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NOMINATION OF ALEX MICHAEL AZAR II

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON THE

NOMINATION OF

ALEX MICHAEL AZAR II, TO BE SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

JANUARY 9, 2018

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NOMINATION OF ALEX MICHAEL AZAR II, TO BE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

TUESDAY, JANUARY 9, 2018

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:02 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Enzi, Cornyn, Thune, Burr, Portman, Heller, Scott, Wyden, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, and McCaskill.

Also present: Republican staff: Chris Armstrong, Chief Oversight Counsel; Jennifer Kuskowski, Chief Health Policy Advisor; and Caitlin Soto, Oversight Counsel. Democratic staff: Joshua Sheinkman, Staff Director; Laura Berntsen, Senior Advisor for Health and Human Services; Anne Dwyer, Health-care Counsel; Peter Gartrell, Investigator; Elizabeth Jurinka, Chief Health Advisor; and Matt Kazan, Health Policy Advisor.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order. Welcome, everybody, to this morning's hearing.

Today the committee will consider and examine the nomination of Mr. Alex Azar to serve as the Secretary of Health and Human Services, one of the most important jobs in any government, anywhere in the world.

I would like to welcome Mr. Azar to the Finance Committee this morning. I want to thank you for being here and for your willingness to serve in this important capacity.

Mr. Azar certainly has his work cut out for him. Health and Human Services is a massive, sprawling department that oversees trillions of dollars in spending and liabilities and encompasses all areas of our Nation's health-care system. As a result, if confirmed, Mr. Azar's work will impact the lives of every single American.

Now, that is a big job. It requires knowledge, experience, and, most important, strong leadership. Fortunately, our nominee brings all of this to the table, having nearly 2 decades of experience in the health-care sector, including about 6 years working at the highest levels of HHS.

During his time at HHS, Mr. Azar played key roles in implementing new policies, including Medicare Part D and the Medicare Advantage program. He was also a leader in HHS's responses to the anthrax attacks shortly after 9/11, the SARS and monkeypox crises, and Hurricane Katrina, just to mention a few.

If confirmed, Mr. Azar will be Congress's primary contact on all matters relating to our Nation's health-care system. He will be responsible for the ongoing efforts to bring down costs, provide greater access to care, and give patients more choices when it comes to coverage.

Whether we are talking about work to modernize Federal health programs like Medicare and Medicaid in order to preserve them for future generations, innovating the CHIP program, or reforming the private market, Mr. Azar will be the administration's primary policy driver.

He has made clear his intentions to address the growing opioid epidemic that continues to ravage communities across the country, including in my home State of Utah. This crisis is robbing families of loved ones, employers of productive and able workers, and communities of the safety and security they once enjoyed.

Now this is an important issue to everybody on this committee, but in particular to me and other members of the committee. I look forward to working with Mr. Azar to figure out how HHS and CMS can make improvements to save lives.

As many know, I co-authored the Ensuring Patient Access and Effective Drug Enforcement Act, which has recently come under scrutiny in relation to the opioid epidemic. This law requires HHS to submit a report to Congress regarding obstacles to legitimate patient access to controlled substances and issues with diversion of controlled substances.

The required report is long overdue, and so, today, I would like to impress upon Mr. Azar the importance of getting this report to Congress so that we can have an opportunity to review and make any necessary changes to the law that may help to turn the tide of this epidemic. I hope to get his commitment to produce and release this report as soon as possible, once he is confirmed.

He has expressed his commitment to succeeding in these important endeavors, and I believe his record shows that he is more than capable of leading HHS through these next few consequential years.

Of course, there are some on the committee who have already made up their mind about Mr. Azar and are committed to opposing his nomination. This is essentially par for the course for the high-profile nominees that have come before us under this administration.

And, as in previous cases, none of the attacks leveled at Mr. Azar is focused on his record, his experience, or his qualifications. Instead, we are hearing talk about supposedly revolving doors and non-existing conflicts of interests.

While I believe Mr. Azar is more than capable of responding to his critics on his own, I would like to take just a moment to address some of the more prominent attacks we have heard thus far.

Opponents of this nomination have claimed Mr. Azar's work in the pharmaceutical industry, where he has been a senior executive for the past 10 years, disqualifies him to serve in this position.

I would hope that my colleagues would want to avoid creating standards or setting new precedents where work in the private sector is somehow a knock against a nominee. That certainly was not the standard they applied to nominees from the previous administration, and it should not apply to this one.

Mr. Azar has committed to fully adhering to all necessary ethics requirements, including the Trump administration's requirement prohibiting nominees from participating in matters involving their former employers and clients for 2 years after the end of their government service. In addition, he has committed to divesting any financial holdings that could present a conflict of interest or even the appearance of such a conflict.

So, we are not talking about anything unethical. We are not talking about a nominee attempting to unduly profit off his government position.

Experience in the private sector in dealing with the policies and regulations that come from government agencies is—in my view—a mark in favor of a nominee's qualifications. Mr. Azar's work in the pharmaceutical industry will give him important insights regarding the impact of policies designed and implemented by HHS. And, when you add that knowledge and background to the years he spent as a senior official at HHS, you have an extraordinary resume for an HHS Secretary.

Once again, I believe Mr. Azar is more than capable of responding to what have so far been empty criticisms. By any objective standard, Mr. Azar is well-qualified to serve as Secretary of HHS. My hope is that we can have a highly productive hearing today and report his nomination in short order.

I want to thank you, once again, Mr. Azar, for being willing to go through this and to appear here today. And I want to thank you, again, for returning to the call to serve the American people. I personally look forward to your testimony.

Now, before turning to Senator Wyden, I would like to reemphasize my support for the Children's Health Insurance Program and my commitment to making sure it gets reauthorized. It is one of the most important programs that I worked on and got through—of course, with the help of Senator Kennedy and others.

We have a bipartisan agreement that was reported out of committee, and I believe it improves CHIP for the long term. Congress has passed patches and fixes, but the time for short-term solutions is over. CHIP needs to be extended by January 19th, and I am going to do all I can to make sure we get it done. Children, their families, and States are counting on us.

[The prepared statement of Chairman Hatch appears in the appendix.]

The CHAIRMAN. With that, now I will turn to my good companion, Senator Wyden.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you very much, Mr. Chairman. I very much appreciate your convening the hearing.

Colleagues, this is the first time we have been together since Chairman Hatch has announced his retirement. And I would just like to take a moment—because we talked on the phone—to say publicly what I mentioned to you.

First, you have always been a gentleman. Every member of this body feels that. We know about your passion. We know about your dedication. We know about the fact that you have always had an ear for your colleagues.

Often when you and I talk, you say, "What are my Democratic friends up to? Who should I be listening to?" Always there with an ear, and I would just like to note something I do not think everybody knows, but Chairman Hatch was a boxer. And basketball players know a little bit about endurance, but, colleagues, just picture 40 years in the ring, 40 years a boxer. That is real endurance.

So I am sure we are going to have other colleagues talk at greater length, but since this is the first time we have actually been together publicly, Mr. Chairman, I just wanted to note that.

I also appreciate the fact that you mentioned CHIP. As you know, we have teamed up on this now for quite some time. I would like to think that the fact that we came out of the gate early, moved the House—they did not follow all of our approaches to being bipartisan, particularly as it came to revenue. But I think we all understand that we have to get this done, and we have to get it done quickly.

And the American people said to me during the break—what happened at the end of the year is, the kids got a patch. And if you were powerful, you ran a multinational corporation, you got permanent relief. We are better than that.

Mr. Chairman, I just want to say, I am looking forward to working closely with you. We have virtual unanimity in this committee with respect to CHIP. And getting this across the finish line and ensuring that families across this country do not go to bed at night in near panic about the prospect of an emergency illness the next day is critical. So I look forward to working with you on that.

Now to today's business. The same Donald Trump who said almost exactly a year ago that price-hiking drug companies were getting away with murder has nominated a drug company executive with a documented history of raising prescription drug prices. Mr. Alex Azar is here before the committee, nominated to serve as the next Secretary of Health and Human Services.

It is my view that the issues he will work on, if confirmed, are going to be defining domestic issues in 2018.

That is because the American people heard a lot of promises 2 years ago about how great their health care would be under a President Trump, and how the era of skyrocketing drug prices was over. Americans are going to want to know, come this November, if all those big promises, if all those big pledges they heard in the fall of 2016, actually happened. To say the administration has not yet delivered would be a wild understatement.

Now, Mr. Azar was the president of Eli Lilly's U.S.-based subsidiary, Lilly USA, from 2012 to 2017. He chaired its U.S. pricing, reimbursement, and access steering committee, which gave him a major role over drug price increases for every product Lilly marketed in the United States.

Now, Chairman Hatch suggested—and I appreciate him doing this, because he and I talked about this—focusing on the record, the public record. So our staff has done a fair amount of homework on it, and I want to spend some time looking at the track record.

The price of Lilly's bone-growth drug Forteo, used to treat osteoporosis, more than doubled on Mr. Azar's watch. The price of Effient, used to treat heart disease, more than doubled. The price of Strattera, used to treat ADHD, more than doubled. The price of Humalog, used to treat diabetes, more than doubled. These are just some of the drugs that were under Mr. Azar's purview as head of Lilly USA.

Significantly, Mr. Azar told the committee staff that while he chaired the company's pricing committee he never—not even once—signed off on a decrease in the price of a drug.

Now, this morning the committee—in my view—is likely to hear from Mr. Azar and colleagues that this is the way things work. It is the system that is at fault. It is the system that ought to be blamed.

My view is, there is a fair amount of validity in that. The system *is* broken. Mr. Azar was part of that system. Given ample opportunity to provide specific examples as a nominee of how he would fix it, Mr. Azar has come up empty.

If Mr. Azar is confirmed, it will not be the first time the President and his health-care team broke their promises. A virtual parade of Trump health-care officials have come before this committee and the HELP Committee and promised to uphold the law with respect to the Affordable Care Act.

Right out of the gate, we remember Tom Price telling us it would be his job to administer the law—administer the law at HHS, not be a legislator. The track record does not look so great there, because in effect, on Day 1 it sure seems that the sabotage policy kicked in.

Along with allies in Congress, the Trump team wasted no time undermining private health insurance markets. They cut the open enrollment period in half. Advertising budgets were slashed. It became harder for people having difficulty signing up for coverage to get in-person assistance. They attacked a rule that says women have to have guaranteed no-cost access to contraception, but fortunately that has been a move that has not been held up in the courts.

And what has been particularly troubling to me, because it goes back to my days when I was director of the Gray Panthers, the administration made it easier to sell junk insurance that fails people when they have a health emergency. All in all, the Trump administration has made millions of people's health care worse, and there does not seem to be a serious plan to undo the damage.

Mr. Azar will have to explain today whether he is going to continue that policy. We talked about it in the office yesterday. And he should, because it stands in stark contrast to what Mr. Azar did

when he was a member of the Bush administration to help launch Medicare Part D. He was part of a bus roadshow, public events, and local media appearances.

So, when it came to promoting the Medicare prescription drug benefit—and I was one of the Democrats who voted for it—he toured like he was in the Grateful Dead. Now he is set to join an administration that has tweeted less about open enrollment than about Thanksgiving safety.

Finally, there has been a lot of talk about welfare reform coming up. Mr. Azar told me he believes Medicaid counts as welfare. But everybody you ask seems to have a different answer for what exactly "welfare reform" means.

The common thread to the Republican talk here is pretty obvious: substantial draconian cuts to programs that are lifelines—Medicare, Medicaid, Social Security, anti-hunger programs, and support for struggling families. With respect to Medicaid, for millions this program is at the heart of health care in America, and it spans generations, from newborns to two out of three older people in nursing homes.

Today, Medicaid is built on a guarantee. The Trump team says it wants to end that. Those are public statements: end it. They have set into motion plans that would make it harder for a lot of people to get the care they need. In some cases it is older people, sometimes it is folks with disabilities who need long-term care. In other cases it is adults of limited means—people who struggle to climb the economic ladder. That is kind of my background, so I am interested in hearing what Mr. Azar has in mind with respect to seniors.

To me, risking the Medicaid guarantee so essential for long-term care for the eligible seniors—I want everybody to know that is a non-starter here. Furthermore, my view is, you cannot get ahead in life if you do not have your health, so endangering the health of low-income Americans, in my view, is the absolute wrong way to go.

So there are going to be other issues that fall under the welfare umbrella. Mr. Azar has no experience in those areas. I am one who feels that people with business backgrounds, those viewpoints can be welcome, but they have to be combined with a set of values that is in line with what I believe are the real priorities for the American people.

So that is my sense of where we are, and I would like to wrap up this way, Mr. Chairman. The leaders on both sides of this committee previously had regular meetings and calls with sitting HHS Secretaries. I see Mr. Leavitt, who went out of his way when he was Secretary to have those kinds of meetings, and Sylvia Burwell, and a whole host of Democratic Secretaries, did the same thing.

I would like to just note, as we wrap up, that in my meeting with Mr. Azar yesterday he noted that he was not going to go along with the last HHS Secretary who broke that bipartisan tradition to the detriment of the Senate and, in my view, good policy. Mr. Azar, without any prompting, said that he was interested in having those kinds of meetings, that he would revive it.

So, Mr. Azar, thank you for being here. Thank you for our meeting yesterday. We look forward to your statements and questions.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. Here to introduce Mr. Azar are two distinguished former Secretaries of Health and Human Services.

We will first hear from former Secretary Thompson. It is really great to see you again. It has been quite a while since I have seen you. We had a lot to do with each other way back when.

He served as the head of HHS from 2001 to 2005. Prior to that time, he served 4 terms as the Governor of Wisconsin, the longest tenure of anybody in that State's history.

As Governor, he was a pioneer in a number of initiatives, including welfare reform, which gained national prominence. As the Secretary of HHS, he oversaw the passage and initial implementation of Medicare Part D and led the Department through the aftermath of September 11, 2001.

Next we are going to hear from a very personal friend of mine—both are friends—we will hear an introduction from my good friend, former Secretary Michael Leavitt, who headed HHS from 2005 to 2009. Before that, Mike served as the Administrator of the Environmental Protection Agency for 2 years and as Governor of Utah for almost a decade.

As Governor, he presided over some very prosperous times for our State and held a number of national leadership positions. As Secretary of HHS, he sounded the alarm about Medicare's long-term fiscal difficulties.

Both Secretary Thompson and Secretary Leavitt are well-respected public servants. Their opinions should carry quite a bit of weight around here. I know they mean a lot to me, I will tell you that.

I want to thank you both for being here today to speak on behalf of the President's nomination of Mr. Azar. We will start with Secretary Thompson, and then we will hear from Secretary Leavitt.

Secretary Thompson?

STATEMENT OF HON. TOMMY THOMPSON, FORMER SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary THOMPSON. Thank you very much, Chairman Hatch, Ranking Senator Wyden, and the distinguished members of this committee. I first want to thank you for this opportunity to appear before you this morning. Before I start, I would like to echo something that Senator Wyden said.

Mr. Chairman, you have always been a friend, a distinguished member, a mentor to me personally, and always a great leader, and I feel that today's meeting is somewhat bittersweet for me. Sweet so that I can be here to endorse my colleague; bitter to find out that you are leaving this august body. Thank you for your service to our country, and thank you for being my friend.

The CHAIRMAN. Well, thank you.

Secretary THOMPSON. I could not be more pleased or prouder to introduce my friend and former colleague, Alex Azar. As the President's nominee to be the next Secretary of Health and Human

Services, Alex is an outstanding individual with a great family. His wife Jennifer, his two children, are both here as well as his father Alex.

And I am here to provide my strongest personal endorsement and to tell you that he has the capacity, the capability, the intellect to be an incredible Secretary.

If confirmed, Alex will serve our Nation honorably and competently. As I am sure you know, Alex has impeccable academic credentials, including having graduated from Dartmouth College and Yale Law School. The only thing I have against him is that he did not go to the University of Wisconsin.

He has also clerked for Justice Antonin Scalia on the United States Supreme Court. I was privileged to have him as my General Counsel when I had the honor of serving as HHS Secretary under George W. Bush.

Alex was an excellent General Counsel who developed a deep understanding of HHS, its mission, and has respect for the rules and laws that regulate and govern these programs. As a result, he deeply respected and passionately was respected by the career civil servants with whom he worked and led.

