneficiaries.

Long: Secretary Azar, the ACA included a Medical Loss Ratio (MLR) provision that, as implemented in CMS regulations, counts agent and broker commissions as overhead. I'm concerned about the negative effects this has had on the marketplace. We all know how important competition is to a healthy marketplace. I think this should be exempt from the broader formula, and I believe HHS has the regulatory flexibility to make this change. Will you commit to looking into this with your general counsel and discussing ways we may be able to achieve this?

Response: As you know, the Medical Loss Ratio (MLR) provision requires issuers to spend a certain amount of revenue on medical care and quality improvement activities. We have and will continue to look to provide as much flexibility to the states and issuers as is permitted under the statute. For example, HHS recently proposed modifications to reduce the burden on issuers and states related to the MLR. I am happy to look into this issue and get back to you.

Representative Long

Question: As you may know, I'm the sponsor of the HHS Cybersecurity Modernization Act, which would give HHS the ability to reorganize its cybersecurity offices and personnel to better reflect modern cyber threats. I believe the bill is especially important considering recent cyber incidents in the health care sector like WannaCry, NotPetya, and other ransomware and malware attacks.

What is HHS currently doing to ensure that both the Department and the health care sector are prepared for and addressing cyber threats? If you could include the roles of ASPR as the Sector Specific Agency, and the Healthcare Cybersecurity Communications Integration Center in particular, I would appreciate it.

Response: HHS has multiple roles with respect to cybersecurity. With respect to our role as a Federal Department and a provider of public services we are responsible for the security of internal systems across the Department's Operating and Staff Divisions. We are also a regulator of certain aspects of healthcare industry cybersecurity, especially with respect to the privacy and security of patient information, including electronic protected health information, and the safety of medical devices and other regulated healthcare products. On the non-regulatory side, we are designated the Sector-Specific Agency (SSA) for the Healthcare and Public Health Sector under Presidential Policy Directive 21. As an SSA we are responsible in part for serving as a "day-to-day Federal interface for the dynamic prioritization and coordination of sector-specific activities" with the Healthcare and Public Health Sector.

While there are components of these responsibilities that must remain separate in order to maintain the integrity of our internal and regulatory programs, we coordinate whenever and wherever possible. The HHS Deputy Secretary (currently Eric D. Hargan) serves as the senior official responsible for coordinating cybersecurity activities across the Department. Mr. Hargan convenes the HHS Cybersecurity Working Group, which brings together representatives from all Operating and Staff Divisions with cybersecurity responsibilities for senior-level coordination on policy and program matters.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) works on behalf of the Department to coordinate private sector partnership efforts related to cybersecurity and other critical infrastructure protection matters. ASPR does not do this alone, but relies on a Government Coordinating Council (GCC) of HHS, other Federal Department and Agency, and state and local government partners to provide a unified governmental voice to the private sector. This GCC interfaces with a Sector Coordinating Council (SCC) composed of major national trade associations and large, medium, and small companies from across the breadth of the Healthcare and Public Health Sector. Among the current collaborative cybersecurity efforts undertaken by this partnership are the analysis of cyber risk across the Sector, the identification of cyber-dependent critical infrastructure, the development of guidelines and best practices for enhancing cybersecurity, and the sharing of cyber threat and vulnerability information.

Subject matter experts within the Office of the Chief Information Officer are an essential component of all of these collaborative efforts with the private sector. For example, ASPR is working closely with the Healthcare Cybersecurity and Communications Integration Center (HCCIC) to address one of the most important findings of the Health Care Industry Cybersecurity Task Force, which is the imperative to “improve information sharing of industry threats, risks, and mitigations.” With its unique perspective within HHS and its relationships with the Defense Health Agency and Veterans Health Administration (including through the Healthcare Threat Operations Center), the HCCIC has access to a wide range of information on cyber threats impacting healthcare organizations. Working through the ASPR-coordinated private sector partnership and in close coordination with the Department of Homeland Security, HCCIC is able to fuse this information with information received from industry partners and develop products that are shared with the private sector through ASPR’s standard information sharing mechanisms.

Question: Is ASPR currently in charge of the Healthcare Cybersecurity Communications Integration Center? If not, will the H-CCIC be moved under ASPR in keeping with ASPR’s role as the health care Sector Specific Agency?

Response: The Healthcare Cybersecurity and Communications Integration Center (HCCIC) resides within the Office of the Chief Information Officer (OCIO), within the Office of the Assistant Secretary for Administration (ASA). While the HCCIC provides information analysis for sharing with the private sector, it also has functions that are internally focused and essential to the protection of HHS information systems. When HCCIC shares information with the private sector, it is done in close coordination with the Department of Homeland Security and within the public-private sector collaboration structures established by the Office of the Assistant Secretary for Preparedness and Response (ASPR), as the lead HHS component with respect to HHS’s obligations as the Sector Specific Agency for the Healthcare and Public Health Sector under PPD 21.

Question: Do you believe that HHS needs to do more to help both the Department and the health care sector better manage cyber threats? If so, what steps do you think the Department should take?

Response: The Healthcare Industry Cybersecurity Task Force report has provided HHS and our industry partners with a roadmap for improving cybersecurity across our organizations. The challenge is large, and there is much work to be done. We believe that many of the efforts we are undertaking now, including expanding our information sharing systems and developing guidelines and best practices under Section 405(d) of the Cybersecurity Act of 2015, will go a long way toward improving cybersecurity across the Sector. In everything we do, we must continue to rely on and leverage the expertise of our private sector partners. We are encouraged by the dedication they are showing this issue and their current efforts to respond to the Task Force recommendations. As cybersecurity concerns continue to challenge us, we must continually seek to expand the depth and

breadth of our private sector engagements to build a more secure and resilient Healthcare and Public Health Sector.

Representative Mullin

Mr. Secretary – As you know, my home state of Oklahoma has been working with CMS for over a year to renew its Medicaid waiver. As part of that waiver, the state, in a budget neutral manner, since the 1990s has sought and has received permission from CMS to operate an arrangement that allowed for University of Oklahoma (OU) and Oklahoma State University (OSU) to treat Medicaid patients expanding access into rural areas, but also train future physicians of the state in needed specialties.

However, this Administration has taken steps to stop this arrangement in its tracks, putting in jeopardy not only services for patients in rural areas and specialties, but also the training of the next generation of physicians.

While the state and CMS have had good discussions lately on a solution going forward, I'm concerned that CMS will continue on its path to clawback \$31 million paid to the state for services already provided. Would you please provide me an update, in writing, about the steps your department will take to ensure Oklahoma's medical schools are able to treat patients, as well as train future physicians? Specifically, I would like HHS and CMS to work together to find an acceptable path forward on the payments to the state to support the medical colleges for 2017 and 2018, but also work with the schools to find a long-term solution to this very important issue. Attached is further background on this issue. I respectfully request your attention to this very important matter and need your help to get to the bottom of this situation, and quickly.

Response: We appreciate the urgency of the situation in Oklahoma. As you may be aware, the state submitted an amendment to its 1115 demonstration in order to receive supplemental payments for Oklahoma public universities that offer qualified physician residential training programs, and to offer a physician qualified loan repayment program. On February 1, 2018, CMS alerted the state that its application was complete, and posted the amendment request on Medicaid.gov for a 30-day Federal public notice and comment period, which closed on March 4th, 2018. After careful review of the state's proposal and evaluation of the demonstration amendment requests against the specific statutory authorities that establish the Medicaid program, CMS alerted the state, on April 17, 2018, that it will not approve Oklahoma's amendment request as it is currently written. Since the issuance of that letter to the state, CMS has been actively engaged with the state to find an approvable path forward.

Representative Pallone

Question: The CMMI RFI states that, "CMS may publicly post the comments received, or a summary thereof." Does CMS plan to publish all the public comments that were submitted for the Centers for Medicare & Medicaid Services: Innovation Center New Direction, a summary of the public comments, or both? How many comments has the agency received to date?

Who at your agency decides whether public comments or a summary of the public comments will be published? What is the criteria by which the agency selects comments for publication?

If CMS plans to publish the public comments or a summary of the public comments for the CMMI RFI, when is publication expected? Please provide a copy of the summary of public comments.

Please provide a briefing on the process being utilized to determine CMMI's New Direction.

Response: Our existing partnerships with healthcare providers, clinicians, states, payers and stakeholders have generated important value and lessons and CMS is setting a new direction for the Innovation Center. That is why, in September 2017, CMS released a Request for Information (RFI) seeking public feedback on ways to promote patient-driven care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. We are grateful for the comments and thoughtful ideas that we received in response to the RFI. Overall, through the close of the comment period in November, CMS received approximately 1,000 submissions. CMS continues to review these submissions, and they will be an integral source of information as CMS moves forward with the agency-wide efforts to promote innovation, including through the design and testing of additional Advanced APMs that will aim to improve the patient-provider experience. However, our engagement with stakeholders has not ended with this RFI and we look forward to continuing to working with all stakeholders to make sure we are delivering results and putting the patient in the driver's seat. We are committed to following the Administrative Procedures Act (APA) and while the comments were not solicited as part of any proposed rule, and therefore CMS is not obligated to post the comments, we plan to make comments available on the Innovation Center's website and are happy to work with you and relevant stakeholders to share any additional information as needed. We are happy to engage with you and your staff and provide additional information you may need on the work of the CMS Innovation Center.