From his tenure as General Counsel, he went on to serve as Deputy Secretary of HHS, further deepening his experience with the understanding of his department, its important responsibilities, and its world-class employees. And most recently, he successfully led a large and important health-care company in this country.

But the basis of my recommendation is not just Alex's intellect, his leadership experience, or the deep understanding of the department which he might lead. One of the most important attributes of Alex Azar is his character. I know from personal experience that he is very honest, dedicated, passionate, and trustworthy. He says what he means, and he means what he says. He is quite simply a man of great integrity.

If the United States Senate were to confirm him, the members of this great committee would have a thoughtful partner who truly understands the complexity of our health-care system and human services programs and knows how to get things done at the Department of HHS. Further I believe, because he wants to take on these challenges, he would work collaboratively with you and would passionately articulate and carry out your wishes and with you try and find the solutions to the pressing health-care problems and find ways to improve it for our great country. If Alex says he will do it, I can assure you that he will.

Mr. Chairman, and all members of this committee, thank you for giving me this opportunity to help introduce Alex Azar.

The CHAIRMAN. Well, thank you. Those words are very, very strong and very good.

Secretary Leavitt?

STATEMENT OF HON. MICHAEL LEAVITT, FORMER SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary LEAVITT. Chairman Hatch, Senator Wyden, and members of the committee, I join with my colleagues in expressing grat-

itude and appreciation for your friendship, Senator, and look forward to the coming year and all that you accomplish.

I join as well today with Secretary Thompson and want to be completely associated with his comments about Alex Azar. I too unequivocally recommend that he be confirmed as the 24th Secretary of the Department of Health and Human Services. He is supremely qualified for that purpose, and he will carry out that duty with fidelity.

I too, along with Secretary Thompson, feel well-equipped to be able to offer an evaluation of Alex Azar. Alex was General Counsel when I became Secretary, but subsequently he was confirmed by the Senate of the United States as Deputy Secretary of HHS.

As has been related, HHS is a large, very complex Federal agency. It not only looks after administering the Nation's health-care system, but it also looks after all of the human services that we jointly as a country provide.

HHS oversees the Nation's public health system and much of the national, medical, and scientific research. It carries out a significant set of responsibilities related to disaster recovery, as well as representing the United States of America in various matters around the world.

As Deputy Secretary, Mr. Azar functioned essentially as the Chief Operating Officer of the Department. I delegated much of the day-to-day operation to his supervision. In that role, he demonstrated the skill as a collaborative leader. I will cite an example.

President Bush had a management agenda to improve the efficiency of the Federal Government. They had developed a series, almost three dozen different areas, of evaluations that were to be graded on a chart that had green, yellow, and red.

Mr. Azar set a goal to have HHS become the first department in the Federal Government to have every measure green. He organized an effort among HHS's 27 operating centers, and he met that goal—the first.

I am also witness that Mr. Azar is a man of good judgment. As Secretary, I delegated oversight of the Department's administrative rulemaking responsibility. In a very lawyerly and impartial way, he oversaw the rulemaking process and made recommendations to me as Secretary that I learned to have great confidence in. He is a man of good judgment.

I have seen Mr. Azar under fire. It has been referenced before: he is a steady leader in crisis. There was a period during my service when we were managing the recovery from Hurricane Katrina. We were preparing for what appeared to be a potential pandemic influenza, and we were implementing Medicare Part D all at the same time. Mr. Azar was measured, yet he was responsible. He established priorities, and he accepted responsibility.

Should you choose to confirm Mr. Azar, I want to assure you that you will find him as I did, as an effective communicator. I believe you will see bipartisan communication from Mr. Azar. It is his way. He is a world-class policy leader, a policy thinker. He is a person who brings unique experience from the private sector, something that I believe will be of immense importance over the course of the next years.

And lastly, I will close with two final observations. The first is Alex Azar, by my experience, is a very good person. And he is a man of compassion, which is an attribute, in my judgment, that is critical in carrying out the important mission of HHS.

Based on his previous experiences, I do not know that there is a person who has ever been nominated as Secretary of Health who is in a position to hit the ground running like Alex Azar. He will serve the people of the United States well.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you both very much.

That is high praise, indeed, Mr. Azar. And we will turn to you right now.

And we are grateful to the two of you for showing up here today and helping us to understand this even further.

I have had a long experience with Mr. Azar. I could not have a higher opinion than I have right now. And I am just very, very pleased that he has had this nomination.

We will turn to you, Mr. Azar, for your comments.

STATEMENT OF HON. ALEX MICHAEL AZAR II, NOMINATED TO BE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. AZAR. Thank you very much, Mr. Chairman. If you would not mind, I would like to introduce my family who are here today.

I am joined today by my wife Jennifer, my daughter Claire, and my son Alex, as well as my father Dr. Alex Azar, my sister Stacey, and her husband Mick. Unfortunately my mother, Lynda, could not be here today, and most tragically my step-mother Wilma passed away just last July from cancer. Thank you all to my family members. Having an opportunity such as this simply does not happen without family support and guidance, as all of you know personally, I am sure.

Mr. Chairman, Ranking Member Wyden, and members of the committee, thank you for the opportunity to appear before you as the President's nominee to be the Secretary of Health and Human Services.

I cannot tell you how touched I am to hear the words of Secretary Thompson and Secretary Leavitt. Thank you both so much for those kind words and for your friendship and mentorship over the last 20 years. I simply cannot think of two gentlemen from whom I have learned more professionally and personally in terms of leadership than the two of you, and it just means so much to be sitting here with you. I never thought that day would happen. Thank you.

I also thank President Trump for the confidence that he has bestowed on me in nominating me for this awesome responsibility.

Ninety-seven years ago, my grandfather, an impoverished teenager who spoke not a word of English, stepped out of steerage on the *S.S. Argentina,* completing his long journey from Amioun, Lebanon to America. As he entered the receiving hall of Ellis Island, he met an individual who was wearing a military uniform.

That person possessed the power to admit him or to send him back to poverty and uncertainty. That person was a member of the United States Public Health Service.

It is a testament to all that I love about this country that just 97 years after my grandfather went through his 6-second physical on Ellis Island with no discernable prospects other than the political, economic, and religious freedom that America offers, his grandson might be in charge of that very same Public Health Service, as well as all of the other world-renowned components of the Department of Health and Human Services.

The mission of HHS is to enhance and protect the health and well-being of all Americans, through programs that touch every single American in some way every single day. Through its outstanding leaders and career staff, HHS is primed to meet that challenge. The task is humbling, I will say.

Marshaling and leading the incredible resources of the Department require innovating, never being satisfied with the status quo, and anticipating and preparing for the future. I hope I gained these skills in the dark days after 9/11, as we faced the health and human consequences of those attacks; through the subsequent anthrax attacks and preparedness for potential further biological, chemical, radiological, or nuclear attacks; in the implementation of our completely novel Part D prescription drug benefit for seniors; by helping to build global, national, State, and local pandemic flu preparedness in our response to threats such as SARS and monkeypox; in our efforts to continue to reform welfare programs to make them as modern, responsive, and empowering as possible for the individuals and families that we serve; through innovation in the private sector to bring life-improving therapies to our people and the people of the world; and finally, in harnessing the power of big data and predictive analytics to make us more efficient and capable of serving our fellow Americans.

With a department the size and scope of HHS, it can be difficult to prioritize. Nonetheless, should I be confirmed, I do envision focusing my personal efforts in four critical areas.

First, drug prices are too high. The President has made this clear. So have I. Through my experience helping to implement Part D and with my extensive knowledge of how insurance, manufacturers, pharmacy, and government programs work together, I believe I bring skills and experiences to the table that can help us tackle these issues while still encouraging discovery, so Americans have access to high-quality care.

Second, we must make health care more affordable, more available, and more tailored to what individuals want and need in their care. We all share a common concern for our fellow Americans who are struggling to achieve access to quality health care, even if we do not necessarily agree on how best to go about addressing that challenge.

Under the status quo, premiums have been skyrocketing year after year, and choices have been dwindling. We have to address these challenges for those who have insurance coverage as well as for those who have been pushed out or left out of the insurance market by the Affordable Care Act.

Third, we must harness the power of Medicare to shift the focus in our health-care system from paying for procedures and sickness to paying for health and outcomes. We can better channel the power of health information technology and leverage what is best

in our programs and in the private, competitive marketplace to ensure that the individual patient is at the center of decision-making and his or her needs are being met with greater transparency and accountability.

Finally, we must heed President Trump's call to action and tackle the scourge of the opioid epidemic that is destroying so many families, individuals, and communities. We need aggressive prevention, education, regulatory, and enforcement efforts to stop overprescribing and overuse of these legal and illegal drugs. And we need compassionate treatment for those suffering from dependence and addiction.

These are serious challenges that require a serious-minded sense of purpose, and if confirmed, I will work with the superb team at HHS to deliver serious results.

I thank President Trump for this important opportunity to serve the American people, and I thank this committee for your consideration of my nomination, Mr. Chairman.

The CHAIRMAN. Well, thank you very much.

[The prepared statement of Mr. Azar appears in the appendix.]

The CHAIRMAN. You are really qualified for this position; in fact, one of the most qualified I have seen in my whole term in the United States Senate. So I am really pleased you are willing to sacrifice to come here and help turn this mess around and get it working better.

Let me just ask this question. Mr. Azar, as you know, I have fought hard to extend the CHIP program for a full 5 years to support the 9 million families that rely on it. And I think we will get this done as soon as possible. And when that happens, HHS will have the 5 years of runway to work with.

What should HHS be doing to bolster CHIP and ensure its continued success?

Mr. AZAR. Well, Mr. Chairman, the Children's Health Insurance Program is such an important part of your personal legacy, and I really do look forward to the very swift reauthorization so we can secure that program for this year and for the years to come for our people. It really serves as a very important bridge and stable force for the children of our country.

I would just continue to look forward to working with you and other members of the committee on any ideas that you have, following reauthorization, in terms of implementation, ways that we can make that program more responsive, more effective for any of the beneficiaries in that program, ways that we can make our programs more efficient so that we can spread the dollars that you give us to reach as many children as humanly possible, but very much just open-minded approaches from your learnings, your extensive learnings with the Children's Health Insurance Program.

The CHAIRMAN. Well, thank you.

Senator Cardin, we will turn to you.

Senator CARDIN. Thank you, Mr. Chairman.

First, let me welcome Mr. Azar here. I particularly want to welcome your dad, Dr. Azar, who is with us.

Mr. Chairman, Mr. Azar grew up in Salisbury, MD. His father is a distinguished physician and was involved in the policy development in our State of Maryland on health-care policy. And I had a

chance to work with him when I was in the State legislature. So it is good to see the family that is here, and we thank Mr. Azar for his willingness to serve in this very important position.

So the first question I am going to ask you is going to be a parochial one with Maryland—if necessary, I will get your father involved here—and that is protecting some of the initiatives that we have had in Maryland. We have, as you know, an all-payer rate system for our hospital care that requires the attention of HHS to make sure that we can continue to provide this uniform-type service in our State.

Many States have come up with innovative ways to try to help in our health-care system, and we had a chance to talk about it, but I just urge you to pay attention to these types of initiatives and be understanding that we may need some special attention in order to be able to preserve this type of access to care.

Mr. AZAR. Senator, thank you, and thank you for the wonderful meeting that we had where we got to discuss this particular issue. If confirmed, I would love to come back home to Maryland and spend time with you really learning more about the Maryland approach. It is very innovative. It is cutting-edge, and you have my commitment that, if I am confirmed as Secretary, I will want to work with you and be a good partner in that.

I think that all kinds of innovation and different approaches at the State level, as you said, are what we need to be trying. No one entity, no one person, has the right answers. So I want to be supportive of you and the State of Maryland in what they are trying to do here.

Senator CARDIN. I appreciate that.

One of the major accomplishments under the Affordable Care Act was to elevate the Office of Minority Health and Health Disparities as a full institute at the National Institutes of Health, but also to establish minority health offices in all the agencies of HHS.

It is important that the Secretary get directly involved in these issues. The historic discriminations in our country are well understood.

Do we have your commitment that you will pay particular attention to this particular priority to make sure that we do right for minority health in America?

Mr. AZAR. You do.

And thank you for your long-standing commitment in that area. If confirmed, I would also just love to be getting your ideas of ways we can—things that we can do to be better in that space. The color of one's skin, one's sex, whatever, where one lives—we ought to be doing everything we can at HHS to ensure that people have the highest quality access to the value care in the United States.

Senator CARDIN. I want to talk about one area where the Trump administration has deviated from previous Republican administrations in re-imposing the so-called gag order which deals with services on contraceptives and other areas, the Mexico City policies. I disagree with this policy. I think it compromises women's health in America. It compromises our ability to work internationally with different organizations to protect health generally, but the manner in which this was implemented under the Trump administration is compromising our ability to work with international health organi-

zations in dealing with issues from AIDs to malaria to so many of the other issues in addition to women's health issues.

Are you willing to take a look at this to see whether we can get a more rational way? Again, I disagree with the policy to start off with, but the way it is being implemented now is counterproductive to global health priorities, and it does really require some attention of the Secretary and input into the way that these policies are implemented.

Mr. AZAR. So, Senator, I am not deeply familiar with the ways in which any implementation of the Mexico City policy changed at the beginning of this administration compared to the past one. My sense is, there were some differences, as you mentioned.

I want to learn more about that and would be happy to discuss that with you. I clearly share the overarching view that the United States needs to be deeply engaged in global public health. The rest of the world's health impacts us.

As the Deputy Secretary's General Counsel, I was engaged in those issues, with the leadership of Secretary Thompson and Secretary Leavitt, so I am happy to look at that issue and learn more about any changes that were made and hear from you on that.

Senator CARDIN. Thank you.

And lastly, you spoke in your opening statement about drug prices being too high in this country. We all know that. We pay about twice the average of Canada, on average, of the cost of prescriptions. Globally, it is even more out of step.

Tell me how you intend to address this issue of bringing down the cost of prescription drugs to consumers in this country, particularly in light of your previous experience at Lilly.

Mr. AZAR. So, Senator, thank you.

I actually hope that from having worked these last several years in that space, it brings a knowledge anyone else coming in as Secretary—this is such a complex area. The learning curve for any other individual would be so high. To just know how that system works and what the incentives are, I think, brings a great advantage to being able to hit the ground running.

We need to deal with issues of competition. We have to ensure we have robust generic competition, branded competition. I want to ensure we create a very viable and robust biosimilar market also, to compete against branded companies in that high-cost biologic space. So that is critical.

I also want to make sure that we go after any types of gaming or exploitation of exclusivities or patents by branded drug companies. I fought against this when I was General Counsel, actually led development of a rule that changed—for the first time ever—regulations that saved $34 billion for patients over 10 years as a result of our efforts.

There is no silver bullet here, though. I want to be very clear. There is not one action that all of a sudden fixes this. I want to hear ideas from others.

The most important thing we have to figure out is, can we reverse the incentive on list prices? There is a lot that we all know we can do on the discounted prices. But I want to work with this committee and anyone who is smart and thoughtful about creating incentives that actually pull down those list prices so that, when

the patient walks in needing to pay out of pocket at the pharmacy, they are not hit with that kind of cost.

That is one of the harder issues to solve, but I am deeply committed to working with you on that.

Senator CARDIN. I am sure my colleagues will have other questions on this issue. Thanks.

Mr. AZAR. Thank you.

The CHAIRMAN. Well, thank you, Senator.

I have some obligatory questions that I ask all nominees before this committee that I have not asked yet. So I am going to take the time to do that.

First, Mr. Azar, is there anything that you are aware of in your background that might represent a conflict of interest with the duties of the office to which you have been nominated?

Mr. AZAR. No, Mr. Chairman. Although, I will follow the advice of the career designated agency ethics officials to ensure that I manage any potential conflicts that come about through the ethics approvals as part of the confirmation process also.

The CHAIRMAN. Well, thank you.

Second, do you know of any reason, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities of the office to which you have been nominated?

Mr. AZAR. No, Mr. Chairman.

The CHAIRMAN. Third, do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of Congress, if confirmed?

Mr. AZAR. Yes, Mr. Chairman.

The CHAIRMAN. Finally, do you commit to provide a prompt response in writing to any questions addressed to you by any Senator of this committee?

Mr. AZAR. Yes, Mr. Chairman.

The CHAIRMAN. Well, thank you very much.

We will turn to Senator Grassley now.

Senator GRASSLEY. As I promised you in my office, you would know about the questions I am going ask. I only have two questions.