Question: Transparency for the review and decisions on 1115 waivers must improve. It is the Committee's understanding that Section 1115 waivers have been approved without adequate time allowance for the public to comment with the benefit of the context of major changes to agency policy, such as work requirements. For instance, the Kentucky 1115 waiver was filed long before the Administration issued its guidance on work requirements; the public should have had the opportunity to comment on Kentucky's waiver with the knowledge and understanding of CMS' broad policy changes to the program. Instead, the Administration approved the Kentucky waiver just one day after issuing guidance for the program tying Medicaid to a work requirement.

In the instance of Kentucky and their waiver for work requirements, how was this waiver reviewed? Did CMS conduct an assessment of the number of individuals this would affect, who it would affect, and the implications it may have on the insured rates and health care outcomes of families in Kentucky?

How does HHS plan to improve the transparency of the 1115 waiver process?

What will HHS do to avoid conflicts exemplified by the Kentucky waiver approval and CMS guidance release in the future?

Currently, five states: Maine, Arizona, Utah, Wisconsin and Kansas, have applied for waivers from the Department of Health and Human Services to put a cap on how long Medicaid beneficiaries can receive health benefits. Additionally, 10 states have applied for work requirement waivers: Arizona, Arkansas, Indiana, Kansas, Kentucky, New Hampshire, North Carolina, Maine, Utah, and Wisconsin.

What process did HHS use to review these submitted waivers?

Response: CMS has worked over the years to enhance policy and practice to increase transparency and to ensure the public has sufficient notice and opportunity for meaningful input on state section 1115 proposals submitted for Federal consideration, while also being mindful of the need to avoid

duplicative processes and unnecessary administrative burdens and delays as we work with states to test new approaches in response to rapidly evolving state and Federal health policy.

With the enactment of the Affordable Care Act, Congress set forth additional requirements to increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and to further enhance transparency in the Federal review and approval of section 1115 demonstration applications. Specifically, the Affordable Care Act amended section 1115 of the Act by adding a new subsection (d) to require the Secretary to issue regulations that would ensure the public has sufficient opportunities to provide meaningful input into the development of state demonstration projects, as well as in the Federal review and approval of state demonstration applications and renewals. This required the establishment of a process to provide for public notice and comment at the state level before a demonstration application is submitted to the Secretary and then again at the Federal level once a complete application is submitted but has not yet received a final HHS determination.

Effective April 27, 2012, CMS published a final rule which established a formal process for seeking public input and increases the degree to which information about Medicaid and CHIP demonstration applications is publicly available. The regulation also establishes a process so that the development and review of demonstration applications proceeds in a timely and responsive manner. Pursuant to the final rule, states must provide at least a 30-day public notice and comment period for applications for new demonstrations and extensions of existing demonstrations. Once a State's 30-day public comment period has ended, the State will submit an application to CMS. Within 15 days of receipt of the application, CMS will determine whether the application is complete. CMS will send the State written notice informing the State of receipt of the complete application, the date on which the Secretary received the application, and the start date of the 30-day Federal public notice period. If CMS determines that the application is not complete, CMS will notify the State of any missing elements in the application.

HHS and CMS take these transparency requirements seriously as we believe that public engagement and input is vital to successful state demonstrations approved under section 1115 authority. In addition to the requirements outlined in the ACA and the final rule, HHS and CMS continues to engage with states and stakeholders throughout the entire demonstration approval process to ensure a successful and workable demonstration. CMS evaluated and approved each of the waivers mentioned above under these requirements, and we will continue to adhere to these requirements as we consider pending 1115 waiver applications and renewals.

Question: At the hearing we discussed a recent letter that was sent to you and Administrator Verma regarding the state of Idaho's recent release of guidelines for their state health insurance marketplace that eviscerate critical consumer protections that are enshrined in the ACA. This would allow insurers in Idaho to deny individuals with pre-existing conditions health insurance coverage, deny pediatric vision and dental care coverage, increase health insurance costs for older Americans, and exclude coverage for maternity and newborn care. When questioned at the hearing about your understanding and response to Idaho's transgression of the ACA health insurance market consumer protections, you stated that you "would need to check under the 1332 waiver authority" and complete a "review for compliance with the legal obligations that we have in our statutes". Given the importance of this issue to working families in Idaho, we hope that you have prioritized this matter and conducted a thorough review of Idaho's guidelines.

1. Following your review, please explain if HHS and/or CMS believes that Idaho's actions are in full compliance with the Federal law and provide any documentation that provide the legal justification.

2. If you have concluded that any of the provisions in the Idaho guidelines are in violation of Federal law, what enforcement actions do you intend to take to hold the state of Idaho accountable?
3. If you have determined that Idaho's guidelines are in compliance with Federal law, please describe the review process you conducted Idaho's health insurance "statebased plans" that are to be sold to consumers.
4. In addition, please respond fully to the questions that were included in our letter sent on January 31, 2018 regarding Idaho's "state-based plans".

Response to 1-4: I am committed to working with states to grant flexibility wherever appropriate to provide their citizens the best possible access to healthcare. However, the Affordable Care Act remains the law. CMS informed the State that its State-based plan proposal, as originally issued, is inconsistent with the law.

The Department looks forward to working to explore ways in which Idaho can achieve its policy goals while ensuring that health insurance coverage sold within the state complies with all applicable federal laws and requirements.

Question: Since the Affordable Care Act was first implemented, the uninsured rate steadily declined, year after year. From 2010 to 2016, 20 million Americans gained health insurance. Unfortunately, The Department has made it difficult for people to gain coverage in the health insurance exchanges, by drastically reducing funding for outreach and education activities, limiting the time for enrollment, and giving consumers less opportunities to make informed choices. These actions have made it much harder for Americans to access and afford the vital health insurance coverage they rely on. As a result, for the first time since the ACA was implemented, the uninsured rate actually increased. According to Gallup, 3 million more Americans were uninsured in 2017 compared to 2016. It was also the largest single-year increase that has been observed since Gallup began collecting this data.

1. How does HHS plan to reverse this negative trend of insured rates?
2. Does HHS commit to working towards stabilizing the health insurance marketplaces? If so, what methods does HHS plan to take to improve the health insurance marketplaces?

Response to 1-2: Please note that the previous Administration proposed that the open enrollment period be shortened to the current length starting for the 2019 plan year, and that this policy aligns more closely with the one month open enrollment periods we typically see in the employer-sponsored insurance market and the seven week Medicare open enrollment period, the two markets where the vast majority of Americans are successfully enrolled, year after year.

I will examine the data and work with the Administrator to make the best, evidence-based decisions, balancing prudent use of resources with faithful execution of the law. As it relates to advertising expenditures, it is my understanding that the current level of spending is consistent with what is spent on promotion for Medicare Advantage and Part D, and that Navigators were funded at levels based partly on their ability to meet their enrollment goals from the prior year, so as to inject accountability into that program.

Ultimately, Congress will need to act to make the broader reforms that are needed in order to create a health insurance system that is more affordable and responsive to the needs of individuals and their families. I have been encouraged by the efforts ongoing in Congress to address the issues, and look forward to continuing to work with you to support these efforts.

Question: The Administration has sabotaged the health insurance markets by cutting off cost-sharing reductions, reducing ACA marketplace enrollment periods and outreach, and allowing the sale of “junk” insurance plans that don’t provide adequate healthcare coverage or financial protection for families. Many independent analysts, including CBO, estimated that premiums increased an average of 20% as a result of the decision to pull CSRs.

At the hearing, you expressed your interest in ensuring access to health care and that having health insurance is a key part of providing access. What steps is HHS taking to ensure that there is full implementation of the ACA?

Response: Short-term, limited-duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other forms of insurance, or who are otherwise priced out of the unaffordable ACA insurance markets. Americans need more insurance options, and they need less Federal micromanagement of their insurance options.

The status quo is not working for millions of Americans – whether it is those who are in the insurance market or those who have been left out of it. Although there are many Americans who may not be best served by a short-term, limited-duration plan, expanding the availability of such plans creates affordable options for those who understand how to choose and use these flexible, short-term products. HHS is working with the Departments of Labor and the Treasury, and across the Executive Branch, to create a health insurance system that is more affordable and responsive to the needs of individuals and their families, so that we have a healthcare system that is more affordable and accessible, where individuals and their families can choose the type of insurance coverage that works best for them, including the option of short-term, limited-duration insurance. The changes to short-term, limited-duration plans in the proposed rule are intended to provide additional, often much more affordable coverage options. The comment period on the proposed rule ended on April 23, 2018. I will work to ensure the least disruptive approach to implementing these policies, and to appropriately consider the concerns expressed by stakeholders during the rulemaking process.