The first one involves the Physician Payment Sunshine Act that I worked hard to get passed and is part of Obamacare. Background to my question: in March of 2017, the University of Iowa reported a growing crisis of prescription opioid use and overdoses in Iowa. While lower than some States, Iowa has seen rates of prescription drug deaths quadruple since 1999.

In addition to concern about misuse of these drugs, I also think it is important to protect patient access to needed medications. One strategy to achieve that balance is to ensure that prescribing decisions are made in the best interest of the patient and not as a result of inducement to health-care providers by drug companies.

Recent reports have raised concern about payments from pharmaceutical companies to health professionals and the effect on opioid prescribing practices. The bipartisan Physician Payment Sunshine Act was designed to provide transparency regarding payments to physicians from drug companies. This law created the open payment database at CMS.

In November, Senator Blumenthal and I wrote a letter to your department thanking them for the support that CMS's Center for Program Integrity has given. In that letter, we further encourage the prioritization of funding and administration of the open payments database.

Now, you may wonder why I am asking this question. Before I ask it, Mr. Chairman, I would like to have the Blumenthal-Grassley letter and the University of Iowa report put in the record.

The CHAIRMAN. Without objection.

[The documents appear in the appendix beginning on p. 162.]

Senator GRASSLEY. A year ago—I think it was in the omnibus appropriation's bill—a group of doctors and the House of Representatives tried to gut this legislation. We prevented that.

So a very simple question to you: will you commit to continuing to collect and post all the data currently available on the open payments website?

Mr. AZAR. Yes, Senator Grassley.

As you know, I am a big supporter of the Sunshine Act and your work there, and I supported it at the time that you had first proposed it. I think that transparency is extremely helpful.

Senator GRASSLEY. Yes.

My second and last question: since the EpiPen misclassification fiasco, I focused a lot of my oversight on the Medicaid drug rebate program. In the course of my oversight, I found that during the Obama administration, CMS did not properly oversee the program, causing billions in taxpayer dollar losses.

For just the EpiPen, the taxpayers may have lost out on more than a billion dollars. It is kind of this way: $1.7 billion lost, but DOJ recovered $475 million, so a $1.3-billion loss. Now why they did not go after the other $1.3 billion, I never got an answer from DOJ.

In December 2017, the HHS Inspector General released a report on the rebate program and found that hundreds of drugs were potentially misclassified. For instance, out of a sampling of just 10 drugs from 2012 to 2016, Medicaid may have lost $1.3 billion in rebates. Now that is just from a sampling. So we do not know how many billions of other dollars may have been lost.

So my question to you—by the way, I would like to also have submitted for the record a letter that I have to former CMS Administrator Slavitt.

The CHAIRMAN. Without objection.

[The letter appears in the appendix on p. 166.]

Senator GRASSLEY. Yes. Okay, thank you.

So this question—there is a lot of taxpayer money at stake here. How will you approach fixing the Medicaid Drug Rebate Program so that it is properly overseen and taxpayers' losses are kept to a minimum?

Mr. AZAR. Thank you.

Senator, I was very concerned to see the media reports and to read that report from the Inspector General on the rebate program. I certainly will work with Administrator Verma as well as with CMS to ensure that the program is improved to get at that.

One of the key issues, I think, is to ensure that the regulations and guidance there are clear so that those companies know what

their obligation is, and if necessary, moving to enforcement to ensure that they understand that these are obligations that need to be held up.

Senator GRASSLEY. Thank you, because doing that, you can save a lot of taxpayers' money.

The CHAIRMAN. All right.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Mr. Azar, I am going to ask some questions about these price issues, and we are going to hold up some charts. Certainly, if you have any questions about the charts that are being used, we welcome your comments.

During the 5 years that you were president of Lilly USA, you had direct responsibility for pricing strategies of the biomedicines unit, including the osteoporosis drug Forteo. You also chaired the company's U.S. pricing committee.

I am going to quote how you described your role as it related to Forteo in a written statement to the committee. You said to the committee, "As chairman of the Pricing, Reimbursement, and Access Steering Committee for Lilly USA and as the relevant profit and loss business unit leader for the biomedicines business unit for the United States, I approved pricing recommendations for this medicine." That is your quote.

During your time in these positions, based on work by the Finance Committee's Democratic investigative team, the company's annual financial reports showed that Forteo's U.S. revenue increased 58 percent, reaching $770 million in 2016. Each year the company told shareholders that revenue increased because Forteo's price went up.

You have told the Finance Committee that you were responsible for approving the price of Forteo. So let us look at the prices.

This chart that we are holding up shows the wholesale package price of Forteo. And your watch is the red line, where the price is just going up and up and up. The blue line, as I indicated, is the price before you became president. The red line is the price while you were president.

The price more than doubled on your watch from a little more than $1,000 to more than $2,700. That is a 164-percent increase in 5 years. *The Wall Street Journal* recently showed how these price increases affected consumers when the paper did a profile of one older person who was on Medicare who paid $5,600 of her own money to buy Forteo after she broke her back.

Now, Mr. Azar, this certainly indicates the wholesale price for Forteo in the United States, in fact, more than doubled on your watch. Yes or no?

Mr. AZAR. I believe that data is directionally correct. I do not have the actual pricing information, but I believe that is correct.

Senator WYDEN. Okay. Let me take a look now at Strattera. This is another drug under your purview which is used to treat Attention Deficit Hyperactivity Disorder.

This chart shows how the price of the drug changed over the years. Again, the price before you became president is blue. The price while you were president is red. This is another big jump in

pricing that began shortly—based on our investigations—after you became president.

If these were isolated incidents, it could be written off, in my view, as an anomaly. It seems like people have gotten hurt, but it would be an anomaly. But the company's annual financial report showed that during your time at Lilly's U.S. pricing committee—when you ran that—higher prices drove U.S. revenue for drug after drug after drug, even when demand for the products fell.

So one more question in this line of questioning: as chairman of the U.S. pricing committee for this company, did you ever lower the price—ever—of a Lilly drug sold in the United States?

Mr. AZAR. Drug prices are too high, Senator Wyden. I have said that. I said that when I was at Lilly.

And every——

Senator WYDEN. That is not the question.

Did you ever lower the price? That is the question I——

Mr. AZAR. I do not know that there is any drug price of a branded product that has ever gone down from any company on any drug in the United States, because every incentive in the system is towards higher prices.

And that is where we can do things together, working as the government to get at this. No one company is going to fix that system. That is why I want to be here working with you.

Senator WYDEN. Let the record show that when that specific question for Mr. Azar was asked—when the bipartisan Senate Finance Committee was present—did he ever lower the price of a Lilly drug sold in the United States, Mr. Azar said "no." Let the record show that that is what we were told.

And now we are going to have to make some judgments about how you are going to approach the issues of helping to shrink pharmacy receipts. You and I talked about legislation that I have introduced that would ensure that the consumer got the price reduction at the window. I introduced that legislation. So we are probably going to ask whether you are going to urge the President to support it.

The CHAIRMAN. Your time is up, Senator.

Senator WYDEN. Okay.

Thank you, Mr. Chairman. I will have questions on the second round. Thank you.

The CHAIRMAN. Okay.

Senator Enzi?

Senator ENZI. Thank you, Mr. Chairman and Ranking Member Wyden, for your quick work in holding this hearing so that we can move the nomination of Mr. Azar to the full Senate for consideration.

The Secretary of Health and Human Services is a role that should not sit vacant. There are too many vital priorities in health care that need immediate attention, and I appreciate you moving forward. I also appreciate Mr. Azar's willingness to serve.

Mr. Azar, in my meeting with you after your nomination, I was pleased to get your top priorities for your time as Secretary, if confirmed.

Appropriately, he will be focusing on the affordability of prescription drugs. This is something that everyone around this dais knows about and hears from constituents about.

The problem is complex and does not have a simple solution, but I am very encouraged to hear his commitment to taking this on and know that he has real expertise and understanding of the manufacturer side of the equation. I think that is something that we really need. This is something that I believe can and should have a bipartisan approach, and I hope to hear that kind of commitment from my colleagues here as well.

Mr. Azar, you have listed and now restated your priorities of drug prices, insurance market affordability and choice, working toward a value-based system in health care, and the opioid crisis. I completely agree. These are where the Secretary's focus must be, and I look forward to working with you to get that job done.

Mr. Azar has been before the Senate before, but I think this environment this time around is obviously very different. I am impressed by his willingness to go through this very difficult process and appreciate his willingness to serve.

Now, to get to a question, Wyoming's Department of Health has had a Medicaid 1115 waiver application sitting at the Centers for Medicare and Medicaid Services for over 2 years. It is a tribal uncompensated care waiver.

I understand that the waiver is under consideration, but I would encourage you, if confirmed, to take expeditious action in making a determination on this long-awaited application. This is something that we have discussed before, which I know that you, not currently being in the position, are not able to comment upon. However, I would appreciate your commitment to examining this application as quickly as possible.

Mr. AZAR. Senator, thank you for raising that, and again, thank you for taking the time to meet with me.

I obviously do not know the parameters on the Wyoming waiver, but I will tell you that I am very concerned about the amount of time that you have mentioned that it has been pending. I do want to ensure that if I am confirmed as Secretary that CMS works with the States on any of these demonstration projects or waivers as a very good partner and is responsive and timely.

So I will, if confirmed, get on that right away, looking at that for you with Wyoming.

Senator ENZI. Thank you very much.

Now you have also talked about your priorities on drug pricing, and that seems to be the topic here. I appreciate your willingness to take on that very serious and complicated issue. I appreciate the background that you bring to that issue.

I am sure you are familiar with the announcement by Novartis about their discussions with CMS to think differently about how they price the new leukemia drug Kymriah. I know that is not a finalized agreement. I know there is not long-term data showing how these kinds of arrangements work.

But it seems like an interesting approach and one that is worth exploring further. What is your view of value- or outcomes-based contracting in the private sector and the possible applicability to public payers like Medicare?

Mr. AZAR. Senator, I think value-based or outcome-based contracting around—first, generally within the health-care system, but especially with medicines, can be vitally important. And I also think that there are some of the regulations and approaches that we have within Medicare that actually get in the way of that.

I know that when I was doing this in the private sector, I wanted to be able to put our money where our mouth was, to say, if it works, pay us. If it does not work, take a greater discount. But some of the rules around government price reporting—and other rules—can actually be a barrier to that.

I think there is actually fairly broad bipartisan support to try to address those to open the door to that so we could get real value-based contracting, paying for value and paying for outcomes on these medicines. So I am quite excited and think that can be an important part of how we think about drug pricing and value for taxpayers and for customers.

Senator ENZI. Thank you.

I appreciate the expertise you bring, but also the record that you have of working in the government in the past. So thank you for being willing to serve.

I yield the balance of my time.

The CHAIRMAN. Thank you, Senator.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

I first want to personally thank you for your commitment on the Children's Health Insurance Program. I have a real sense of urgency about this as you do, and I want to thank you as well for your leadership over the years.

The CHAIRMAN. Thank you.

Senator STABENOW. Mr. Azar, welcome. Welcome to your family.

You have indicated that you will hit the ground running, and my question is, in what direction will you be running? And I think that is the real question.

I share the concerns of Senator Wyden in terms of what happened when you were at Eli Lilly. The fact is—and I will talk about just another drug, and that is Humalog, insulin, and the fact that that particular product is so critical for people, obviously with diabetes.

From 1996 to 2017, it went up 700 percent. During the time that you were at Eli Lilly, it also doubled. It doubled in price. So I am wondering, when you say that drug prices are too high, do you agree that $255 for Humalog, for one vial—and multiple vials are needed—do you believe that $255 for one vial is too high?

Mr. AZAR. So across the board, drug prices are too high, including for any product like that. And insulin's prices are too high. All drug prices are too high in this country.

And the increases, you know, this is what is so bizarre about the way the system is organized, that those price increases happen—and my former employer has said this publicly—yet during that same period, the net realized price by the company stayed flat. And yet the patient who is walking into the pharmacy—so just to cover for increased rebates, the patient walks into the pharmacy whose insurance may not be paying for that, and is absorbing that cost.

That is what I want to work with you to try to solve.

Senator STABENOW. Well, Mr. Azar, first of all, insulin was basically first approved 100 years ago. So any cost to the company to recoup for any R&D in addition to what taxpayers pay for would already have been done.

I appreciate that you say that it is too high. Yet in that position, with this system, you doubled the price.

So you were taking advantage, certainly, of that system. That was a choice that you had as president, which is of concern to me, because I am assuming the price of manufacturing the insulin did not double. Is that correct?

Mr. AZAR. So you know this—I do not have the data. I did not run the diabetes business unit at Lilly, so I do not have the data on the price of manufacturing.

The system, it works for those players in the system, but it does not work for the patient walking into the pharmacy.

Senator STABENOW. Okay.

Let us talk about how to make it work.

Mr. AZAR. I would love to.

Senator STABENOW. President Trump has been back and forth on this, but he has said in the past that he supports negotiating prescription drug prices. Do you believe the government should negotiate prescription drug prices?

Mr. AZAR. I think where the government does not have negotiation, it is worth looking at. So for instance, one of the things I have talked about is in Part D, we do significant negotiation through pharmacy benefit managers that get the best rates of any commercial payers. We do not do that in Part B, which is where we have physician-administered drugs. We basically pay sales price plus 6 percent or some other number.

I would love to take those——

Senator STABENOW. So just in the interest of time, I am really—I do not mean to be rude, but in the interest of time—so you are saying, yes to negotiation of prescription drugs, because——

Mr. AZAR. Where we can do so, that preserves innovation and preserves access for patients. I want to look at anything that is going to help us with drug pricing.

Senator STABENOW. Okay.

Mr. AZAR. So in Part B, I think we should be looking at those approaches.

Senator STABENOW. Okay.

So the National Academies of Sciences, Engineering, and Medicine have indicated that buyers in the biopharmaceutical sector, buyers often appear to be in a weak position with little alternative but to purchase the drug at whatever the price. They say the effect of not allowing HHS to negotiate prices is to tilt the bargaining power further in favor of drug manufacturers.

Now Part D, as it was originally passed, basically prohibited—it was on the side of the drug company saying, you cannot negotiate.

So do you support changing the law so that under Medicare Part D you can negotiate on behalf of seniors and the American people to bring prices down?

Mr. AZAR. So right now, negotiation is happening in Part D. It gets the best rates there are out there.

The National Academies—they are just wrong on that. These are incredibly powerful negotiators who get the best rates available.

Senator STABENOW. So when they say it is in favor of the drug companies, you disagree with that?

Mr. AZAR. They are incorrect.

Senator STABENOW. You disagree with that. All right.

Mr. AZAR. For the government to negotiate there, we would have to have a single national formulary that restricted access to all seniors for medicines. Even CBO, Peter Orszag, has said this. That would be the only thing that could change. I do not believe we want to go there in restricting patient access.

Senator STABENOW. Well, the President's Commission on Combating Drug Addiction and the Opioid Crisis also recommended using emergency powers for naloxone, a lifesaving drug related to the opioid addiction problem. They just recommended that negotiation be used for that lifesaving drug against opioid addiction.

Would you support negotiation for that drug?

Mr. AZAR. So Senator, I want to look at that and learn more about that situation. But if the government is the purchaser—so let us say, for instance, if we are going to be buying that as part of the opioid crisis program, and we are directly buying that and supplying it out to States and first responders, there is absolutely nothing wrong with the government negotiating that.

I did that with ciprofloxacin, under Secretary Thompson, during the anthrax attacks. There is nothing at all wrong with the government directly negotiating for value when we are the purchaser, and then if we are supplying that out.

I need to learn more about that issue from within the government.

Senator STABENOW. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Thank you, Mr. Azar, for being here today. Congratulations on your nomination, and thanks for your willingness to serve, and to your family for being willing to put up with the demands that come with being involved in public life.

I think we all share your priorities of lowering the cost of health care and prescription drugs. I hope that based upon your past experience—it is an industry, obviously, that you understand, that you can help us with with suggestions about how to get those drug prices down, because that is an incredibly important part of health care today, and an incredibly costly part, unfortunately.

So I look forward to working with you on these issues. We have discussed this previously, but we have providers in South Dakota that are working to innovate and ensure access to care for folks in rural areas and in Indian country, yet we have a lot of challenges that exist.