Question: During your confirmation process, you spoke about the need to “fight gaming in the system,” to take action to lower prescription drug prices, and you committed to working with Commissioner Gottlieb on solutions to end the abuse of FDA’s safety protocols and the use of specialty pharmacies to limit access to drug samples. However, in the fiscal year (FY) 2019 budget, the administration does not include any proposals to end these abuses.

Two bipartisan proposals – the FAST Generics Act and the CREATES Act – are market-based solutions to increase competition and lower prescription drug prices. Over 60 organizations now support these solutions and CBO estimates the CREATES Act would generate savings of \$3.8 billion. Commissioner Gottlieb and Janet Woodcock, M.D., as well as the Federal Trade Commission, have indicated the FDA does not have the authority to compel brand companies to provide samples to generic manufacturers and thus Congressional action is necessary. Will you support the FAST Generics Act and the CREATES Act?

The FY19 budget includes a range of policies intended to lower prescription drug costs. However, none of the policies would impact the list price of brand biologics and drugs. With brand biologics accounting for nearly 50 percent of all prescription drug spending, and continued double-digit annual price increases for these blockbuster drugs, why does the budget fail to include any proposals to address the list price of brand drugs?

One of the concerns expressed by President Trump and others in the administration is the high cost of prescription drugs in the United States compared to other countries. The Commonwealth Fund, for example, noted last year that “prices for many blockbuster drugs are markedly higher in the U.S.” than the rest of the world with U.S. spending on pharmaceuticals exceeding \$1,000 per person and prices 30 to 190 percent higher than in nine other countries. In your experience, including your previous position at Eli Lilly, have price increases of brand drugs in foreign countries ever allowed the company to lower drug prices for its products in the U.S.? If so, can you provide specific examples of when this has occurred?

Response: Drug prices are too high. The President has made this clear and, as you note, the President’s FY 2019 Budget includes a number of legislative proposals to reduce the prices Americans pay for prescription drugs. Additionally, I would be happy to work with you and others in Congress on legislative changes such as the FAST Generics Act and the CREATES Act. I also support the FDA’s ongoing efforts to review its regulatory authorities to identify those abuses which can be addressed under existing authorities, those which require a coordinated, cross-government action, and those which require legislative changes. I am particularly concerned about the issues of (1) branded companies using REMS programs to prevent the study of the drug and approval of a generic form of the reference drug subject to REMs, (2) branded companies limiting supplies of reference product on which to conduct needed studies, and (3) branded companies securing patented modifications to the underlying product and withdrawing the previously approved product from the market, thus making entry of a generic competitor to that earlier version of the product more time consuming and difficult. In addition, the Food and Drug Administration Reauthorization Act of 2017 (FDARA), which was signed in to law last year, clarified that FDA may require a drug be superior to other drugs on the market in order to receive market exclusivity. I expect Dr. Gottlieb and FDA will implement these clarifications and look forward to reviewing whether incentives for innovation are adequately balanced with timely access to generic competition as intended under the Hatch-Waxman Act.

Question: Medicaid covers 4 in 10 nonelderly adults with an opioid addiction, 80 percent of infants with neonatal abstinence syndrome (NAS), and is the largest insurer for children. At the hearing you agreed that access to preventative care services and making health care affordable is important. However, President Trump’s 2019 budget proposes \$1.4 trillion cut to Medicaid, more than 25 percent, over 10 years through block grants and per capita caps. These cuts would be devastating to our nation and limit access to preventative health care, mental health, and substance abuse treatment for millions of Americans.

Please describe how DHHS plans to commit to the opioid crisis and ensure health care access for preventative health and substance use disorders.

Response: Our Medicaid program is an important tool in providing healthcare to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That is the challenge that we have as we seek to empower the states with the right incentives to deliver quality service. The FY 2019 Budget provides additional flexibilities to states, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 Budget also repeals the Medicaid expansion and the Exchange program subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's Budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The Budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The Budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question: What resources will be available under President Trump's proposed budget for fiscal year 2019 for treating opioid use disorders, substance abuse disorders, and mental or behavioral health conditions? Provide a list of any resources that will no longer be available and an explanation of why these resources will be cut.

For any resource loss due to President Trump's proposed budget for fiscal year 2019, provide corresponding estimates on the number and demographics of individuals that will be affected.

Response: The Budget makes a substantial investment in addressing the opioid crisis. It targets the funding to help HHS address all five points of our strategy, including improving access to treatment and recovery services. The Budget proposes \$1 billion for the State Targeted Response to the Opioid Crisis program. This will allow states to develop their own targeted approaches to prevention, treatment, and recovery support. In addition, health centers will receive \$400 million to help address substance abuse, including opioid abuse, and the overdose crisis. The Indian Health Service would receive \$150 million to provide multi-year grants based on need for opioid abuse prevention, treatment, and recovery support. We also propose to require Medicaid to cover all medication-assisted treatment and Medicare to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare.

Question: The President's budget includes a proposal intended "to give the Food and Drug Administration (FDA) greater ability to bring generics to market faster by incentivizing more competition among generic manufacturers." It describes the proposal as allowing FDA "to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock," "when a first-to-file generic application is not yet approved due to deficiencies." Can you provide more detail about this proposal? Specifically:

Please describe specific examples of "deficiencies" that this provision is intended to address. How many times has FDA encountered this situation within the past 10 years? Please also provide the number of tentative approvals within the past 10 years obtained by first applicants that did not obtain final approval and within what timeframe, and the reasons for which such final approval was not obtained in a timely way.

As you know, 180-day exclusivity has provided a powerful incentive for generic competition that today saves taxpayers and patients more than \$250 billion per year. Please explain how the proposal would not undermine the value of 180-day exclusivity, particularly given the unknown and unexpected timing of a subsequent applicant's tentative approval that could trigger a first applicant's exclusivity.

How does this proposal safeguard manufacturers who have received a tentative approval and are in good faith working towards final approval?

Response: "First filer" generic drugs that are approvable from a patent/exclusivity perspective, but unapprovable due to substantive deficiencies, can block subsequent applicants under the current 180-day exclusivity provisions of the Federal Food, Drug, and Cosmetic Act for extensive periods of time. Frequently, the substantive deficiencies occur in the inspection of the first filer's manufacturing facilities. Similarly, first filer ANDAs that receive tentative approval but then intentionally delay seeking final approval can block subsequent ANDA approvals. As a result, first filers can "park" their exclusivity and block subsequent generic competitors, and consumers are denied access to generic products and must keep paying brand price. We estimate that first filer ANDAs block the approval of subsequent ANDAs solely as a result of 180-day exclusivity approximately 5 times a year on average.

As you note, the President's Fiscal Year 2019 Budget includes an important legislative proposal to help address this issue. The proposal generally makes the eligibility for tentative approval of a subsequent generic drug applicant that is blocked solely by a first filer's 180-day exclusivity, where the first filer has not yet received final approval, a trigger of the first filer's 180-day exclusivity. Thus, this new trigger would not apply in situations in which the approval of the subsequent applicant was blocked by a 30-month stay or by another patent or exclusivity other than a first filer's eligibility for 180-day exclusivity.

The proposal would not undermine the value of 180-day exclusivity, but would instead address a gap in the current 180-day exclusivity provisions that allows first filers to block generic competition in some situations, either because their application has significant deficiencies that they have not corrected, or because the first filer is deliberately parking its exclusivity by failing to seek final approval once any deficiencies in its application are remedied. The proposal would incentivize first filers to submit quality applications and to seek timely approval of their applications once patent and exclusivity issues with respect to the innovator have been resolved, rather than engaging in gaming tactics that can block subsequent applicants and deny consumers the benefit of generic competition.

Thus, this proposal will enhance competition, facilitate more timely access to generic drugs, and is expected to create meaningful savings.

Question: In January of this year, HHS announced that it would be rescinding guidance issued in 2016 by CMS which clarified existing Medicaid law concerning the freedom of choice provision. This 2016 guidance noted that states are not permitted to deny Medicaid funds to family planning providers solely because they separately offer abortion services. However, in rescinding this guidance, and doubling down by proposing to prohibit these providers from receiving Medicaid funds in the budget, HHS is signaling its support for restricting access to family planning and other preventive health services.

Does HHS intend to allow women who obtain care through Medicaid to access family planning services from their provider of choice?

How will HHS ensure that Medicaid beneficiaries maintain access to comprehensive family planning services if certain reproductive health care providers were prohibited from the Medicaid program?

Response: On April 16, 2016, CMS issued a State Medicaid Director (SMD) letter that provided guidance to state Medicaid agencies on compliance with section 1902(a)(23) of the Social Security Act (the Act), which is often referred to as the “free choice of provider” provision. CMS rescinded this letter on January 19, 2018, due to concerns that the 2016 Letter raises legal issues under the Administrative Procedure Act, as well as limiting state flexibility with regard to establishing reasonable Medicaid provider qualification standards. States are still subject to the requirements under Sec. 1902(a)(23) and 42 CFR sec. 431.51 regarding free choice of providers.

Question: A paragraph in the HHS budget-in-brief notes that the budget prohibits certain abortion providers from receiving Title X funds. HHS has not provided any details on this proposal beyond this paragraph. Providers are only able to use Title X funds to provide affordable contraceptive care, and not for abortion services, and the Title X program has been credited for playing a key role in lowering the unintended pregnancy rate.

How does HHS intend to ensure that patients who receive care through Title X will maintain access to the broad range of reproductive and preventive health services that are currently provided through the program?

Response: The Department is committed to the statutory language governing the Title X program. Accordingly, the most recent Title X family planning services FOA requires Title X projects to offer a broad range of voluntary family planning methods and services, including information and education related to family planning, preconception care, contraception, natural family planning, and infertility services. Such methods and services range along a continuum of care, tailored to the unique needs of the individual. This includes all required services as stipulated in 42 CFR § 59.5, which ensure breadth and variety among family planning methods offered. Specific services mentioned in the FOA within the section on Program Priorities also include cervical and breast cancer screening, prevention of STDs, and HIV prevention education, counseling, testing and referrals.

Question: Following a significant delay, on February 23, 2018, HHS released the Funding Opportunity Announcement (FOA) for 2018 for the Title X Family Planning Service Grants. Title X provides critical grants to public and nonprofit agencies for family planning services, research and training.

What was the reason for the significant delay in announcing the 2018 Funding Opportunity Announcement for the Title X program?

Prior FOAs explicitly stated that family planning services include, “clinical family planning and related preventative health services.” Please explain the reason HHS excludes this language from the 2018 FOA.

The 2018 FOA removed the requirement for providers granted Title X funding to follow Providing Quality Family Planning Services: Recommendations of the CDC and the US Office of Population Affairs (QFP). The QFP is the nationally recognized clinical standards for what defines quality for family planning. Please explain why references to the QFP were not included in the 2018 FOA.

Why does HHS feel that family planning care would be “optimally” provided in comprehensive primary care settings instead of sites that focus on family planning and sexual health care?

Does HHS plan to issue new proposed regulations in relation to the Title X family planning program?

Response: Over the past five years, the Office of the Assistant Secretary for Health (OASH) has worked with the Office of Population Affairs (OPA) to streamline administration of the Title X family planning program, so that it would be administered like all other OASH grant programs. The FY 2018 Title X family planning services FOA is the culmination of that effort. This effort includes realigning Title X service areas, award start dates, and competitive reviews to more efficiently administer the program. This year's Title X grants also included a number of reforms to simplify the process for applicants, such as allowing organizations that work across multiple states to submit just one application, rather than multiple applications.

The Department is committed to the statutory language governing the Title X program. Accordingly, the most recent Title X family planning services FOA requires Title X projects to offer a broad range of voluntary family planning methods and services, including information and education related to family planning, preconception care, contraception, natural family planning, and infertility services. Such methods and services range along a continuum of care, tailored to the unique needs of the individual. This includes all required services as stipulated in 42 CFR § 59.5, which ensure breadth and variety among family planning methods offered. Specific services mentioned in the FOA within the section on Program Priorities also include cervical and breast cancer screening, prevention of STDs, and HIV prevention education, counseling, testing and referrals.

The Department and OPA strongly support Title X clients receiving quality family planning methods and services. As such, the latest Title X family planning services FOA contains references to CDC's guidelines on sexual health assessments and reproductive life plans. The QFP Guidelines were released in 2014.

Title X family planning service sites are not required also to provide primary healthcare services, other than those related to providing family planning services (for example, cervical cancer and STD screening). While comprehensive primary care providers are eligible and encouraged to apply for a Title X grant under the most recent Title X family planning services FOA, primary care services that are not related to providing family planning cannot be provided as part of Title X grant activities. Nevertheless, it is best for patients to have primary care services provided within the same site or for the family planning provider to have robust referral linkages to primary care providers within close proximity to the Title X site. Either of these options helps promote optimal physical, emotional, and social health outcomes, which is the ultimate goal of client-centered care.

While the Department cannot comment on regulatory plans, the Administration's Unified Agenda of Regulatory and Deregulatory Actions, as provided through the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA), includes "Compliance With Title X Requirements By Project Recipients in Selecting Sub recipients," an action that would withdraw the amendment made in a December 2016 Final Rule in conformity with the enacted joint resolution of disapproval under the Congressional Review Act.

Question: Last month, the Wall Street Journal reported that the Centers for Diseases Control plans to significantly scale back its work to prevent, detect and respond to global infectious disease outbreaks in nearly 40 countries when funding for the Global Health Security Agenda runs out in 2019. After that, CDC's global health security work will be limited to just 10 countries. The FY19 budget proposes \$59 million to support the continuation of CDC's Global Health Security Agenda activities. With that funding, will the CDC still need to focus only on 10 countries?

Response: With regard to the recent news about CDC reducing its global presence, CDC is in the process of planning, as the \$1.2 billion supplemental Ebola/Global Health Security funding awarded to CDC in FY 2015 expires at the end of FY 2019. However, the U.S. commitment to global health security and the Global Health Security Agenda (GHSA) specifically, remains steadfast.

The President's FY 2019 President's Budget includes \$59 million for CDC to continue activities that support Global Health Security Agenda implementation—evidence of the continued commitment. The \$59 million for GHSA in the President's FY 2019 Budget are bridging funds that would be used to support the continued development of core public health capabilities in GHSA priority countries as CDC transitions from the funding surge provided by the emergency supplemental funding to the next phase of GHSA implementation.

The U.S. Government strongly supports the GHSA and its objectives to build capacity to prevent, detect, and respond to infectious disease threats at their source. As President Trump has publicly stated, and as reaffirmed by U.S. Administration officials at the GHSA Ministerial Meeting in Uganda in October 2017, the U.S. Government strongly supports the extension of GHSA through 2024.

Many agencies contribute to the U.S. Government's commitment to GHSA, including the U.S. Department of State, Department of Health and Human Services, Department of Defense, U.S. Department of Agriculture, U.S. Agency for International Development, and CDC, through base and supplemental funding. CDC remains committed to the U.S. Government's investment in GHSA partner countries and continuing long-standing work to build health security capacities.

Question: The Centers for Disease Control and Prevention, the nation's public health and prevention agency, actually saw its core programs cut by more than \$1 billion overall, when not adjusting for the \$175 million additional opioid allocation. While some of those cuts come from eliminating or transferring programs from CDC, others such as the more than 10 percent cut in funding for chronic disease prevention and health promotion, would harm our ability to protect the public from costly, preventable disease. At the hearing, you stated that investments were being made in chronic disease and prevention, through the immunization program and emerging infectious and zoonotic diseases. You also stated that the \$1 billion in cuts was mostly the result of "the transfer of the leadership and supervision and budget for the strategic national stockpile."

Please explain how the Administration believes that cuts to CDC will help the Agency better fulfill its mission of being the nation's health protection agency, to protect America from health and safety threats, both foreign and domestic?

Response: In this constrained budget environment, difficult decisions had to be made across the Federal Government, including at the Centers for Disease Control and Prevention (CDC). The President's Budget attempted to prioritize public health risk.

The Administration submitted an addendum to the FY 2019 Budget that includes additional funding for a limited set of Administration priorities under the new, higher cap levels. Additional funds for CDC in the addendum include an additional \$100 million for chronic disease prevention programs.

CDC will continue to conduct critical science and provide health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

Question: The National Institute of Occupational Safety and Health (NIOSH) has been at the forefront on protecting the health and safety of the survivors of the World Trade Center (WTC) attack as well as the brave men and women who responded. Their leadership dates back to the fall of 2001 when Congress first appropriated funding to HHS to screen responders for respiratory complaints. NIOSH's efforts have been invaluable to ensuring that WTC survivors and responders receive the health services they need. NIOSH leadership continues today as Dr. John Howard serves as the Director of the National Institute for Occupational Safety and Health and the Administrator of the World Trade Center Health Program within the Centers for Disease Control and Prevention (CDC). The FY 2019 Trump Budget proposes moving the National Institute on Occupational Safety and Health to the National Institutes of Health (NIH) while leaving the WTC Health Program at CDC.

What is the effect on the WTC Health Program of removing that program from long term leadership of NIOSH? What analysis has HHS completed to understand those effects? Did HHS seek input from the 9/11 health community to understand those effects?

Response: Within CDC, the WTC Health Program will continue to provide medical monitoring and treatment for responders at the WTC and related sites in New York City; in Shanksville, Pennsylvania; and at the Pentagon; and to survivors who were in the New York City disaster area with the goal of no service disruption. The WTC Health Program aligns with CDC's mission to protect America from health, safety, and security threats, both foreign and in the United States. HHS looks forward to engaging with individuals from the 9/11 health community.