For years the Indian Health Service facilities in South Dakota have been found to have serious deficiencies and poor quality of care. For instance, Pine Ridge recently lost its ability to bill Medicare and Medicaid for failing to meet CMS standards. This has to change.

I have been working with Senators Barrasso and Hoeven on the Restoring Accountability in the IHS Act to give HHS greater authority to get IHS back on track. And specifically, the bill would give HHS the authority to terminate poorly performing employees, streamline the hiring process, and create incentives for quality providers to remain on the job.

Is this something that you agree you could work with Congress to achieve?

Mr. AZAR. Absolutely, Senator. I look forward to getting those additional authorities, and I also look forward to any ideas you have. It is unacceptable for us to not be providing high-quality service there.

Senator THUNE. Okay. I appreciate that and look forward to working with you and your team.

As you know, I have been supportive. I share this, I think, as well with you: the desire to find solutions to address the application of Medicare competitive bidding rates in noncompetitively bid areas, an issue that South Dakota medical equipment providers report has caused supplier closures and gaps in Medicare beneficiary access.

HHS was supposed to have issued a report to Congress—this came per the 21st Century Cures Act—on beneficiary access by January 12th of 2017. I am not aware the report has been completed. So I would request that, once confirmed, you would work to have that report completed quickly.

Additionally, if confirmed, I would ask that you commit—will you commit to working with the Office of Management and Budget to quickly approve the interim final rule to provide relief for rural providers that has been pending since October of 2017?

Mr. AZAR. Yes, Senator. I would be happy to work on those issues. Thank you.

Senator THUNE. Thank you.

In the face of provider shortages, South Dakota's health systems have increased access to care in rural areas through telehealth. As you may be aware, several Senators have been working on the Connect for Health Act, which would further expand the use of telehealth and remote patient monitoring in Medicare.

Importantly, one provision of that legislation would provide the Secretary of HHS the authority to waive certain restrictions in current law where telehealth would reduce spending or improve quality of care. If confirmed, would you support Congress enacting that provision to provide you the discretion to expand access to telehealth services?

Mr. AZAR. Senator, as we had the opportunity to discuss together in our meeting, I am a big supporter of telehealth and alternative means of providing care, especially in rural communities. I think sometimes we can be penny-wise and pound-foolish in these areas.

Senator THUNE. Thank you.

Mr. AZAR. I would love to work with you on that.

Senator THUNE. I look forward to working with you and your team on that as well. It is something that has tremendous potential to deliver benefits to areas of the country for which, in many cases, it is difficult to get delivery of health-care services in a timely and a cost-effective way.

So thank you for your answers to those questions. We will hold you to them and follow through with you and look forward to working with you once you are officially installed there. It is a big job, as you know, with lots of moving parts, lots of challenge, but also lots of opportunity to really make a difference in the lives of people in this country who need access to more affordable health-care services.

Mr. Chairman, with that, I yield the balance of my time.

The CHAIRMAN. Thank you, Senator.

Senator Casey?

Senator CASEY. Mr. Chairman, thank you very much.

I want to reiterate what Senator Stabenow said earlier about your service. We commend you for your service and the work you have done over many years in the Children's Health Insurance Program. I hope we can get that done in the next couple of days, I hope by the 19th. We are grateful for that.

Mr. Azar, thank you for putting yourself forward for service, again, in the Federal Government. It is good to see your family.

You and I have common State roots: Scranton and Johnstown. But despite those commonalities, we have a lot of disagreements on health-care policy. I wanted to explore that.

First and foremost, I appreciate the time you spent in our office going back a couple of weeks ago when you were coming before the Health, Education, Labor, and Pensions Committee, a committee of which I am a member. And at that time, we talked a good bit about health-care policy, in particular Medicaid, which is a program that I think many Americans appreciated over many years, but probably never more so or never with greater urgency than this year, when there were proposals which in my judgment—and I think in the judgment of a lot of folks who have followed health-care policy for their whole lives—would have decimated it, some of the proposals this year that were put forth.

I tend to focus on it not only in a programmatic sense, but in a people sense when we get letters from families that are very concerned about Medicaid. I got a letter last year from Pam Simpson. She is from southeastern Pennsylvania.

She was talking about her son Rowen. This is the letter she sent me, back and front. Pictures—you cannot see from where you are, but she concluded the letter by making a plea to me to protect Medicaid because her son Rowen—she described in a letter what his life was like without Medicaid, which we call Medical Assistance in Pennsylvania, and how much better it was, all of the treatment and therapies and benefits that Rowen received.

She ended the letter talking about—or as I said, pleading with me to make sure we take steps to protect it, saying that we should think of her and her husband and their inability to make ends meet without Medicaid—obviously to focus on Rowen's life with it. Then she also said, "Please think of my daughter, Luna, a little girl who is actually younger than Rowen"—he was only, at the time, about 5 years old—saying that she will have to care for him when they are gone because of his own circumstances.

In the last line of the letter she said, "We are desperately in need of Rowen's medical assistance and would be devastated if we lost

these benefits." That is what one mom said about her family and her own circumstances.

I guess I would ask you a broad question. If the proposals put forth in all of the Republican health-care bills this year were enacted into law or—I should say and/or if the administration's proposals on Medicaid, and proposals I think you support, would become law, would Rowen Simpson lose his Medical Assistance?

Mr. AZAR. So first, as you mentioned, we are from the same State. I think we actually share a lot of the same goals for our people for access to care, for access to insurance, for access to quality. Sometimes we may differ about the role of government, the size of programs, techniques, whatever, but we share that commitment. And I share the commitment to the Medicaid program. It is a vital safety net program for our folks.

I do not know that individual's particular circumstances and how they qualify for Medicaid. But obviously, for so many families, Medicaid is a vital link or a bridge to independence eventually or long-term need for them.

If confirmed, my job will be to make that program as efficient, as effective, as responsive, and as available to everybody as possible.

Senator CASEY. But as you know, under current law, there is a guarantee. As long as you are eligible, or I should say some are eligible, some have a guarantee by way of their disability. So, even people of significant means, with jobs and health-care coverage, can avail themselves of Medicaid because of a disability.

My question is, will that guarantee remain in place not only for children with disabilities but for adults as well?

Mr. AZAR. I think, in whatever we do in Medicaid, we have to make sure it is doing its job. And for an individual like that with disabilities who needs to be categorically in, we have to make sure it is funded and supported to do its job for them.

Senator CASEY. I would also ask just in the context of adults, and I know we are running low on time, if you have an individual who relies upon a disability service provider, someone who needs a wheelchair, durable medical equipment, will those individuals continue to get those services?

Mr. AZAR. Again, on any type of reform, those are the kinds of situations we have to look at to make sure that we are still able to deliver for those individuals.

Senator CASEY. Mr. Chairman, I know we are running low on time, but I will try to come back in a second round.

Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

I have had the pleasure of getting to know Alex Azar in his previous roles in government. In fact, when he worked in the Bush administration at HHS, I got to see him in action.

And I can tell you from personal experience, he knows his way around the Department. He has a lot of integrity, a lot of friends and allies here on the hill from those days on the job.

In fact, you would not know it from some of the comments made here today, but he has actually been confirmed twice by the United

States Senate as General Counsel and also as Deputy Secretary. By the way, both times it was by unanimous consent.

So not a single member objected, and that is because he has the experience. He has the background. And I am glad someone with his experience is willing to step forward, because, frankly, we have a lot of challenges, and it is a big, complicated department.

In our conversations, we spoke a lot about the opioid epidemic and what I believe can be done in addition to what is already being done, and there has been progress made in the last couple of years. But HHS plays a central role.

Right now you are helping us implement the Comprehensive Addiction and Recovery Act through SAMHSA, through CDC, through, obviously, Medicaid and Medicare—Medicaid in particular. So this is all going to be part of your bailiwick should you be confirmed.

There is an issue that I think has a very specific HHS element I want to get your views on today—I am not sure we talked about this specifically in our meeting—and that is improving access to care.

This has been something that many of us have worked on over the years. Senator Durbin and I have a bill called the Medicaid Care Act, which would lift this Medicaid Institutions for Mental Disease exclusion, otherwise known as the IMD cap. This is for residential treatment programs as you know.

It is crazy to me that there is a cap of 16 beds on some of the really good, successful residential treatment programs in Ohio that I visited. They literally turn people away because they do not have the ability, based on their taking Medicaid and being involved in the IMD program, to be able to have access. It makes no sense.

I understand why it was put in place in the first place. More on the mental health side—trying to fight back against institutionalization, but I think it needs to change.

So my question to you would be, knowing that CMS has tried to be supportive—the 1115 waivers have been accepted in some cases. But there are still a lot of restrictions on those.

Would you support legislation? Our legislation raises the cap from 16 to 40 beds, for instance. And we have some pay-fors that we are working on.

Would you be supportive of such legislative efforts?

Mr. AZAR. Obviously, as a nominee, I cannot commit the administration on legislation. I can tell you personally I do not understand the existing restrictions, and especially in the face of the opioid crisis and the pressing demand and need for treatment for these individuals.

So I would love to work with you on that, if I am confirmed as Secretary. I do not get it, and I would love to work with you on it, if we could fix it.

Senator PORTMAN. I appreciate that answer. And again, it is not something I think you expected me to raise. I am not sure we talked about it in our meeting as much as some of these other issues that had to do with the prevention and treatment side.

But thank you for that comment. That is another reason I think you would be good in that job, because we need to get that cap raised. And again, we have to pay for it. We understand that. We

have some thoughts about how to do that, and I think it is absolutely crucial right now in my State and so many other States that are getting hit so hard by this opioid epidemic.

Another issue you and I talked about was wellness and prevention. You touched on that a little bit today in your comments to, kind of, rethink how we approach health care in the country.

Paying for good health includes, in my view, providing incentives for better wellness programs. Senator Wyden has been a leader on this. We have introduced legislation in the past called the Better Rewards Bill.

It basically says that for Medicare beneficiaries, they would be given an incentive program to be able to help them with, whether it is smoking cessation, or whether it is heart disease, or whether it is diabetes prevention, things that over time will save the government some money, obviously, but most importantly to me, to make their lives more healthy so they can live longer, healthier lives.

It has worked in the private sector. There is no question about it. Cleveland Clinic in Ohio is probably the best case of that, where they have put this in place for their own employees, and they have seen enormous improvements in people's health. By the way, it is a modest incentive. I know it works, because it works in the private sector, and I believe among seniors it will work even better.

So my question for you is that Senator Wyden and I are looking at maybe trying to make some changes to reintroduce the legislation because, frankly, the Congressional Budget Office does not give us the score they should in my view. But what is your view of this kind of legislation? Would you support it? And I do not think it should be limited to Medicare. I think Medicaid also has an application for this kind of prevention/wellness program.

Mr. AZAR. So, Senator, I have long been supportive of these types of wellness and prevention programs, even when I was General Counsel and Deputy Counsel at HHS as we looked at our own regulations under HIPAA, to enable these types of programs in the first instance, and I will be happy to work with you on that.

I do think it comes up so often where Medicaid and Medicare were designed in the 1960s with, sort of, silos. We will pay for this; we will not pay for that. Now 50 years later, we can be penny-wise, but pound-foolish, as I said before about saying what we will not cover because it does not fit in a category, even if it is going to produce better health for our people and is going to save us money.

So I am very happy to work with you on that.

Senator PORTMAN. Well, I appreciate that attitude.

I know my time is expired, and I look forward to your confirmation.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Nelson?

Senator NELSON. Thank you, Mr. Chairman.

It is either "congratulations" to you, but it is also "thank you" for 4 decades of extraordinary service. And thank you also for your personal friendship.

Mr. Azar, there is a lot of chatter up here about how now we have a trillion-and-a-half-dollar hole, additional budget deficit over

the next 10 years. That is added to the national debt. There is a lot of chatter among our Republican colleagues that we need to make up for that.

So they are specifically looking at Social Security, Medicaid, or Medicare under the guise of so-called "welfare reform." Tell me, do you think in welfare reform that it ought to be Medicaid, Medicare, and Social Security that would be cut?

Mr. AZAR. So, Senator, I am not involved in discussions right now. I am a private citizen. I am not involved in discussions about what is even being contemplated. So I am not aware of cuts in any way being supported by the administration and the President.

Senator NELSON. I am asking you for your opinion. You do not have to comment on what all the Republican Senators are saying—your opinion. Would you consider an order to make up all of this huge budget deficit hole by cutting Medicare, Medicaid, and Social Security?

Mr. AZAR. The President has stated his opposition to cuts to Medicare, Medicaid, or Social Security. He said that in the campaign, and I believe he has remained steadfast in his views on that. My job as Secretary would be to enforce that.

Senator NELSON. So would you advise him to keep his word?

Mr. AZAR. He has kept his word. I would stick with him on keeping his word on that as long as—but I do not have the broader context of any discussions going on. I am here on the sidelines of this. He has made that commitment. I will live up to that, if I am confirmed—to keep his commitments.

Senator NELSON. The last HHS Secretary made some interesting statements about what he preferred. I am curious as to what you prefer.

Do you support raising the Medicare eligibility age?

Mr. AZAR. So I have not voiced support for that. That would have to be considered in the context of everything else.

What we have to do, Senator, is make sure that Medicare is going to be sustainable for our beneficiaries over the long run. I know you agree with that. We need to come up with the right approaches. I, frankly, would like us to run Medicare more efficiently and effectively, as I have said, more driving value and outcomes.

And I think we can stretch that program and make it more sustainable over time just by how we operate it. We can also, as a result of that, lead to great transformation in the broader commercial health-care system if we do that.

That is where my energies are.

Senator NELSON. Well, let the record reflect that the witness did not reject increasing the Medicare eligibility age. I might say, if you get out among the people, you are going to run into people who get into their 50s and 60s, and they are just holding on for dear life because they do not have any health insurance until they reach 65, because they know they get Medicare. And they do not want it extended.

Do you support turning Medicare into a voucher program?

Mr. AZAR. I am not aware of any proposals by the administration to turn the program into a voucher program. What I want to do, again, is really make sure that our Medicare Advantage program—which two-thirds of new enrollees are signing up for and which I

played a role in helping to launch—is an option for our seniors as they come into the program.

They like it, have high levels of satisfaction. So I really want to make sure that we are doing everything we can to make sure it is a strong, robust alternative for our seniors. Again, that is where my energies are. My thoughts are there.

Senator NELSON. Do you support closing the doughnut hole in the Medicare law?

Mr. AZAR. So closing the doughnut hole—the Affordable Care Act actually did have some funding that actually helped senior citizens when they arrive at the pharmacy. I think it gives up to 75 percent coverage in the doughnut hole——

Senator NELSON. Yes——

Mr. AZAR [continuing]. Which I am very supportive of.

Senator NELSON. You are?

Mr. AZAR. Yes.

Senator NELSON. Of keeping all of that?

Mr. AZAR. Absolutely. Yes.

Senator NELSON. Tell me about Medicaid. What is your idea about Medicaid?

Mr. AZAR. Well, I want to make sure that we enable flexibility for States to run those programs in ways that meet the needs of their citizens. As I said with Senator Enzi earlier, I want to make sure that in working with the States, who have the on-the-ground responsibility, that we are being responsible and responsive partner of theirs in looking at flexibility, trying new things.

Senator NELSON. Excellent. Excellent.

Now, how about Puerto Rico?

The CHAIRMAN. Senator, your time is up.

Senator NELSON. Puerto Rico. Medicaid for Puerto Rico. It is a block grant. It cuts off.

Mr. AZAR. I think we all need to work together on that Puerto Rico cliff issue. I agree with you: we need to work together to find solutions there.

The CHAIRMAN. Okay.

Senator Scott?

Senator SCOTT. Thank you, Mr. Chairman.

Mr. Azar, good morning. Thank you for being here.

I know that drug pricing is very important. I think also, beyond drug pricing, the issue of health insurance cost as well is very important.

South Carolina, in 4 years, made 120-percent increases. This last year was a 31-percent increase on the exchange. So there is no doubt that we have to find a way to rein in the prices that our consumers are being impacted by in the health insurance arena.

One of the ways that we do that, I think, would be through the section 1332 waivers, giving States more flexibility, at the same time looking at ACA as the foundation, because we have to. The catastrophic plans are limited to 30 years old and below.

I have legislation co-sponsored by Senators Carper, Warner, and Cassidy that would allow for the catastrophic plans to cover anyone who needs the coverage or who wants the coverage. One of the things I have often criticized within the ACA is that the design

plans are not suited for the actual individuals who want to buy the plans.

So as our next Secretary, what would you do to expand consumer choice and encourage Americans to make healthy, proactive decisions?

Mr. AZAR. So I think, in terms of the Affordable Care Act—I am glad you raised the issue of increasing premiums and lack of choice that you are experiencing in South Carolina. I believe, if I am confirmed as Secretary, I have a very important obligation to make whatever program that I am entrusted with work as well as possible.

Senator SCOTT. Yes.

Mr. AZAR. What we have now is not working for people. It is not working for the 10 million who are in that individual market right now, fully. So for many of those people, it can be a false insurance card. It can be insurance, but a very high deductible or not having access to providers. So it is unaffordable use of care.

I want to solve the problem for them.

Senator SCOTT. Good.

Mr. AZAR. I want to fix the program, as you just mentioned, for the 28 million people who sit outside of that market still, who do not have access in that individual market. And by not being in that market, they are actually causing the premiums to go up for the 10 million in it.

So can we make those offerings? Can we create more choice and make those offerings more attractive to create a better risk pool that is going to help also the taxpayer and people in that market?

So I fully share that commitment. And I want to work with States on these 1332 waivers and work with our authorities to just try to make that health insurance more affordable, and make it real insurance, and make it tailored to what they feel they need.

Senator SCOTT. Thank you.

The next question for you is on the opioid crisis that we are having throughout this country. In 2016 there were 64,000 deaths related to opioids. That is a crisis.

In South Carolina, 616 folks lost their lives, a 9-percent increase. I would love to hear your commitment, not only to address the issue from Washington, but to ask you to let us get outside of Washington. Let us go to the rust belt. Let us go to the places where people are suffering today because of opioids. And let us create remedies that actually work, that are not top-down simply, but truly bottom-up.

Evidence suggests that the best remedies so far have been created through a collaborative effort starting at the local level and moving its way up. I would love to hear you commit to not only running the HHS, but going to places in West Virginia where they have the highest per capita—I think it is 41 out of 100,000 deaths associated with opioids in places like Horry County, Myrtle Beach, where we have the highest level in South Carolina.

But if we are going to understand and appreciate this issue in a very favorable way, we are going to have to do so by putting a face on the issue, not in Washington, but somewhere around the country. Are you committed to actually going to those places with us?

Mr. AZAR. Absolutely. Senator, you know I am a Hoosier, so I am right in the epicenter of the crisis also in Indiana.

Senator SCOTT. Absolutely.

Mr. AZAR. I do believe that there is not necessarily, especially when it comes to prevention and treatment programs, a one-size-fits-all approach. And we need to get out there and see what is working, what are the different programs, not just so that we can support them, but also so we can replicate them and make them available elsewhere at these epicenters. That is, of course, in addition to things we can do at the center with regulatory authority, with education programs, et cetera, that have to drive solutions on this crisis.

Senator SCOTT. I only have about 30 seconds left, so I will not ask a question. I will just make a statement that encompasses my last two points.

Number one, your expertise in the value-based arrangements will be helpful. I think when you look at the opportunities of the future, from BCI to CRISPR, there are a lot of innovative opportunities coming that will improve the quality of life of everyday Americans in ways that we could not even imagine 5 years, 10 years ago.

I would love for us to be able to find ways to make that access to life-changing opportunities affordable.

Second, as we think through drug pricing, I also think that we have to understand and appreciate the necessity of non-addictive alternatives and the pipeline to get there. So I hope that there is a plan in place that you are thinking through for an expeditious approach to non-addictive remedies as well as things that provide abuse deterrence.

Mr. AZAR. That last point, that is a core area of NIH's focus and their public-private partnership: to try to drive non-addictive pain treatment therapies to replace the legal opioids that are getting us into this mess.

Senator SCOTT. I would love to talk with you about that later.

Thank you.

The CHAIRMAN. Senator Warner?

Senator WARNER. Thank you, Mr. Chairman.

Let me join all of my colleagues, as well, in acknowledging and recognizing your great service to this committee and to the people of Utah and the Senate.

The CHAIRMAN. Well, thank you.

Senator WARNER. We are going to miss you, and I very much appreciate our opportunity to work together and the fact that when you had a chance to bump me off this committee, you kept me on this committee. So I am grateful for that.

Mr. Azar, it is great to see you again.

I know some of my colleagues have already been asking about drug pricing. One of the areas I have felt strongly about for some time is, while there are specific policies that we can implement, I have been concerned that in many ways Americans pay for the R&D, for drug pricing for the whole world. And part of the way—we can make programmatic changes here, but some of this also has to be dealt with in our trade policies.

I mean, amongst all the OECD nations, we pay the highest percentage on drug prices. Recognizing that you bring more than a little experience in this matter and in your role at Lilly were involved in the whole pricing issue, what do you think about how we bring down Americans' cost of drugs vis-à-vis all the other industrial nations in the world?

Mr. AZAR. Well, Senator, again, thank you for meeting with me and for raising that important question. I have actually talked about this as a critical issue for, I think, over 15 years when I was in government before, the fact that Europeans, Canada, Japan are not paying their fair share.

They started, finally, investing more through the framework basic program at the European Union and some of the NIH-like basic primary research and funding there, but on the commercial side, they are not paying more, and they are able to have single-payer socialist systems with single formularies that, basically, are take it or leave it pricing.

I do think we have to address that through trade agreements as well as trade negotiations with these trading partners, the fact they are not paying. But that, of course, does not solve the pricing here. That helps with relieving some of the burden of R&D abroad. We have to address that here with some of the measures I have talked about or other measures. I would love to hear any ideas you or others have, because we are going to solve this issue at the list price level, and at the net price systemic savings level.

Senator WARNER. How much more transparency, though, should we have after companies raise their prices? I mean, in terms of the rationale behind—it seems like it is a mismatch and more than a bit arbitrary at this point.

Mr. AZAR. So I am generally in favor of more transparency in the system. I think it is generally very helpful.

We always have to be careful with anything around pricing to make sure we are not doing something that actually could be anti-competitive or actually be counter-productive in what we are trying to do. But if you have ideas there, I do think transparency can be part of the solution as we bring understanding. Where is the money flowing in the system? Who is getting the benefit from it? And what is the benefit or harm to the consumer?

Senator WARNER. I just have to tell you, as someone who for a long time did accept the premise that we need to do the R&D here, that argument has run thin with me as we have seen Americans disproportionately bear this burden. And I think we are going to need some maybe more radical thinking than what we have had in the past.

I want to touch on two other items. I know in your statement you said, harness the power of Medicare to shift the focus in our health-care system from paying for procedures and sickness to paying for health and outcomes.

Obviously that is—everyone makes those comments. One of the things that came out of the Affordable Care Act was CMMI, and while it has not been as productive as I would have liked to have seen at all times, I think it is still a tool that is useful, and I would like your comments on how you would see the role of CMMI going forward.

Mr. AZAR. I completely agree with you and believe CMMI is going to be one of the very important tools we have to drive this type of transformation of our health-care system through Medicare. We need to ideate, to pilot, to test, and then generalize.

Senator WARNER. And I would hope that we would realize that some of those pilots may—and I know we might have a disagreements on this one—include mandatory pilots, because too often those who are on the voluntary system are the ones who have already been able to bring about efficiency. So we need to force more into the system.

Mr. AZAR. Senator, we actually do not disagree there. I believe that we need to be able to test hypotheses. And if we have to test a hypothesis, I want to be a reliable partner. I want to be collaborative in doing this. I want to be transparent and follow appropriate procedures.

But if to test a hypothesis there around changing our health-care system, if it needs to be mandatory as opposed to voluntary to get adequate data, then so be it.

Senator WARNER. Let me get in my last bit here in 15 seconds.

An issue that Senator Isakson and I have been working on for a long time is advanced care planning and end-of-life issues, and CMS, obviously, made a major step forward a few years back where they went ahead and put a coding in for that consult. I would just like to get you on the record in terms of recognizing that we do not want to limit anyone's choices, but we also want to honor and respect people's choice about care planning or end-of-life issues.

Mr. AZAR. I think it is a very important part of all of our personal care management, as we think about our life and our health care and our family members, that we engage in that kind of thoughtful, directive planning of what do we desire. Again, as you said, none of us—it is not about imposing anyone's views on someone else. It is actually about ensuring systems to respect that individual's choice.

Senator WARNER. Right. Absolutely

Mr. AZAR. So enabling that, I think, is very important for us.

Senator WARNER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, sir.

Senator Heller?

Senator HELLER. Mr. Azar, welcome and congratulations. I am thrilled to have you in front of our committee. I welcome your family also, who are being very patient through this hearing.

I may ask you some questions that maybe have already been asked, because I have been down at the Banking Committee, going back and forth a little bit here. So I apologize if anything I do or say is duplicative.

I was proud, as you know, at the end of last year to work with some of my colleagues here on this committee as we worked through the historic tax reform bill. And as you are aware of, portions of that eliminated the individual mandate tax penalty.

And I think that the Obamacare individual mandate was probably the most unpopular element of that law. And its penalty, in my opinion and others, disproportionately affected hardworking Nevadans and Americans across the country who really are struggling to get by.

So repealing that mandate, I believe, restores individuals' abilities to make their own choices about their health insurance and prevents the Federal Government from penalizing these individuals who cannot afford this insurance.

So I guess my main question to you, as we have discussed both in my office and will discuss here, is, under your leadership, will HHS—what will you improve? What are you looking for in quality of access, affordable care, some of these issues, as we are trying to move forward? Because clearly with you in this position—and I am pleased to see you here, taking time to answer these questions—we really need to take a look at affordability and access to health care for Nevadans and clearly all Americans.

Mr. AZAR. Absolutely, and as you mentioned, the way we are doing it now is not working for everybody. That is going to be—if I am confirmed, my job is to take whatever I've got, so the Affordable Care Act is there, and make whatever it is work as well as it possibly can. And part of that is driving a system that is more affordable. So more affordable insurance, more choice of insurance, insurance that actually gets people access to providers, so not a meaningless card for them, but real access, and then finally, insurance that fits their needs as opposed to what I happen to say they should have. And I want to work with States like Nevada and others to come up with different approaches. There is no one size fits all. Also there is not necessarily one right answer here. This is very complex.

Senator HELLER. I agree.

Mr. AZAR. We all, on both sides here, we all share the goal. We want people to have access to affordable insurance that is better than none. We want to work on that.

Senator HELLER. How do you feel about—I am one of the authors of the Graham-Cassidy-Heller-Johnson bill. Have you formulated an opinion or a decision on the direction of that or portions that you do like or perhaps even dislike on that proposal?

Mr. AZAR. So with the Graham-Cassidy-Heller legislation, the elements of that that are very positive are empowering States to run their budgets. Right now, the way we run our Medicaid system for instance, as you know, is the matching system.

So if the State comes up with more money, things just increase from the Federal Government. But it also means in running that program, it is not all their money. So they do not always exercise the level of creativity or fiscal fraud, waste, and abuse stewardship over it as if they owned 100 percent of that money. So I think the incentives can actually be reoriented in a very positive way by more State empowerment as you would see through Graham-Cassidy-Heller.

Senator HELLER. In your opening statement, you talked more about access and competition. And one of the proposals that I have here in Congress is about competition and access across State lines. You know, you can get your car insurance, your house insurance, you can insure anything across State lines except your health care. You can even get, I guess, your car insurance from some lizard in Connecticut, the way it works now.

Have you advocated for this? How do you feel about access across State lines? I know the President has pushed hard to allow this

kind of competition, this kind of access. And I think this is the next step. And I think the administration agrees with that. Just wondering what your opinion was on it.

Mr. AZAR. I am supportive of those efforts; frankly, of anything that can help increase choice. As you said at the beginning, it is access and choice. The more options available to patients and consumers of what they can buy, the more likely they are to find something that is affordable for them and that works for them.

Senator HELLER. I only have a short time left with the chairman, but what we are looking at is shortage. According to the Association of American Medical Colleges, there will be a shortage of more than 150,000 physicians by 2020. What effort do you anticipate will be needed to cover those shortages?

Mr. AZAR. That is a vexing problem. We have programs, of course, at HHS that help with physician shortages and support training, whether it is graduate medical education or the health professions programs, for instance, the tuition subsidy and reimbursement programs there. Some of those are directed more towards the underserved areas, the most rural and remote areas.

I mean, it is just going to be an enduring challenge for us. I would love your ideas if you have any on how we address that shortage.

Senator HELLER. And I will end with this, Mr. Chairman,

I did introduce legislation last year with Senator Nelson, called the Residential Physicians Shortage Reduction Act. And I hope we have a chance and opportunity to take a look at this legislation which would allow Medicare-supported residency of over 15,000 in the next 5 years.

So I certainly appreciated all of your help and support, and I appreciate your chairmanship on this committee. You will certainly be missed.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you, Senator.

Senator Brown?

Senator BROWN. Thank you, Mr. Chairman.

Mr. Chairman, thank you for your earlier comments in support of CHIP. I appreciate that, and I know you were there at the creation. I hope you can convince Leader McConnell, who frankly has resisted moving on CHIP September, October, November, December, and now it is January—I hope you can use your gravitas and hard work to convince him to do the right thing.

The CHAIRMAN. We will get it done.

Senator BROWN. Thank you.

In 2016, 4,000 Ohioans, one of your home States, died from an opioid overdose, more than any other State in the country. Eleven people die in my State a day.

You say, if confirmed, one of your top priorities will be addressing our Nation's opioid epidemic. I am appreciative of that.

You have said we are in a state of war. My question is, "yes" or "no," will you commit to prioritizing this issue?

Mr. AZAR. Absolutely.

Senator BROWN. Thank you. We obviously need stronger leadership than we have seen. We need the President more engaged. We need the Secretary of HHS more engaged.

As part of this comprehensive approach, will you commit to protecting the integrity of the Medicaid program, including Medicaid expansion as it currently exists?

Mr. AZAR. So, if we look at any kind of changes to Medicaid, if the Congress were to look at any kinds of changes to Medicaid, the issue of how we address people who are suffering from substance abuse who are currently getting service under Medicaid is obviously something we would have to look at and meet that need if there is any different structure.

Senator BROWN. Okay. Let me stop you there.

I have heard both you and Ms. Verma use the term "able-bodied adult" a lot when speaking about Medicaid. It is clear that you have both given Medicaid reform and the idea of work requirements in Medicaid a great deal of thought.

Let me ask you this. Is an individual who has been diagnosed with severe mental illness or with a substance use disorder, is that person able-bodied?

Mr. AZAR. I do not have a definition in hand. It would be something we would work out with Congress. I would share your concern, though. That would seem a pretty obvious——

Senator BROWN. So you have no definition of "able-bodied adult" that would be appropriate for differentiating between and among Medicaid recipients that you can share with us?

Mr. AZAR. I just have—philosophically, I would like us to work in our programs to help avoid any type of cliffs that we have in benefits to try to smooth out the approaches so that individuals have an incentive and an ability——

Senator BROWN. You can understand—I am sorry to cut you off. You can understand our skepticism and concern when we hear top elected officials and appointed officials in this country talk about able-bodied adults and disqualifying them from Medicaid.

And then we realize in my State, 200,000 people right now, 200,000 Ohioans are getting Medicaid, are getting opioid treatment, and getting it because of the Affordable Care Act, mostly through Medicaid.

I was with a gentleman in Cincinnati at the Talbot House, sitting next to him and his 30-year-old daughter. He turned to me and said she would not be alive if it were not for Medicaid.

So you spent 6 years working at HHS, many of those as General Counsel. You looked at definitions of Medicaid and much else. You, if confirmed, will be in charge of regulations. That is why all of us want to know exactly how you could rationalize requiring individuals struggling with an illness, whether it is cancer, whether it is opioid addiction, whether it is some kind of severe mental illness, how you will rationalize requiring individuals struggling with those illnesses to work in order to remain eligible, especially when such a requirement is in direct, in direct contradiction to the objectives of Medicaid programing.

I mean, if you consider someone with cancer to be able-bodied, what about an individual diagnosed with depression? I would like you to do this. I would like you to please submit your proposed definition of "able-bodied adult" to this committee, to be included in the record of today's hearing before this committee votes on your confirmation.

Mr. AZAR. Senator, I do not have a proposed definition of able-bodied. You are imputing to me a desire that I have not stated. I want to work on ways that can make the program customized to the different types of beneficiaries.