As mentioned above, the Director of NIOSH also serves as the Administrator of the WTC Health Program. Please describe how the leadership of the WTC Health Program would be handled under the Budget proposal? Would the Director of NIOSH remain the Administrator of the WTC Health Program?

Response: The WTC Health Program would continue to execute its statutory responsibilities through a WTC Program Administrator as defined by Section 3306 of the PHS Act.

The WTC Health Program relies on the expertise of NIOSH staff, and in fact, in some instances uses shared staff positions to fulfill its mission. Under the President's proposal, how would HHS ensure that WTC Health Program maintains the expertise and staffing necessary to meet the needs of 9/11 responders and survivors?

Response: Within CDC, the WTC Health Program will continue to provide medical monitoring and treatment for responders at the WTC and related sites in New York City; in Shanksville, Pennsylvania; and at the Pentagon; and to survivors who were in the New York City disaster area with the goal of no service disruption. The WTC Health Program aligns with CDC's mission to protect America from health, safety, and security threats, both foreign and in the United States.

Question: In the last year, there have been a number of ethical lapses that have plagued HHS and its operating divisions over the last year. Those lapses have raised serious concerns regarding whether the Trump Administration is truly committed to working in the public's best interest.

The former Secretary Tom Price, was forced to step down after the public learned that he had taken 24 flights on private charter planes at a cost of more than \$300,000 in just his first five months of service. According to Politico, between the months of May and September 2017, Secretary Price's travel cost taxpayers more than \$1 million.

Will HHS be conducting a thorough review to determine whether any other instances of federal travel regulations were violated at HHS and each of its divisions?

Response: Several Congressional inquiries have reviewed this matter. If you are interested in viewing our responses, we will provide them.

Question: Who at HHS approved and processed former Secretary Price's flights as well as instances where federal travel regulations may have been violated?

Response: The Inspector General announced in September that they are reviewing this matter as requested by your office. Out of respect for their process we are awaiting the completion of their review.

Question: What measures is HHS taking to ensure full compliance with federal travel regulations and to prevent the waste of taxpayer dollars on chartered flights when more cost-effective modes of travel are available?

Response: During my tenure I will always strive to be a responsible steward of taxpayer dollars. I expect the same of Department employees.

Question: In January, former CDC Director Brenda Fitzgerald, the country's top public health official, resigned over investments she made in tobacco companies one month into her tenure as head of CDC. What steps are you taking to determine whether other HHS officials have similar conflicts of interest that prevent them from serving the public without undue influence?

Response: Pursuant to Departmental policy, prior to entering Government service at HHS, the Ethics Division reviews the reported financial interests of each potential political appointee, including those imputed to the individual; determines whether any of the interests create a conflict or appearance of a conflict under the rules; and document in an Ethics Agreement a method for resolving these conflicts. Under the Ethics in Government Act, conflicts are resolved through recusals, divestiture, waivers, authorizations, reassignment, and other appropriate means.

Question: What measures are you taking to ensure full compliance by HHS officials with applicable federal ethical regulations, policies, and procedures pertaining to conflicts of interests? How will you ensure that all HHS political appointees disclose any conflicts of interests, in particular those that might seriously limit their ability to do their jobs, to HHS ethics office?

Response: All political appointees, like all Members of Congress, are required to file a public financial disclosure statement that includes reports all of the individual's financial interests. The Stop Trading on Congressional Knowledge (STOCK) Act requires all public financial disclosure filers to file timely updates of any financial transactions that exceed \$1,000. Individuals who fail to meet their filing requirements in a timely matter are subject to \$200 late fees. Individuals who fail to file or who falsify reports can be subject to criminal action, civil penalties up to \$59,028, and other appropriate personnel action.

Representative Eshoo

Question: Contraception coverage was a critical aspect of the Affordable Care Act's (ACA) preventive health goal. In October 2017, HHS announced two interim final rules (IFRs) which significantly broadened the ability for employers to seek exemptions to the ACA's contraceptive coverage guarantee. Members of this Committee wrote to HHS in October asking a series of questions regarding the Department's decision to issue interim final rules expanding the exemption for contraception coverage. We have yet to receive a response to that letter.

1. Do you believe that health insurance coverage for contraception and related preventive services help to ensure full and equal health coverage for women?
2. How will HHS ensure contraception coverage for women who have lost coverage through their employer or university as a result of these IFRs?
3. Why did HHS choose to finalize these rules effective immediately, and not subject the rules to the APA-required notice and comment period?
4. What steps is HHS taking to ensure more women have access to the full-range of FDA approved contraceptive methods?
5. Do you commit to ensuring HHS continues to implement the HRSA preventive services guidelines as they relate to contraception?

Response to 1-5: I look forward to working across the Administration and with Congress to ensure that women have access to the care they need – that may include care for cancer, diabetes, maternity care, family planning, cardiovascular health and many other issues affecting women, men and families – while simultaneously implementing the many conscience-protecting statutes that Congress has enacted in healthcare. We are working to provide more options for individuals and families by making healthcare and healthcare insurance more affordable, so that Americans have access to the care that they need.

Question: Your agency purports to support increasing mental health treatment for the nearly 10 million Americans with serious mental illness. The President's budget creates new programs and centers to address mental health and substance abuse. The same budget slashes \$1.4 billion from Medicaid, our nation's primary source for mental health and substance abuse treatment coverage.

How will people enrolled in Medicaid access mental health services if and when they lose their health insurance coverage because of the budget proposals to cut and cap Medicaid?

Have you met with a Medicaid recipient?

Response: Stakeholder feedback is a vital part of CMS's work across all of our programs, including Medicaid. In addition to following HHS's standard rulemaking process, which involves seeking feedback from the public, HHS uses several other methods to gather input from patients, providers, plans, and state and local officials when designing improvements to our programs. For example, I recently traveled to Ohio to participate in a listening session at an inpatient care facility, where I was able to hear from local officials, providers, families, and children about how opioid addiction has impacted them.

Medicaid is a safety net program that provides coverage for life-saving medical care to millions of Americans facing some of the most challenging health circumstances. In addressing the diversity and complexity of Medicaid recipients, we have a duty to ensure the highest level of quality, accessibility, and choices for Americans who rely on the program, including those who need mental health services and substance abuse treatment. For that reason, it is crucial for states to have the flexibility to tailor the Medicaid program to meet the needs of their constituents. I am working to ensure that states are empowered to tailor solutions that work for their citizens with mental illnesses and substance use disorders and that they receive the proper supports from their federal partners at HHS. Our aim is to restore a strong state-federal relationship while also modernizing

the program to deliver better outcomes for all populations being served. We need a system that will provide stability and predictability for both state and Federal budgets, and most importantly, will protect future recipients by ensuring the Medicaid program's long-term viability.

Question: The FY18 budget addendum includes moving funding for Project BioShield from the current annual appropriations process to advanced appropriations and provides additional funding for this program.

Is Project BioShield currently limited in its ability to make investments in promising products because it is appropriated annually?

Response: Project BioShield (PBS) was initially supported under the Special Reserve Fund (SRF), an advanced appropriation of \$5.6 billion (2004). The SRF was meant as a market guarantee to encourage participation from industry in the development of critical medical countermeasures (MCMs) to address chemical, biological, and radiological and nuclear (CBRN) threats. For the vast majority of these critical MCMs, there is no other market outside the U.S. government. Contracts that were awarded under the SRF supported all late-stage activities and an initial procurement of product. The options that were included were for additional procurement to increase preparedness or replenish expiring product. This type of contract, full support and procurement in the base award, fulfilled the market guarantee intended under PBS. PBS was reauthorized in 2013 under the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), which authorized appropriations of \$2.8 billion for FYs 2014 – 2018. Starting in FY 2014, yearly appropriations have been provided to support PBS activities. Even though additional progress continues to be made by supporting new products under PBS, our private sector partners no longer have the long-term market guarantee that an advance appropriation provides. PBS funding has been provided at \$255 million for FY 2014, \$255 million for FY 2015, \$510 million for FY 2016, \$510 million for FY 2017, and anticipated \$710 million for FY 2018. This equates to \$2.240 billion of the \$2.8 billion authorized.

Question: Starting in FY 2014, fourteen new products have been supported under PBS. The success in transition of products from advanced research and development (ARD) to PBS is because of the funds provided for ARD starting in FY 2007 under the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA). The success has led to more products becoming eligible for transition to PBS, but with insufficient yearly PBS funding to support all late-stage activities and initial procurements in the base award(s), as was done under the SRF. As a result, PBS contract awards starting in FY 2014 only included support for a portion of the necessary late-stage development activities in the base award. The remaining late-stage activities are included as options that could only be executed based on availability of funds. The procurement of product is also included as an option(s). Therefore this model no longer supports the market guarantee intended under PBS. Additionally, this has had a domino effect on funding availability, since new PBS products funded in FY 2014 or 2015 have additional out year costs that further decrease the level of downstream available funding for new starts in later fiscal years, even when funding increased to \$510 million per year.