The individuals——

Senator BROWN. Again, I apologize——

Mr. AZAR [continuing]. That you mention, I have never singled out and said——

Senator BROWN. I understand. I do not question your motives. I understand that, but I have sat here and seen members of this committee, all of whom have insurance provided by taxpayers, trying to strip Medicaid away as my Governor, a Republican, and I, a Democrat, in my State have fought to keep Medicaid in place, to keep the expansion in place. Virtually everybody on the other side of the room here has voted to cut Medicaid eligibility, to throw many of those 200,000 Ohioans—200,000 Ohioans right now are getting opioid treatment who get it because of the Affordable Care Act, and they, getting government insurance themselves, are willing to take it away.

I apologize, perhaps, but excuse my skepticism that nobody in your department, Ms. Verma, you—you are not there yet, I understand—have thought about what the definition of able-bodied is. Then you will come in here—Senator Nelson's comments about, you have blown a hole in the budget. This committee did that. Thank you very much. And we now have to close that huge hole.

You go after things that generally conservatives do not like—Medicare, Social Security, Medicaid, unemployment insurance—to cover this hole. What happens to these people? I hope, and my time has run out, but I hope that you will think about those 200,000 people in the State you lived in for part of your childhood, how they will lose their opioid addiction treatment coverage if this administration does what it tried to do earlier.

I know you said President Trump is living up to his promise not to touch Medicare or Medicaid or Social Security, but the fact is that he is not, because he wanted to sign a bill that would strip Medicaid from those 200,000 Ohioans.

And I just need answers for that, Mr. Chairman.

The CHAIRMAN. Okay.

Senator McCaskill?

Senator MCCASKILL. Thank you, Mr. Chairman.

At the company you worked at, Mr. Azar—welcome, by the way. Thank you for your willingness to serve the public.

Mr. AZAR. Thank you.

Senator MCCASKILL. Which was larger in the last year that you were in charge, the budget for research and development or the budget for advertising?

Mr. AZAR. The budget for research and development should have been. I think the budget at Lilly for R&D was approximately $5 billion out of $20 billion of revenue.

Senator MCCASKILL. And how much was the budget for advertising?

Mr. AZAR. I do not know the exact number across the board. It would have been vastly less than $5 billion.

Senator MCCASKILL. Would you mind getting that figure?

Mr. AZAR. No, I would not be able to get you that figure. That is proprietary information. I have been gone from Lilly for a year now.

Senator MCCASKILL. Okay.

Overall, the cost of advertising has dramatically gone up for pharmaceutical companies in this country. Everybody in America knows it, because you cannot watch an hour of TV without being told what you should ask your doctor to prescribe for you.

Do you believe the American taxpayer should be subsidizing prescription drug advertising?

Mr. AZAR. So I think that consumer advertising can be helpful where it prods an individual to think about a disease condition they have, to assess that, as a call to action to actually address that with a physician.

Senator MCCASKILL. That is not my question.

Mr. AZAR. There is a lot—I share your concern. There is a lot of drug advertising on television. I share that view. I want to work——

Senator MCCASKILL. You know what? I can be thin. I can be happy. I can even—I mean, the one that kills me is the one for erectile dysfunction where they have them in two bathtubs. How crazy is that? That is not happening. I mean, it is nuts.

So I just do not understand why the American taxpayer is subsidizing this gross overuse of television advertising, not for, you know, Pepto-Bismol, not for over-the-counter, where you need information, but rather to tell your doctor you want it.

Mr. AZAR. Of course, we have taxes for business expenses across the board on so many practices in everything that we do in business.

I do agree with you, though, that there is a lot of television and other consumer advertising that does—it does seem there is so much of it out there, and I would love to work with Dr. Gottlieb to think at FDA, is our approach in balance to how we authorize and approve direct-to-consumer advertising? Is it correct, and do we have data? Is it working, and are patients taking the right messages from that information?

Senator MCCASKILL. Oh, it is working. People are—the most heavily advertised are the most heavily prescribed. It is working. That is why they are spending so much money on it.

My question is, should taxpayers be helping foot the bill by it being deductible?

Capitalism—you believe in capitalism.

Mr. AZAR. I do.

Senator MCCASKILL. And you believe in a free market.

Mr. AZAR. I do.

Senator MCCASKILL. And one of the most basic tenants of free markets is negotiation for prices based on volume, correct?

Mr. AZAR. Yes.

Senator MCCASKILL. Walmart became the behemoth they are because they negotiated with their suppliers based on volume to get lower and lower costs to them, which they then passed on to the consumer, correct?

Mr. AZAR. Yes.

Senator MCCASKILL. Okay.

You said earlier today that, "every incentive is towards higher prices in the pharmaceuticals." So do you believe that negotiation, in fact, would be an incentive to lower prices?

Mr. AZAR. So negotiations do lower net prices off of list price. They do, in fact, and it succeeds quite well I think. That is absolutely correct.

Senator MCCASKILL. That would be an incentive. That would be an incentive that is currently—there is no incentive for lower prices right now.

Mr. AZAR. List prices—that is what is unfortunate. It is not an incentive on list prices. We have negotiation that pulls down what the taxpayer pays and what the individual pays.

But that list price, the incentive is towards higher prices there.

Senator MCCASKILL. I am very aware there is a lot that goes on behind the curtain. I am very aware that for most folks who are getting their drugs, they are getting more and more expensive, and we do not have the ability in the Federal Government to negotiate for lower prices based on volume.

Mr. AZAR. We actually do.

Senator MCCASKILL. No, we do not.

Mr. AZAR. That is actually—I——

Senator MCCASKILL. We do not on Medicare Part D.

Mr. AZAR. We actually—the largest prescription benefit programs get the best net pricing of any commercial payers in the United States. I did that world. I know that world.

Senator MCCASKILL. Okay.

So what you are saying is, there would be no difference in the price if we removed the provision in the law that prohibits the Federal Government from negotiating for lower prices?

Mr. AZAR. That is what the Congressional Budget Office, that is what Peter Orszag has said: you would not get better pricing by removing that.

Senator MCCASKILL. That is just crazy. That is just nuts. Then there is something really wrong with the system.

So what you are telling me with a straight face is, if we remove the provision that prohibits negotiating for lower prices, that it is not going to make any difference in the prices?

Mr. AZAR. There is no provision prohibiting negotiating for lower prices. That is happening right now. The government has these entities that do that negotiation, and they are——

Senator MCCASKILL. But they are getting paid to do that. The government could do it directly.

Mr. AZAR. And they would not do any better.

Senator MCCASKILL. You have all kinds of—and by the way, would that not save us money?

Mr. AZAR. They would not do any better. What we need to do is——

Senator MCCASKILL. No, no, no, no. No, there is a middleman now, Mr, Azar.

Mr. AZAR. The issue for patients when they show up at the——

Senator MCCASKILL. There is a middleman now that is doing that negotiation. It is not the government.

Mr. AZAR. Right, and they do it better than the government would right now.

Senator MCCASKILL. And the benefit is a government benefit. So if you take—you are saying because it is private-sector, we should pay somebody to do it in the middle because the government cannot do it?

Mr. AZAR. What we should be doing is—those techniques that drive such good net pricing in Part D, what can we take from the learnings there into Part B? I would focus, if I were you, on Part B, which is physician-administered drugs, where we pay sticker price plus a mark-up on that.

Senator MCCASKILL. Right.

Mr. AZAR. With no negotiation out of the government or any other entity—can we take learnings from how we are actually managing to be under budget in Part D on our expenses and managing a program people enjoy, have high satisfaction with, and take some of those learnings into Part B for taxpayers? And there, if we can drive prices down, that hits the patient, the senior citizen out of pocket because they pay, always, a percent of that Medicare reimbursement for drugs.

Senator MCCASKILL. I will absolutely work with you on Part B.

The CHAIRMAN. Senator——

Senator MCCASKILL. But I refuse to acknowledge what you are saying, and that is—the pharmaceutical industry wanted that in the law for a reason. They lobbied for it. The guy who helped get it through went to run pharma after he finished getting it through.

It was not average consumers who wanted to make sure that it was illegal to negotiate for lower prices. It was pharma. And they were powerful, and they did it. I refuse to believe that they did not want that there for a reason.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

In light of your news of your decision, I wanted to thank you for your work on the Low-Income Housing Tax Credit, not just this year but for several years, and making sure that that program continues to work cost-effectively.

The CHAIRMAN. Thank you so much.

Could I make one comment before you begin?

I believe, having listened to Senator Brown's questioning, I believe Senator McConnell is supportive of our CHIP agreement. And I hope that our colleagues on the other side, especially Senator Brown, will help convince Senator Schumer to support this as well.

Senator CANTWELL. He does.

The CHAIRMAN. Well, I have not seen it so far. So all I can say is that I intend to get that done.

Senator WYDEN. Mr. Chairman?

The CHAIRMAN. Yes?

Senator WYDEN. A very few seconds.

I appreciate your interest in getting this done. I spoke on CHIP on the floor yesterday. Senator Schumer came right after me and said he was very much committed to our legislation, our bipartisan legislation.

So thank you for that.

The CHAIRMAN. Okay.

Senator Cantwell?

Senator CANTWELL. Yes, thank you, Mr. Chairman.

I would be remiss not to mention that I met with my provider community this weekend on the CHIP issue, and obviously, the level of anxiety in making sure that we have continuity, the notices that patients are getting, is starting to definitely cause anxiety.

But anyway, I wanted to go back to Medicaid, if I could. Our expansion was over 600,000. And our uninsured rate was cut by 60 percent. Uncompensated care was slashed.

So to me, the expansion has been a success. Do you support an end or sunset or curtailing of the Medicaid expansion?

Mr. AZAR. So I want to implement the program that we've got. If we end up looking at any changes on the Affordable Care Act to Medicaid expansion, I do not believe any of the proposals that the President or I would support involve cutting Medicaid or cutting the expansion, but rather slowing the rate of growth over the next 10 years in the interest of sustainability.

That is my understanding of the math on that.

Senator CANTWELL. So you are saying you actually support the block-granting?

Mr. AZAR. Whether it is block-granting or other changes. Block-granting—the devil there is in the details of, is there enough money for the program? Of course, you would have to figure out appropriate formulas and approaches around what is the amount of money there.

There is a lot that can appeal from notions of block-granting, because I do think it helps align incentives better, where the States have the empowerment and also the accountability to manage those dollars as their own, and to really—as Washington State does—really be creative and customize the use of the program and stretch it for their citizens.

So I do think there is much that can be appealing.

Senator CANTWELL. Listen, I get you are a nominee by this administration. But I just want to be really clear on this point, because my State has been really clear on this point.

The proposals that have been considered on block-granting and a per capita cap, my providers have been very clear—very clear—they are no innovation. They are simply a budget mechanism to cut Medicaid. And the CBO saying that it would end up cutting one-third over the next 2 decades, I think, is support for that.

So my support of you is going to be based on this, not because of politics of who you are or any of that. It is going to be on whether I am casting a vote to continue these policies or not.

They are working. And my State will be the first—the first—the first to innovate because we already are, and we had some conversations about that. So I just want to be clear that I view the previous proposals of block-granting and a per capita cap as cuts, as my provider community has made very, very clear to me.

They have also said that with that kind of approach, they expect the private market insurance rates to go back up, that they have seen downward pressure on those prices, given the expansion. And they do not want to see those go back up.

So another example of that is the delivery system reforms we were able to do to get the population to move off of long-term care

to community-based care. I am assuming you support those kinds of efforts as a true way of reforming and driving down costs.

Mr. AZAR. Well, as we spoke in your office, I am completely supportive of such notions. Sometimes institutional care for some individuals makes sense, but alternative home-based, other care, I am completely supportive of these kind of innovations.

Senator CANTWELL. So what could we do to drive that to a faster implementation, because we incented States to do it under the Affordable Care Act, but if we took a more aggressive approach, that is where you would really see some savings.

Mr. AZAR. Yes, I do not know what the barriers are, Senator. I do not understand it. It seems so attractive to me. I do not understand it. So I would love, if confirmed, to get your ideas. If there are things that HHS is doing that are getting in the way of that, I would want to know that, because I am 100-percent committed to where you are on this issue.

Senator CANTWELL. Do you support Medicare's move from fee-for-service to value-based care?

Mr. AZAR. I absolutely do. It is one of the four core priorities that I would try to focus on as Secretary.

Senator CANTWELL. And what about the basic health plan which is part of the—do you support the concept of allowing some States to bundle up their low-end population and drive down costs?

Mr. AZAR. It seems to me—and I was just delighted to learn more about it from our meeting. It just seems to me a very attractive notion of how one helps in that transition between the Medicaid eligibility and the subsidy elements of the Affordable Care Act. I want to learn more about it, but it seems to be very attractive.

Senator CANTWELL. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Let us see.

Senator Wyden?

Senator WYDEN. Thank you very much. Mr. Chairman, I have a couple questions, but I want to make two unanimous consent requests, if I might, to put documents into the record at this point, because I think Mr. Azar has, in response to colleagues, given incorrect answers.

Senator Nelson, for example, asked whether he was supportive of the President's position with respect to these issues: Medicare, Medicaid, or Social Security. Mr. Azar said that the President promised he would not cut them, and that he has adhered to that promise. That is simply untrue.

The President's first budget proposed cutting Medicaid by hundreds of billions of dollars through proposals like block grants. So I would like to put the budget into the record, not the entire budget, Mr. Chairman, but the part that indicates the answer to Senator Nelson's question was incorrect.

Also, we have just gotten information that——

The CHAIRMAN. We will be happy to do that, but we should let Mr. Azar respond to that.

Senator WYDEN. This is just a request to put information into the record.

The CHAIRMAN. Your earlier statement—I wonder if he has any comment about that.

Mr. AZAR. I think this has to do with Washington-speak, that slowing the rate of growth of a growing program is simply not a cut in my mind or the President's mind.

Senator WYDEN. Well, we are talking about hundreds of billions of dollars, and the State Medicaid directors, point blank, said no flexibility is going to make up for the fact we are talking about hundreds of billions of dollars' worth of cuts.

I also ask unanimous consent, Mr. Chairman, that we put into the record documents from the Pew Trust and global data that certainly suggest the answer to Senator McCaskill with respect to advertising and R&D was incorrect, because in 2013, according to these documents, Lilly spent $5.7 billion on sales and marketing and $5.5 billion on R&D. And he said that these budgets were not remotely close to each other.

The CHAIRMAN. Without objection.

[The documents appear in the appendix beginning on p. 170.]

Senator WYDEN. I would like those placed in the record.

Let me now, if I could——

Mr. AZAR. Mr. Chairman, I would clarify.

The Senator's question was about the advertising budget, which was about direct-to-consumer, and there is no way that was even remotely close to $5 billion at Lilly. Not overall sales, general administrative expenses.

I do not have the balance sheets of Lilly in front of me, so I cannot speak to that. But I know there is no conceivable way any advertising budget at Eli Lilly was remotely close to the R&D spending.

Senator WYDEN. We will let people evaluate that data. You said the two were far apart. That is certainly not what the documents suggest.

Let me go to my two questions quickly. And I appreciate the Chairman's thoughtfulness.

Mr. Azar, weeks before at the Senate HELP Committee, you said that you supported proposals that would wipe out the Medicaid guarantee for our senior citizens. This is the guarantee that picks up the tab for two out of three older people in nursing homes—four thousand seniors in Oregon each day, and you would wipe out that guarantee by folding Medicaid into a block grant.

I would like to know whether you still support walking back the Medicaid guarantee for these older people and, again, as I indicated, the nonpartisan Medicaid directors stated, "No amount of flexibility," their words, not mine, "is going to compensate for those types of cuts."

Would you like to walk back your earlier position with respect to that commitment to older people who did everything right, that they are still going to have a guarantee of nursing home coverage?

Mr. AZAR. I believe what we talked about at the HELP Committee hearing was around the fact that I can find a lot of appeal in block-granting. Now, as I said there and I think I said here, the devil is in the details on how one structures the notion of any type of block grant, both in terms of the dollar amounts and then what strings from the Federal Government are attached to it, in terms

of who needs to be covered, who is eligible but not necessary to cover.

That all would need to be worked out in legislation, which we are certainly far from.

Senator WYDEN. Why do you not amplify those details for the record, and, because of the chairman's courtesy, I am going to do this last one very quickly.

It looks to me like you still want a block grant, though the State Medicaid directors say no amount of flexibility is going to be able to compensate for those cuts.

My last question, we have not talked about. That is title IV–A of Social Security. This is, of course, what people know as welfare, AFDC, a hugely important program to help families escape poverty and find work.

Right now, it looks to me like the measure of success is reducing the caseloads at that program. I would like a different measure and would like to see if you would work with us on it. I would like the measure of success to be finding jobs for people so you can get out of poverty.

So the question is, that is not the measure today. Would you work with Democrats and Republicans to change the measure, to actually change the program so that the measure is not reducing caseloads, but it is having people find work to get out of poverty? That is a "yes" or "no."

Mr. AZAR. Absolutely.

Senator WYDEN. Thank you.

Thank you, Mr. Chairman, for the extra time.

The CHAIRMAN. Thank you.

As I understand it, Senator Casey has one question, and then we will wrap it up.

Senator MCCASKILL. [Off mic.]

The CHAIRMAN. You have one too?

Senator CASEY. Mr. Chairman?

The CHAIRMAN. Go ahead.

Senator CASEY. Thank you very much, Mr. Chairman.

Mr. Azar, I wanted to ask an additional question regarding the approach the administration has taken with regard to implementing the Affordable Care Act, making our health-care system work.

It came to my attention, and I think the attention of people across the country, from a story in *Politico* about efforts made by the administration to, I would argue, sabotage the Affordable Care Act. I have a report coming out that will outline some of those actions taken—restricting enrollment is one, canceling coverage, all kinds of efforts undertaken—that resulted in us pushing to get a document from Health and Human Services. It took months to get it.

Now we are told that there is a new document that we referred to in a letter that we sent December 21st, to Mr. Hargan, the Acting Secretary. We state, and I am quoting from the letter, "HHS has developed a list of hundreds of other actions to sabotage health care for people nationwide." We go on to say, "reference a spreadsheet." We conclude by saying, "please provide the spread sheet reference above," which lists more than 200 regulatory actions the ad-

ministration is planning to take to further undermine health care. That is our request.

The response from Health and Human Services on January 5th said that they will not turn that over. In our HELP Committee hearing, you said the following when I asked you about faithfully implementing the Affordable Care Act. You said, "My job is to faithfully implement the programs as passed by Congress, whatever they are. That would include if the Affordable Care Act is the law of the land and remains such, to implement it as faithfully as possible."

So my question is, in light of this recent history, not theory, history of what I would argue is sabotage, do you commit to providing that document that I referred to in the letter sent on the 21st, detailing the more than 200 planned regulatory actions that was developed and maintained by HHS? Would you provide that and provide it in a timely manner and without redactions?

Mr. AZAR. I will be happy to look at that. As a nominee, I cannot, obviously, commit to governmental action. And I do not know if that document was prepared during the Obama administration or during the Trump administration. I will be happy to look at that.

What I can tell you is, if I am confirmed as Secretary, I am a problem-solver. I want to work with you and every member of this committee and other committees here to make this program work for people as best it can.

I do think changes are needed. I think statutory changes are in the way. But whatever we can do, I want to make insurance affordable. I want to make it work. I want to get people enrolled.

Senator CASEY. That is great, but—

Mr. AZAR. So you have my commitment.

Senator CASEY. I appreciate that, but this document was developed under this administration. More than 200 proposed actions, and it is hard to square your statement in the HELP Committee and some other statements today of faithful implementation with this undermining of the Affordable Care Act with your support, which is evident from some other questions about legislation that would further undermine it, especially on Medicaid.

But I hope that the American people will have the kind of transparency that they should have a right to expect when it comes to this kind of sabotage.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Carper?

Senator MCCASKILL. Thank you. Oh, sorry.

The CHAIRMAN. Did you have one more question?

Senator MCCASKILL. I had questions, yes.

The CHAIRMAN. Well let me first go to Senator McCaskill. Then I am coming to you, Senator Carper. You are going to be last.

Senator MCCASKILL. Okay.

Senator Susan Collins and I did a long and thorough investigation in the Committee on Aging last year on price spikes. A couple of really good poster children for hedge funds found a drug that was being sold for pennies, and then they managed to spike it up until it was thousands and thousands of dollars.

Have you had a chance to read the report from our investigation?

Mr. AZAR. I have only seen summaries of it, but I do want to look at that and get any ideas that you all were able to come up with there that we could do if I am confirmed at HHS to work on these issues.

Senator MCCASKILL. I would appreciate that. We spent a lot of time looking at it. It is obscene. It is really—nobody was happier when Mr. Wu-Tang was convicted.

Mr. AZAR. Senator, one of the things I know that Doctor—I do not know if you have worked with Dr. Gottlieb on this yet. I know he is very concerned. There is this issue of these generic distortions that happen and how can we build more competition there, and invite it in. I am very committed on that.

Senator MCCASKILL. Okay.

Do you believe the patent system is being abused?

Mr. AZAR. I think there are abuses that happen, absolutely, Senator.

Senator MCCASKILL. Okay.

And do you believe that the orphan drug law is being abused?

Mr. AZAR. I do think we need to—I do not know if I want to call it "abuse." I want to look at it more, because I do not know enough to use that word. But I know that there are issues around continued exclusivity across all indications or expansion where there is an orphan indication.

I want to look at that. It may be simply what the law provides, in which case, if we do not like that, that is a legislative question for us as opposed to manipulating a loophole.

I do not know. I would like to learn more from you about that.

Senator MCCASKILL. I would love to work with you on that.

Daranide—last week, it was announced it went from $0 to $15,000 a bottle. That drug has been around for decades, for decades. And they just slapped $15,000 on one bottle of it.

Mr. AZAR. I would love to work with you to learn more on that.

Senator MCCASKILL. There is something really wrong here. I am going to take you at your word. We are all skeptical over here because of what we have been through the last 12 months.

Mr. AZAR. I hope if I am confirmed, I can earn your trust and your confidence in my treatment of these issues.

Senator MCCASKILL. Me too, because drug prices are a huge problem in the country right now.

Mr. AZAR. And I want to work with you, and I hope that a year from now, you will say, "You proved me wrong."

Senator MCCASKILL. I hope so too.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Carper?

Senator CARPER. Would you just briefly tell us who the folks are right behind you, please?

Mr. AZAR. Oh yes, Senator Carper. Thank you very much.

So I am joined by my wife Jennifer, my daughter Claire, my son Alex, my father, Dr. Alex Azar—who was in Newark, DE when he worked at DuPont when I was a child growing up—my sister Stacey, and her husband Mick.

Senator CARPER. All right.

Mr. AZAR. Thank you, Senator.

Senator CARPER. Welcome, one and all. We are glad you are here.

When I was Governor, one of the things we focused on was, we set up a family services cabinet council. It involved about half of my cabinet. We focused for 8 years, from 1993 to 2001, on the basic building block of our society: families. How do we strengthen and stabilize families?

We started with a State-wide campaign on teenage pregnancy. Delaware had one of the highest teen pregnancy rates in the country.

We put together a bunch of kids from high schools, every public high school in the State, to tell us what we ought to do in a comprehensive State-wide approach. And we did it.

The teen pregnancy rate in Delaware is a lot lower now than it used to be. It is still too high. The unplanned pregnancy rate in our State, in our country, is still around 50 percent. Think about that. It is still up around 50 percent.

One of the most reliable forms of contraception available are something called LARCs, long-acting reversible contraceptives. They are the most reliable form of contraception. I think barely 10 percent of all women, actually, take advantage of inter-uterine devices or implants, but they work. And they work for a long time. You do not have to worry about taking them every day or stopping what you are doing and, you know, getting ready for making children or not.

But in any event, what are the policy and economic barriers to expanding the use of these long-acting reversible contraceptives? What specific steps do you think we could take to expand access to them and lower the rate of unintended pregnancies in the United States? Again, roughly half of the pregnancies are unintended. A lot of them are really young people who are involved.

Mr. AZAR. Senator, I am not as knowledgeable there as I would like to be, and I would love to learn more about it from you. I am assuming that we provide that through title 10 at HHS. But if there are barriers, I would love to learn more from you about that. Obviously, you have studied this issue more than I have.

Senator CARPER. Yes. I am one who believes in going after root causes. And a lot of times, we have people say the problem is—one of the big problems we have in our society is poverty.

And I think it was Marian Wright Edelman who used to say that if you take a 16-year-old girl who is in high school, she becomes pregnant, has a child, drops out of school, does not marry the father of her child, there is an 80-percent likelihood they will live in poverty—80 percent.

The same 16-year-old girl does not become pregnant, does not drop out of school, waits till 21 to have a child, and marries the father of the child, the likelihood that that family will end up in poverty is 8 percent.

Eighty percent on the one hand, 8 percent on the other. When I found out that, I got serious.

Last year, I think, Massachusetts, under the leadership of Governor Charlie Baker—very impressive government there, very impressive leader; you probably know him—they passed legislation to require all health insurance plans to cover all forms of birth control without cost sharing. I just want to ask if—again, this may not be

a fair question, but if it is not, you can say so. But do you agree with the Massachusetts requirement that all health insurance plans in their State should cover all forms of birth control without cost sharing?

Mr. AZAR. I have no issue with States making those choices. That is exactly the kind of competition—States making choices like that—that is what they ought to be doing is making their choices about how to run their health system.

Senator CARPER. All right. Thank you.

When I came in the room Senator McCaskill was asking questions on drug pricing. And I hope I am not going to cover the same territory, but let me just ask this question nonetheless. If you would bear with me, I would appreciate it.

The current administration has repeatedly promised to tackle high drug prices. They have neglected to back up the rhetoric with meaningful results, at least to this point in time.

Several drug companies have tried to address the challenge of high drug prices with more price transparency and proposals for value-based pricing. What regulatory and statutory barriers impede the use of value-based pricing to lower drug costs, and, as HHS Secretary, how will you bring together the drug companies, one of which you used to lead, how would you bring together pharmacy benefit managers, health insurers, other stakeholders, to put together a value-based drug pricing proposal that can be implemented quickly to bring some relief to consumers?

Mr. AZAR. So, it is a great question. You put your finger on one of the key issues, which is value-based pricing. How can we have outcome-based, value-based—basically pay for the value that you are getting on the drugs?

One of the biggest barriers is the price reporting regulations that HHS has. It really has to do with how you report over time, because of course, you are striking an agreement and paying for a drug here, but then it might be several quarters later until you get the data on the results.

And the problem is, then you would end up having a true-up or a change on past price reporting, which is generally not viewed as a good thing. So I do believe this is within HHS's jurisdiction, that if I am there, we can fix that and we can address that to create pathways where you can really put your money where your mouth is and support the value on the drug, and if it does not deliver, then pay more discounting or rebates in return.

So I actually think this is very actionable, Senator.

Senator CARPER. That is great.

I want to commend you on your choice of people to sit up there with you at the beginning of the hearing: Mike Leavitt, who succeeded me at the National Governors' Association; Tommy Thompson from Wisconsin, who preceded all of us as chairman of the NGA, two of my favorite people. I loved being part of the NGA, loved being their colleagues. You could not have two finer people sitting next to you.

I think you have some really good ones sitting behind you as well. And I would say the one of them who worked at DuPont for many years—my wife is retired from DuPont, went to work there over 35 years ago, and had a great career, great career.

We love DuPont in our State, as you might know.

Thanks.

Mr. AZAR. Thank you so much.

Senator CARPER. Good luck and congratulations.

The CHAIRMAN. Okay.

Well, we finally got to the end. I want to thank you for what I consider to be very elevated testimony. There is no question in my mind—and there should not be in anybody's mind—of your competence and your abilities to be able to handle this very, very important job.

In all the time I have served in the U.S. Senate, I have worked with HHS and other agencies as well. And I have to say that you are one of the best public servants whom I have seen in the whole time that I have been here. And I think you handled yourself very well in front of this committee, and hopefully we can get you up and out as soon as we possibly can.

So with that, I just want to welcome your family and thank them for sitting through this. And I am going to come back and say "hello" to everybody, but God bless you.

And with that, we will recess until further notice.

[Whereupon, at 12:30 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. ALEX MICHAEL AZAR II, NOMINATED TO BE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I'm pleased to be joined today by my wife Jennifer, my daughter Claire, my son Alex, and my father Dr. Alex Azar. Unfortunately my mother, Lynda, could not be here today, and most tragically my step-mother Wilma passed away just last July from cancer. Thank you all. Having an opportunity such as this does not happen without family support and guidance.

Thank you, Mr. Chairman, Ranking Member Wyden, and members of the committee, for the opportunity to appear before you as the President's nominee to be the Secretary of Health and Human Services.

Secretary Thompson and Secretary Leavitt, thank you so much for those kind words and for your friendship and mentorship over the years.

I thank President Trump for the confidence he has bestowed on me.

Ninety-seven years ago, my grandfather—an impoverished teenager who spoke no English—stepped out of steerage on the *S.S. Argentina,* completing his long journey from Amioun, Lebanon, to America. As he entered the receiving hall at Ellis Island, he met an individual in a military uniform. That person possessed the power to admit him or to send him back to poverty and uncertainty. That person was a member of the United States Public Health Service. It is a testament to all that I love about this country that just 97 years after my grandfather went through his 6-second physical on Ellis Island with no discernable prospects other than the political, economic, and religious freedom America offers, his grandson might be in charge of that very Public Health Service, as well as all of the other world-renowned components of the Department of Health and Human Services.

The mission of HHS is to enhance and protect the health and the well-being of all Americans, through programs that touch every single American in some way, every single day. Through its outstanding leaders and career staff, HHS is primed to meet that challenge. The task is humbling. Marshaling and leading the incredible resources of the Department require innovating, never being satisfied with the status quo, and anticipating and preparing for the future. I gained these skills in the dark days after 9/11, as we faced the health and human consequences of those attacks, through the subsequent anthrax attacks and preparedness for potential further biological, chemical, radiological, or nuclear attacks, in the implementation of our completely novel Part D prescription drug benefit for seniors, by helping to build global, national, State, and local pandemic flu preparedness, in our response to threats such as SARS and monkeypox, in our efforts to continue to reform welfare programs to make them as modern, responsive, and empowering as possible for the individuals and families we serve, through innovation in the private sector to bring life-improving therapies to our people and the people of the world, and in harnessing the power of big data and predictive analytics to make us more efficient and more capable of serving our fellow Americans.

With a department the size and scope of HHS, it can be difficult to prioritize. Nonetheless, should I be confirmed, I do envision focusing my personal efforts in four critical areas. First, drug prices are too high. The President has made this clear. So have I. Through my experience helping to implement Part D and with my extensive knowledge of how insurance, manufacturers, pharmacy, and government programs work together, I believe I bring skills and experiences to the table that

can help us address these issues, while still encouraging discovery so Americans have access to high-quality care.

Second, we must make health care more affordable, more available, and more tailored to what individuals want and need in their care. We all share a common concern for our fellow Americans who are struggling to achieve access to quality health care, even if we do not necessarily always agree on how best to go about addressing that challenge. Under the status quo, premiums have been skyrocketing year after year, and choices have been dwindling. We must address these challenges for those who have insurance coverage and for those who have been pushed out or left out of the insurance market by the Affordable Care Act.

Third, we must harness the power of Medicare to shift the focus in our healthcare system from paying for procedures and sickness to paying for health and outcomes. We can better channel the power of health information technology, and leverage what is best in our programs and in the private, competitive marketplace to ensure the individual patient is at the center of decision making and his or her needs are being met with greater transparency and accountability.

Finally, we must heed President Trump's call-to-action and tackle the scourge of the opioid epidemic that is destroying so many individuals, families, and communities. We need aggressive prevention, education, regulatory, and enforcement efforts to stop over-prescribing and overuse of these legal and illegal drugs. And we need compassionate treatment for those suffering from dependence and addiction.

These are serious challenges that require a serious-minded sense of purpose, and, if confirmed, I will work with the superb team at HHS to deliver serious results.

I thank President Trump for this important opportunity to serve the American people, and I thank you for your consideration of my nomination.

SENATE FINANCE COMMITTEE

STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name (include any former names used): Alex Michael Azar II.
2. Position to which nominated: Secretary of Health and Human Services.
3. Date of nomination: November 14, 2017.
4. Address (list current residence, office, and mailing addresses):
5. Date and place of birth: June 17, 1967, Johnstown, Pennsylvania.
6. Marital status (include maiden name of wife or husband's name):
7. Names and ages of children:
8. Education (list secondary and higher education institutions, dates attended, degree received, and date degree granted):

   Parkside High School, September 1981–June 1984, High School Diploma, June 1985 (diploma received after completing required English course in first year of college; senior year of high school skipped to attend college).