How will advanced appropriations promote and enhance the work that Project BioShield currently does?

Response: Please refer to the response to the question above. In addition, advanced appropriations will restore PBS funding, providing the intended market guarantee that was established under the SRF. It will allow for full funding of all late-stage activities and procurement of product in the base award. The options will provide additional procurements to increase preparedness or replenish expiring product.

Question: I'm working with my colleague Rep. Susan Brooks to reauthorize the Pandemic and All-Hazards Preparedness Act so I'm familiar with the threats that emerging infectious diseases pose. These threats are not going away any time soon, the risk posed by these diseases is only increasing. How does your agency plan to protect against the growing threat of emerging infectious diseases if the emerging and zoonotic infectious diseases program, which is responsible for detecting, controlling and preventing these threats, is cut by \$60 million?

Response: Much of this funding has traditionally supported state health departments to prepare for and respond to outbreaks of infectious disease and antibiotic resistance. In this constrained budget environment, difficult decisions had to be made across the federal government, including at CDC. CDC's NCEZID will continue to conduct critical science and provide health information that protects our nation against dangerous health threats.

Representative DeGette

Question: On December 6, 2017, Representative Tom Reed and I sent a letter asking HHS to apprise the Diabetes Caucus of steps CMS and FDA are taking to ensure that seniors with diabetes receive diabetes testing supplies that work as intended. That request was prompted by a June 2017 study that evaluated the accuracy of some of the most commonly used personal-use blood glucose testing systems, including those most commonly furnished to Medicare beneficiaries through the Medicare Competitive Bidding National Mail Order program, that found that only six of eighteen systems tested met the study's accuracy standard. On January 24, 2018, Acting Secretary Hargan responded with a list of steps FDA has taken and intends to take with respect to product review and monitoring, but with respect to CMS, the letter said only that CMS has been monitoring health outcomes data for beneficiaries receiving tests strips, and that "to date [CMS] has not detected any negative trends." Outcomes data may be a prudent way to identify adverse beneficiary outcomes, but according to the study, Medicare is paying for items that fail to meet basic performance standards, and more than 61 percent of the strips furnished to Medicare beneficiaries during the period October through December 2016 failed accuracy standards under this study. Do you believe that CMS also has a responsibility to ensure that the items it pays for function as intended, and that CMS should undertake additional steps to ensure that it is managing the public's Trust Fund consistent with its fiduciary responsibility?

Response: All Medicare DMEPOS suppliers must furnish items that are cleared by the FDA as safe and effective and all suppliers must be in compliance with the Medicare supplier standards and quality standards. If a Medicare DMEPOS supplier furnishes items that do not comply with FDA standards or Medicare standards and requirements; they will be dealt with through use of our existing authorities and remedies.

Representative Schakowsky

I would also like to ask about reports that high ranking officials within HHS and CMS coordinated with the anti-abortion organization "Alliance Defending Freedom", one that has been designated a hate group by the Southern Poverty Law Center, before the Administration's January 19th announcement that it was rescinding critical Medicaid guidance concerning where beneficiaries can receive family planning and reproductive health care.

I'm concerned about who is calling the shots at HHS. Coordinating with right-wing ideological organizations raises serious ethical questions. It also calls into question the legitimacy of any policy decisions by Trump's HHS.

1. Are there other occasions when non-HHS employees have drafted HHS guidance documents, regulations, or other written proposals? Or if HHS officials have sought input on policy decisions from ideologically conservative organizations outside of the appropriate notice and comment process?

2. Can you commit that you will take steps to ensure that HHS officials are not coordinating with biased ideological organizations to further specific policy proposals in the future?

Response (1 and 2): The Department has replied to an inquiry from Ranking Member Cummings on this issue, and a copy of our response will be provided to your office. Department issued guidance documents, regulations, or written proposals will always be a product of the Department's own deliberative process. I think it is important to note, however, that policy proposals from outside interest groups are commonplace, and a means by which citizens exercise their First Amendment right to petition their government.

Representative Butterfield

Question: According to a recent FDA publication, "Expanded Access of Investigational Drugs: the experience of the center of drug evaluation and research over a 10-year period," the FDA review of expanded-access requests includes knowledge of the totality of data and information that the commercial sponsor has submitted to the FDA for the development program, including data (e.g., safety/toxicity data, dosing considerations) that may not be publicly available. In addition, it states, "the FDA can recommend revisions to the treating physician's desired treatment plan to better protect the patient's safety." Would you agree that FDA plays a critical role in evaluating a favorable benefit-risk profile and assuring patient safety?

Response: Yes, I agree FDA plays a critical role in evaluating potential benefits and potential risks and assuring patient safety. FDA takes seriously its core mission to help ensure the safety and efficacy of the medicines upon which patients depend. Adequate policies and processes must be in place to appropriately balance individual patients' needs for access to investigational therapies while recognizing the importance of maintaining a rigorous clinical trial paradigm for testing investigational products to demonstrate safety and efficacy.

FDA's expanded access program is operating efficiently, demonstrated by the fact that currently, 99.6 percent of individual requests are allowed to proceed, and usually within a very short time period.

Question: According to a paper by the FDA, "How Often Are Drugs Made Available Under the Food and Drug Administration's Expanded Access Process Approved?", the mean response time for non-emergency single patient INDs is four (4) days. Moreover, overall, 98% of individual patient Expanded Access requests were allowed to proceed. Would it be reasonable to conclude that the current system is operating efficiently?

Response: See answer above.

Representative Matsui

Question: Last year, we were all shocked by the outrageous price increases in the EpiPen, a branded product where the actual drug (epinephrine) is cheap and common, but the auto injector device is unique to the company. One way to prevent skyrocketing prices on products like these is to ensure adequate

competition. The Cures provision to streamline the combination products approval process is intended to do that.

Has the Office of Combination Products been stood up and what assistance has been provided thus far or plans to be provided?

Response: I understand that enhancing the efficient, effective, consistent, and transparent regulation of combination products is a top priority for FDA. The Office of Combination Products (OCP) was established on December 24, 2002, as required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The 21st Century Cures Act made further revisions to facilitate the timely review of, and feedback on, applications for combination products. OCP is taking a variety of actions to support the development and regulation of combination products, including: developing policies to clarify and streamline premarket and post market expectations; implementing more efficient inter-center consultation processes; enhancing staff training; updating IT systems; and pursuing ongoing assessment of policies, systems, and procedures.

Question: Do you agree that a streamlined process will enhance the potential for competition of combination products in the market?

Response: Yes. Section 3038 of the 21st Century Cures Act provides mechanisms to streamline and enhance the clarity and certainty of the combination product review process, which will enhance the potential for combination product competition. FDA efforts discussed above in response to question-1 intend to facilitate efficient, consistent, and predictable combination product regulation, including streamlining the review process of all premarket applications and reporting requirements of post market adverse events.

By improving the inter-center consult process and clearly conveying FDA's regulatory and scientific expectations to stakeholders, the Agency will be able to meet its commitment of ensuring timely and effective review of combination products. The sooner generic versions of combination products are approved, the more choices can be available to patients, enhancing the potential for competition.

Question: I'd also like to talk about patient-focused drug development and inclusion of real-world evidence. These provisions are not necessarily specific to rare disease patients, but I think they are especially useful for rare diseases as they provide additional opportunities to collect information about treatments.

Can you elaborate on FDA's work on patient-focused drug development? Where are we in the implementation of patient engagement staff and the inclusion of patient experience data in the approval process?

Response: I can assure you that FDA supports the goal of using science-based methods to incorporate patients' voices into drug development and the regulatory decision-making process. Both the Cures Act and PDUFA VI included enhancements to facilitate the patient voice in the regulatory decision process.

FDA has begun implementing the patient-focused drug development provisions in the Cures Act. This includes, for all new drug applications approved at least 180 days after the Cures Act enactment, the requirement to make public a brief statement regarding patient experience data and related information that may have been submitted and was reviewed as part of an application. This

also includes FDA's May 2017 publication of a five-year plan for the issuance of draft and final patient-focused drug development guidances to implement provisions under the Cures Act, section 3002.

On December 18, 2017, FDA held a workshop on Patient-Focused Drug Development, which allowed it to obtain feedback on standardized terminologies, methods for collection of patient data, and reporting, management, and analysis of patient input. FDA had over 600 people registered for in-person and on-line attendance. This was done as part of the work to gather public input related to the guidance content required under the Cures Act section 3002(c)(1). The agency plans to issue draft guidance related to this provision before the end of FY 2018.

In addition, FDA will hold a public workshop on March 19, 2018, to seek public stakeholder input for inform agency development of the guidance content under the Cures Act, section 3002(c)(5). This guidance relates to developing and submitting draft guidance relating to patient experience data for FDA consideration. The agency plans to issue draft guidance related to this provision before the end of FY 2018.

FDA also established a Patient Engagement Staff (PAS) within the Office of Medical Products and Tobacco (OMPT). The purpose of PAS is to:

- Serve as a single, central entry point to the Agency for the patient community.
- Provide triage and navigation services for inquiries from patient stakeholders.
- Provide a more transparent, accessible, and robust experience for patient communities.
- Host and maintain data management systems that incorporate and formalize knowledge shared with FDA by patient stakeholders.
- Provide cross-center coordination for the policies that we adopt with respect to how patients are being incorporated into the process.

The goal is to maintain and enhance FDA's existing relationships with stakeholders, and enable new groups and groups that might not already have those kinds of relationships to interact with the Agency.

Question: Can you also provide a more in-depth update on FDA establishing a new program to evaluate the potential use of real world evidence?

Response: Use of Real world evidence (RWE) has the potential to make the medical product development process more efficient and less costly. RWE may also help answer questions about treatment effects and outcomes that are more generalizable to a broader patient population than those seen in a specialized research environment.

As required by the Cures Act, FDA is currently focused on developing a framework for a program that will evaluate the use of RWE to help support regulatory decisions for new indications for drugs approved under section 505(c) of the FD&C Act, or to help support or satisfy post-approval study requirements for drugs. FDA is on schedule to issue this framework by December 2018 and implement the program by December 2019. By December 2021, FDA will issue draft guidance addressing the use of RWE to help support a new indication of a drug approved under section 505(c) or to help support or satisfy post-approval requirements, including RWE data quality and standards, and analysis methodologies.

FDA is already working with stakeholders to inform these policies. FDA supported a public workshop convened by Duke-Margolis Center for Health Policy on September 13, 2017, that

discussed potential elements of a framework. FDA also supported the National Academies of Sciences, Engineering, and Medicine meetings on RWE. The first meeting was held in September 2017: **Examining the Impact of Real-World Evidence on Medical Product Development: A Workshop Series | Workshop 1: Incentives**, and the second meeting was held on March 6-7, 2018: **Workshop 2: Practical Approaches**. An additional meeting is planned for the summer of 2018 on operationalizing the collection and use of RWE.

Question: Finally, FDA has funded several demonstration projects to better understand different aspects of RWE. This includes the first randomized, controlled clinical trial conducted using the infrastructure created by the FDA's Sentinel Initiative -Implementation of a Randomized Controlled Trial to Improve Treatment with Oral Anticoagulants in Patients with Atrial Fibrillation (IMPACT-AFib) (NCT02082548) FDA has primarily used the Sentinel system to generate RWE about medical product safety.

This will also be particularly helpful for those with rare diseases as real world evidence is sometimes all the evidence that we have for those patients. How can NIH's Precision Medicine initiative benefit rare disease patients?

Response: The NIH's All of Us Research Program, part of the Precision Medicine Initiative, will be a broad, powerful resource for researchers working on a variety of important health questions. By combining health-related information from one million or more diverse participants, much of it collected directly from the participants, All of Us will have the right scale and inclusive scope to enable research for a wide range of diseases, both common and rare. This participant-provided information matched with clinical data collected longitudinally and genomic data will help researchers understand the etiology of many types of diseases, including rare diseases that might share common pathways with other rare and common conditions.

Question: The 21st Century Cures Act includes language that permits manufacturers of medical devices whose products have been approved for use by the European Medicines Agency, but denied or not yet reviewed by the FDA, to request a peer review of that data by a panel appointed by the FDA and paid for by the device manufacturer.

Would you support policy that would allow similar treatment of pharmaceutical products?

Response: The Administration would have serious concerns about a policy that would allow manufacturers, whose products have been approved for use by the EMA, but denied or not yet reviewed by FDA, to request a peer review of that data by a panel appointed by the FDA and paid for by the drug manufacturer. The 21st Century Cures Act did not include such language for devices.

With respect to approval of drugs, one of the critical functions of FDA reviewers is to examine and analyze the data provided by the company to ensure that the manufacturing and testing of the product meet our scientific standards and that the benefits of the product outweigh its risks. For companies seeking marketing approval of drugs, it is in their best interest to present the product's benefits and risks in the best possible light. In numerous cases, FDA reviewers raise important concerns with respect to the information submitted by the company, sometimes resulting in non-approval of the product.

The U.S. is the only country that reviews the raw clinical trial data provided by the companies seeking approval. Other countries, including every country currently included in section 802(b)(1) of the Federal Food, Drug, and Cosmetic Act, base their approval decisions on the analyses and summaries of the data provided by the companies. Unlike FDA, regulators in these countries do

not have access to the complete data sets, do not have the resources to examine the data in detail, and generally do not produce their own independent analyses.

Thus, the Administration would be concerned about any legislation if it would allow approval of drugs based on limited information, largely as interpreted in the eyes of the manufacturer, with mostly an over-reading by regulators in other countries and peer-reviewed by an outside panel, even if such panel were appointed by FDA.

Question: One area of research that I believe really has a long way to go and has great potential is research on the brain. We just don't know enough about how it works and how diseases of the brain manifest themselves.

Diseases of the brain are some of the most prevalent and impactful in our society. One in five people is affected by a mental illness and over 5 million Americans are diagnosed with Alzheimer's every year, including 630,000 Californians. The impact of these diseases are only going to grow as our population ages and as we face mental illnesses head on rather than pushing them to the shadows.

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative at NIH intends to get at this problem – the lack of understanding of the human brain. BRAIN is helping researchers seeking new ways to treat, cure and prevent brain disorders.

Question: Another priority in the 21st Century Cures Act has been to ensure that historically underrepresented populations – including minorities, women, and children – are included in medical research.

Children's medical research has long been a priority for me. As you know, we originally created the National Children's Study to look at long-term environmental impacts on children's health and development. NIH is currently following through on that idea with the Environmental Influences on Child Health Outcomes, or ECHO, Project. I look forward to continuing to work with NIH to ensure that that project meets the goals of understanding the effects of environmental exposures on child health and development. In Cures, we included Sections 2071 and 2072 to promote pediatric research and inclusion of children in NIH research by creating national and global pediatric research networks.

Can you discuss NIH's efforts in this area and how the provisions in Cures have helped move things forward?

Response: The Environmental Influences on Child Health Outcomes, or ECHO, Program meets the priorities of 21st Century Cures Act by incorporating historically underrepresented populations – including minorities, women, and children – in both the cohort and clinical trials components of the program. ECHO is a nationwide research program comprising 62 grant awards, 110 principal investigators, and 250 performance sites across 44 states, the District of Columbia, and Puerto Rico.

The clinical trials component of ECHO, the IDeA States Pediatric Clinical Trials Network (ISPCTN) awards provide medically underserved and rural children and their families with access to state-of-the-art clinical trials, apply findings from relevant pediatric cohort studies to children in IDeA state locations, and build pediatric research capacity at a national level. The participants in these trials incorporate a diverse set of minorities, women, and children in states with high burdens of childhood health conditions.

Also, across the NIH, for nearly 20 years, it has been the official agency policy that children must be included in all NIH-supported research involving human subjects, unless there are scientific or

ethical reasons not to include them. The NIH is committed to the inclusion of all relevant age groups, including children and older adults, in the clinical research studies and clinical trials it supports. NIH has taken several steps to implement provisions in the 21st Century Cures Act requiring NIH to publish data on relevant age categories, including pediatric subgroups. In December 2017, NIH revised its policy on inclusion, effective for applications received on or after January 25, 2019. Now titled the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, the revised policy applies to individuals of all ages and requires NIH-supported clinical research studies to submit de-identified individual-level data on participant sex/gender, race, ethnicity, and age at enrollment in progress reports. NIH looks forward to the availability of additional data on the age of participants in clinical research studies, including more information on children.

Representative Welch

Question: Secretary Azar, I want to turn for a moment to one of the factors driving high drug costs and that is abuse of our regulatory system by some brand manufacturers to extend their patent life or to further delay competition. One such problem I have been focused on trying to fix is the abuse of REMS programs, which were put in place to ensure the safe use of certain drugs, but are being used by brand manufacturers to delay the ability of generic manufacturers to purchase samples of drugs needed to conduct studies to support FDA approval. Commissioner Gottlieb has recognized this gaming and has called on brand manufacturers to “end the shenanigans.”

The tactic of using REMS to delay competition has had a very real impact on patients. Take the recent story of Pam Holt, who has been using Revlimid to treat her multiple myeloma. Her co-pay is \$640 a month, and despite the fact that Revlimid has been available since 2005 there is still not a generic on the market. David Mitchell, founder of Patients for Affordable Drugs, who also has had to take Revlimid to treat his cancer, has testified before Congress that the lack of a generic on the market is due to the manufacturer repeatedly denying generic manufacturers samples under the guise of a REMS program.

And if you don't believe the patients, Dr. Woodcock has confirmed herself that there have been around 150 inquiries from generic manufacturers to FDA reporting about difficulties they have had in obtaining samples from brands for bioequivalence testing.

1. Do you agree that we need more competition in the pharmaceutical marketplace and that we must address the gaming of our regulatory system by brand companies that delays generic competition?

Response: I agree that we need more competition in the pharmaceutical marketplace and that we must address the gaming of our regulatory system by brand companies that delays generic competition.

2. There have been two bipartisan proposals to address REMS abuse introduced this Congress – the FAST Generics Act and the CREATES Act. Will you work with me on legislation to help end REMS abuse and to facilitate access to samples?

Response: I support the goal of preventing the delay of generic drug development by ensuring both that interested developers have access to the reference listed drugs they need to support competing applications, and that the stalling or blocking of single shared system risk evaluation mitigation strategies (REMS) development not be used to prevent or delay the market entry of competing products.

This past November, FDA announced a two-pronged approach to address REMS issues—work to find ways to encourage use of shared system REMS and explore new steps to reduce the likelihood that branded companies can use REMS to slow generic competition. Also in November, FDA released draft guidance for industry to make it easier for manufacturers to make certain submissions as part of a shared system REMS. On November 8, 2017, FDA and FTC conducted a workshop to examine competition and high drug cost issues.

We are happy to continue working with the sponsors of legislation in this area to provide feedback on their proposed solutions.

Representative Schrader

Question: The Campaign for Tobacco Free Kids estimates that:

- Annual Federal and state government smoking-caused Medicaid payments: \$39.6 billion [Federal share: \$22.6 billion per year, States' share: \$17.0 billion]
- Federal government smoking-caused Medicare expenditures each year: \$45.0 billion
- Other federal government tobacco-caused health care costs (e.g. through VA health care): \$23.8 billion

Given these numbers, I'm encouraged by the fact that the FDA has stated a goal to "enable greater use of safe and effective options to help those who are addicted to nicotine get the help they need to quit combustible cigarettes altogether." FDA's plan to lower the amount of nicotine in cigarettes to minimally or non-addictive levels is an important part of achieving that goal. Given the potential public health benefits to children who we hope never start smoking and to adults who want to quit, shouldn't this be a faster-moving priority?

Response: Protecting children from the harms of tobacco use is indeed a high priority. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth in the United States smoke their first cigarette every day, lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit more easily.

The Federal Food, Drug, and Cosmetic (FD&C) Act provides FDA with the authority to establish tobacco product standards. This includes the authority to adopt a tobacco product standard if the Agency finds that it is appropriate for the protection of the public health. In making such a finding, the Agency must consider scientific evidence concerning: (1) The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

To begin the process, FDA has initiated a public dialogue about lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels. FDA has issued an advanced notice of proposed rulemaking (ANPRM) to obtain information regarding the issues FDA would need to address in a tobacco product standard regulation to regulate nicotine levels in combustible cigarettes and render them minimally or non-addictive. Reviewing the science and hearing from stakeholders will help FDA form the basis for regulatory action.

If FDA determines that a rule establishing a maximum nicotine level is appropriate for the protection of the public health, the next step would be for FDA to issue a proposed rule and obtain

public comment. Then, after consideration of comments from stakeholders, FDA could publish a final rule establishing a maximum nicotine level in cigarettes.

This effort is a high priority for FDA. I share Dr. Gottlieb's commitment to public health, and to moving this forward as quickly as the science and the regulatory process allow.

Representative Kennedy

Question: The Comprehensive Addiction and Recovery Act (CARA), P.L. 114-198, included provisions requiring HHS to establish an inter-agency task force to identify, review, and issue best practices on pain management within two years. While the Pain Management Best Practices Inter-Agency Task Force created in CARA does not have rule-making authority and cannot supplant existing CDC's 2016 Guidelines for Prescribing Opioids for Chronic Pain, it can supplement CDC's invaluable work. Can you provide me with an update on the status of the Inter-Agency Task Force and whether or not it has convened any meetings to date?

Response: We expect to announce members of the Pain Management Best Practices Inter-Agency Task Force in mid to late spring and a meeting will follow shortly thereafter. We look forward to convening this Task Force.

Question: The 21st Century Cures Act, P.L. 114-255, includes provisions requiring HHS to enhance compliance with mental health parity laws. While HHS missed the June deadline for holding a public listening session, the law includes several other critical deadlines. Please provide a status update for each of the responsibilities assigned to HHS and listed in Section 13001 of the 21st Century Cures Act. Specifically, has the Department taken any measures to issue additional guidance to health insurance plans regarding their obligations under existing mental health parity laws; has the Department solicited public input and finalized the Task Force action plan; and has the Department issued a compliance program guidance document, including illustrative examples of previous findings of compliance and non-compliance? For all deadlines that HHS has missed, when will the Department fulfill the requirements under Section 13001?

Response: HHS is working collaboratively with the Departments of Labor and the Treasury to implement the provisions of Title XIII of the 21st Century Cures Act (P.L. 114-255). Federal or State law requires group health plans and health insurance issuers to disclose certain documents to participants and beneficiaries, contracting providers, or authorized representatives to ensure compliance with MHPAEA.

On April 23, 2018, the Departments published the parity compliance program guidance document required by section 13001 (a) the 21st Century Cures Act (the Act). On that date, the Departments also issued the parity documents required by section 13001(b) of the Act, which includes guidance regarding both non-quantitative treatment limitations as well as disclosure and other guidance provided in the form of proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Act, and, finally, a re-proposed model disclosure form. On January 11, 2017, the Employee Benefits Security Administration (EBSA) released its annual MHPAEA Enforcement Fact Sheet summarizing the agency's closed federal MHPAEA investigations and findings in fiscal year 2016. EBSA recently released its Fiscal Year 2017 MHPAEA Enforcement Fact Sheet, which reports its closed investigations and findings of violations for Fiscal Year 2017. All of these documents can be found on the EBSA website, <https://www.dol.gov/agencies/ebsa>.

In addition, as you know, in July 2017, the Departments, together with other Federal and State partners held a meeting to develop an Action Plan for improved federal and state coordination of enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA). As part of that

process, the Departments also accepted written comments from stakeholders. HHS is working diligently with the other Departments to review comments and feedback and finalize the Action Plan. More information about this process can be found here: <https://www.hhs.gov/programs/topic-sites/mental-health-parity/achieving-parity/cura-act-parity-listening-session/index.html>. We expect that the additional guidance on nonquantitative treatment limitations and the compliance program guidance document to be released this spring.

Finally, in December 2017, HHS posted a Mental Health Parity and Addiction Equity Act Enforcement Report. That report is available here: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf>

Question: It is my understanding that as recently as 2016 the Department's Office of Inspector General has investigated Universal Health Services (UHS) for a variety of violations at their numerous mental and behavioral inpatient facilities. Please provide a status of all investigations into UHS that HHS has conducted and is conducting. Additionally, please provide information regarding any fraudulent reimbursements that UHS or any of its affiliate facilities billed Medicare or Medicaid. Specifically, detail how many instances of fraudulent billing occurred, over what period of time, involving which facilities, and for how much money.

Response: The HHS OIG has a general practice of neither confirming nor denying the existence of any investigation it may be conducting. Therefore, despite references in public filings and elsewhere to HHS OIG involvement in a specific inquiry, HHS OIG cannot speak to ongoing matters, should there be any, at this time.

Question: Can you elaborate on the BRAIN Initiative and share any examples of success thus far? Are there any projects with great potential that you are excited about? What can we expect in the future and how can we ensure that the research from the BRAIN Initiative is translated into medical practice for patients?

Response: Disabilities that arise from neuro/mental/substance use disorders are the result of disruptions in the underlying circuitry of the brain. However, progress in developing new treatments has been slowed by the difficulty in clearly defining the structure of brain circuits and recording the complex information flow through those cells. The BRAIN Initiative® seeks to accelerate the development and application of innovative neurotechnologies by revealing how brain cells and circuits dynamically interact in time and space, and will ultimately enable new diagnostic and treatment strategies for many types of brain disorders. The BRAIN Initiative currently funds grants in 30 U.S. states.

Since 2014, the BRAIN Initiative has invested more than \$559 million in over 500 investigators across 368 awards, resulting in over 330 publications. Of these awards, 84 have involved human subjects research, and 16 have targeted therapeutic interventions for nine distinct disorders.

Going forward, the tools and technologies developed through the Initiative will continue to enable a deeper understanding of how the brain functions normally and what goes wrong in neuro/mental/substance use disorders. BRAIN Initiative investigators are developing imaging techniques to generate accurate ultra-high resolution brain images that reflect brain activity as opposed to simply brain structure. Other researchers are working to visualize fine structures within the brain and to map brain activity with unprecedented spatial and temporal resolution.