   Dartmouth College, September 1984–June 1988, A.B., June 1988.

   Middlebury College Summer School of Arabic, June 1985–August 1985, no degree granted (course credit granted by Dartmouth College).

   Yale Law School, September 1988–June 1991, J.D., June 1991.
9. Employment record (list all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment):

   Member, board of directors, HMS Holdings, Inc., Irving, TX, October 2016–present.

Chairman and founder, Seraphim Strategies, LLC, Indianapolis, IN, January 2017–present.

President, Lilly USA, LLC, Eli Lilly and Company, Indianapolis, IN, January 2012–January 2017.

Vice president, managed healthcare services and Puerto Rico, Lilly USA, LLC, Eli Lilly and Company, Indianapolis, IN, April 2009–December 2011.

Senior vice president, corporate affairs and communications, Eli Lilly and Company, Indianapolis, IN, June 2007–March 2009.

Deputy Secretary, U.S. Department of Health and Human Services, Washington, DC, July 2005–February 2007 (Acting Deputy Secretary from April 2005–July 2005).

General Counsel, U.S. Department of Health and Human Services, Washington, DC, August 2001–July 2005.

Senior Advisor to the Secretary, U.S. Department of Health and Human Services, Washington, DC, June 2001–August 2001.

Associate, then partner since January 1999, Wiley, Rein, and Fielding, Washington, DC, October 1996–June 2001.

Associate Independent Counsel, Office of the Independent Counsel, Washington, DC, October 1994–September 1996.

Associate, Kirkland and Ellis, Washington, DC, October 1993–October 1994.

Law clerk to Associate Justice Antonin Scalia, Supreme Court of the United States, Washington, DC, July 1992–July 1993.

Law clerk to Circuit Judge J. Michael Luttig, U.S. Court of Appeals for the Fourth Circuit, McLean, VA, October 1991–June 1992.

Law clerk to Circuit Judge Alex Kozinski, U.S. Court of Appeals for the Ninth Circuit, Pasadena, CA, July 1991–August 1991.

Summer associate, Steptoe and Johnson, Washington, DC, June 1991–June 1991.

Summer associate, Sullivan and Cromwell, New York, NY, July 1990–August 1990.

Summer associate, Steptoe and Johnson, Washington, DC, June 1990–July 1990.

Volunteer extern to Circuit Judge Alex Kozinski, U.S. Court of Appeals for the Ninth Circuit, Pasadena, CA, June 1989–August 1989.

10. Government experience (list any advisory, consultative, honorary, or other part-time service or positions with Federal, State, or local governments, other than those listed above):

Member, board of directors, Indianapolis Airport Authority, Indianapolis, IN, January 2009–December 2012.

Ex officio United States member of the U.S.-Ireland Research and Development Steering Committee, Washington, DC, July 2005–February 2007.

Ex officio member of the United States Architectural and Transportation Barriers Compliance Board, Washington, DC, August 2001–July 2005 (General Counsel sits as Federal member for the U.S. Department of Health and Human Services).

Volunteer intern, Health and Income Maintenance Division, Office of Management and Budget, Washington, DC, March 1986–June 1986.

11. Business relationships (list all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution):

Member, board of directors and chairman of the Strategic Planning Committee (since 2015), American Council on Germany, New York, NY, December 2010–present.

Member, board of directors and member of the Audit Committee, Indianapolis Symphony Society, Indianapolis, IN, November 2008–present.

Biotechnology Innovation Organization (BIO), Washington, DC, April 2013 to January 2017. Member of the board of directors. Member of the executive committee of the board (since 2016). Member of the health section governing board. Co-chairman of the board, Standing Committee on Reimbursement. Member of the Regulatory Environment Committee and the Intellectual Property Committee.

Healthcare Leadership Council, Washington, DC, January 2008 to January 2017. Member of the board of trustees. Treasurer (since 2013) and member of the executive committee of the board of trustees (since 2012).

Yale Law School Association, New Haven, CT, 2010 to 2013, member. Vice president of the executive committee of the association, elected to 3-year term (2011 to 2013).

Indianapolis Airport Authority, Indianapolis, IN, January 2009 to December 2012. Member of the board of directors. Chairman of the Human Resources Committee (since 2010). Appointed by the Mayor of Indianapolis.

National Association of Manufacturers, Washington, DC, March 2008 to 2012. Member of the board of directors.

Health Coverage Foundation, Washington, DC. Member of the board of directors of a non-profit foundation dedicated to assisting the uninsured in obtaining health-care coverage in the private marketplace, providing premium assistance, and educating the public on the availability for such coverage (January 2008 to December 2011).

The Eli Lilly and Company Foundation, Inc., Indianapolis, IN. Ex officio member of the board of directors of the foundation, which is a tax-exempt private foundation created by Eli Lilly and Company that awards cash grants to support philanthropic initiatives that are aligned with the company's business strategy, including a discretionary grants program, the employee matching gifts program, and the employee volunteer recognition program (June 2007 to March 2009).

12. Memberships (list all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations):

Bar of the Supreme Court of the United States (November 1999 to present).

Bar of the Court of Appeals of Maryland (December 1993 to present).

Bar of the District of Columbia Court of Appeals (April 1995 to present).

Bar of the U.S. Court of Appeals for the District of Columbia Circuit (January 1994 to present).

Bar of the U.S. Court of Appeals for the Fourth Circuit (January 1994 to present)

Bar of the U.S. District Court for the District of Maryland (March 1994 to present).

Bar of the U.S. District Court for the District of Columbia (November 1999 to present).

Maryland State Bar Association (1993 to present, except I do not believe I was a member of this voluntary association for fiscal years 1994–1995, 1997–1998, 2000–2002, and 2008–2009).

The Mory's Association (Yale University affiliated dining club), member, New Haven, CT (approximately 1990 to present).

The Cosmos Club, non-resident member, Washington, DC (January 2006 to present).

Meridian Hills Country Club, member, Indianapolis, IN (August 2007 to present).

The Chevy Chase Club, non-resident member, Chevy Chase, MD (October 2017 to present).

Saint George Antiochian Orthodox Church, member, Fishers, IN (August 2007 to present), altar server (August 2007 to present), chairman of the Prison Ministry Committee (approximately 2010 to 2011).

Order of St. Ignatius, life member, Antiochian Orthodox Archdiocese of North America (November 2016 to present).

The Zetema Project, panelist (January 2017) and contributor (current), San Francisco, CA.

Center for Corporate Innovation, Inc. (CCI), member, Los Angeles, CA (January 2015 to present).

Honorary advisory boards:

Indiana University School of Medicine External Advisory Board, member, Indianapolis, IN (2008 to November 2010).

George Mason University School of Law board of advisors, member, Arlington, VA (joined December 2008 and do not know if still in existence; I have never participated in any meetings and do not consider myself a member). The Texas Review of Law and Politics honorary board of advisors, member, Austin, TX (2001 to March 2005)

Voluntary legal professional memberships:

American Health Lawyers Association, member, Washington DC (2001 to approximately 2007).

American Bar Association, member (1998 to 2016), executive branch liaison to the Administrative Law Section (August 2006 to February 2007), Washington, DC.

The Federalist Society for Law and Public Policy, member (September 1988 to 2007). Member of the National Practitioners Advisory Council (joined December 2008, but never participated on calls or in meetings; I am informed this group has been inactive for at least 4–5 years). Vice chairman of the Federalism and Separation of Powers Practice Group (June 1997 to December 1999). Chairman-elect of the Federalism and Separation of Powers Practice Group (January 2000 to June 2001), Washington, DC.

The Federalist Society for Law and Public Policy, Yale Law School chapter, member (September 1988 to June 1991) and vice president (approximately September 1990 to June 1991), New Haven, CT.

The Becket Fund for Religious Liberty, chairman of the Lawyers' Council, Washington, DC (February 1998 to June 2001).

Federal Bar Association, member, Washington, DC (approximately 1993 to 1998).

American Judicature Society, member, Washington, DC (approximately 1993 to 2000, with various periods when not a member).

College and law school associations:

Yale Law School class of 1991, member of various reunion gift committees (most recently in 2016). Currently leading efforts to raise money to pay for portrait of Associate Justice Sam Alita, New Haven, CT.

Dartmouth College class of 1988. May have been member of various reunion gift committees (most recently might have been 2013); conducted alumni interviews of candidates in central Indiana (2015 to 2016), Hanover, NH.

Yale Law Journal, member (1989 to 1991) and executive committee member (April 1990 to June 1991), New Haven, CT.

Religious memberships:

Saints Peter and Paul Antiochian Orthodox Church, member (April 1999 to July 2007) and parish council member (January 2001 to December 2003), Potomac, MD.

Saint John's Episcopal Church, member (approximately 1993 to February 1999). Christian education committee member (approximately 1996 to February 1999). Acolyte program director (approximately 1994 to February 1999). Chalice bearer (approximately 1994 to February 1999), Washington, DC.

Episcopal Church at Yale, member (September 1988 to June 1991) and chalice bearer (approximately 1990 to June 1991), New Haven, CT.

Other organizations:

Indianapolis Museum of Art, Indianapolis, IN. Member of the nominating committee for the board of governors (2008 to 2009) (I assisted the board and CEO in identifying candidates for selection to the board, but was never myself a member of the board).

Rollingwood neighborhood association, member, Chevy Chase, MD (December 1997 to August 2007).

Rock Creek Pool, Inc., summer member, Chevy Chase, MD (approximately 1999 to August 2007).

Over the years, I have been simply a dues-paying member of various organizations, such as the U.S. Equestrian Federation, the Brown County Art Guild, the Indianapolis Children's Museum, the Smithsonian Institution, the Indianapolis Zoo, the National Zoo, the Art Institute of Chicago, the Hoosier Salon, and the Indiana Plein Air Painters Association. There may be similar additional such memberships I do not presently recall.

13. Political affiliations and activities:

a. List all public offices for which you have been a candidate.

None.

b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

During the 2008 campaign, I believe I may have been a nominal member of a campaign constituency group called Arab Americans for McCain. I may also have signed up for Lawyers for McCain, but do not recall.

During the 2012 campaign, I served on a campaign policy working group on health-care policy for the Romney campaign. I believe I participated in a few conference calls and email exchanges.

During the 2016 campaign, I was a member of the Indiana State steering committee for Jeb Bush. I later was listed as one of many Indiana State co-chairs for Ted Cruz. Both positions were honorific and entailed no activity or fundraising. At some point prior to the election, I believe I agreed to assist the Trump/Pence campaign transition team with regard to health policy, but do not recall any active engagement, calls, or meetings.

I was a co-host, along with Lilly's CEO, of a fundraiser for Indiana Speaker of the House Brian Bosma on October 1, 2014. I was listed as a host for a Dan Coats for Senate fundraiser on June 22, 2010, by virtue of a contribution I previously gave. I do not remember serving on any other political organizations during this period, although while a senior executive at Eli Lilly, on occasion, I reached out to other executives to contribute to political fundraisers or to the Lilly PAC.

c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of $50 or more for the past 10 years.

Friends of Todd Young, Inc.	November 7, 2016	$2,500
TENNPAC	August 29, 2016	$2,500
Committee to Elect Brian Bosma	August 29, 2016	$1,000
Trump Victory	July 12, 2016	$2,700
Jackie Walorski for Congress	April 22, 2016	$500
Indiana Republican Party	April 21, 2016	$200
Committee for Najjar for Judge	March 20, 2016	$500
Friends of Todd Young, Inc.	March 18, 2016	$1,500
Portman for Senate Committee	March 18, 2016	$2,000
Indiana Republican Party	December 7, 2015	$2,000
Jeb 2016, Inc.	October 8, 2015	$2,700
Mike Pence for Indiana Committee	October 2, 2015	$1,000
Friends of Todd Young, Inc.	June 21, 2015	$1,000
Brooks-Bucshon Joint Fundraising Committee	June 7, 2015	$1,000
Stutzman for Congress	November 3, 2014	$500
Bucshon for Congress	November 3, 2014	$500

Susan Brooks for Congress	November 3, 2014	$500
Committee to Elect Brian Bosma	October 6, 2014	$1,000
Luke Messer for Congress	September 30, 2014	$500
Dan Coats for Indiana	September 30, 2014	$1,000
Friends of Connie Lawson	June 4, 2014	$250
Ben Sasse for Nebraska	May 9, 2014	$1,000
McConnell Senate Committee 2014	April 19, 2014	$2,100
Friends of Todd Young	March 25, 2014	$1,000
Walorski for Congress	March 20, 2014	$500
McConnell Senate Committee 2014	April 26, 2013	$500
Dan Coats for Indiana	December 6, 2012	$500
Mike Pence for Indiana	October 24, 2012	$200
Sue Ellspermann for Lt. Governor	October 15, 2012	$250
Hoosiers for Richard Mourdock, Inc.	October 15, 2012	$500
Romney Victory, Inc.	September 6, 2012	$2,500
Ted Cruz for U.S. Senate	September 4, 2012	$500
Friends of Todd Young	September 4, 2012	$500
Todd Rokita for Congress	September 4, 2012	$500
Todd Rokita for Congress	June 28, 2012	$500
Stutzman for Congress	June 14, 2012	$500
Hatch Election Committee	June 7, 2012	$1,000
Bucshon for Congress	May 6, 2012	$500
Wendy Long for New York	April 14, 2012	$500
Luke Messer for Congress	April 14, 2012	$500
Tommy Thompson for Senate, Inc.	March 13, 2012	$2,500
Friends of Dick Lugar	November 6, 2011	$500
Dan Coats for Indiana	October 26, 2011	$500
Mike Pence for Indiana	October 20, 2011	$2,500
David McIntosh for Indiana	September 28, 2011	$2,500
Romney for President, Inc.	September 23, 2011	$2,500
Greg Ballard for Mayor Committee	June 30, 2011	$2,000
Jackie Walorski for Congress	June 30, 2011	$1,000
Marion County Republican Central Committee	June 9, 2011	$100
Hoosiers for Rokita	October 24, 2010	$500
Aiming Higher	October 10, 2010	$1,000
Aiming Higher	September 23, 2010	$1,000
Friends of Todd Young	September 8, 2010	$250
Dan Coats for Indiana	September 1, 2010	$2,400
Mike Pence Committee	August 18, 2010	$500
Mark Massa for Prosecutor	August 4, 2010	$250
Dan Coats for Indiana	March 29, 2010	$2,400
Hershman for Congress	March 29, 2010	$500
Brett Davis for Lieutenant Governor	January 5, 2010	$100
Sam Saad for City Council	January 5, 2010	$100
The Scott Brown for U.S. Senate Committee	January 15, 2010	$500
Teresa Lubbers for State Senate Committee	October 21, 2008	$100
Mike Murphy Committee	October 21, 2008	$100
Committee to Elect Brian Bosma	October 21, 2008	$100
Zoeller for Attorney General	October 21, 2008	$100
JonElrod.com Committee	October 21, 2008	$100
Marion County Republican Central Committee	October 21, 2008	$100
Mitch for Governor Campaign	October 10, 2008	$500
Hoosiers for Buyer	October 10, 2008	$500
Indiana Republican Party	October 7, 2008	$300
National Republican Senatorial Committee	September 30, 2008	$1,000
McGoff for Congress	April 24, 2008	$100
McConnell Senate Committee 2008	March 25, 2008	$2,300
John McCain 2008	February 13, 2008	$2,300

From December 15, 2007, until January 31, 2017, I had $208 per pay period (2 pay periods per month) withdrawn as a contribution to the Lilly PAC.

14. Honors and awards (list all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement):

Surgeon General's Medallion.

Phi Beta Kappa Society, Dartmouth College.

Nelson A. Rockefeller Memorial Fellowship for "Honors thesis of such scholarly merit that it shows promise of publication," Dartmouth College.

Colby Government Prize for "excellence in the Government major," Dartmouth College.

Rockefeller Prize in Comparative Politics for "outstanding thesis in the field of comparative politics," Dartmouth College.

Rockefeller Public Service Internship Grant, Dartmouth College.

High Honors Rufus Choate Scholar, Dartmouth College.

Saint Peter's Church Van der Bogart Scholar, Salisbury, MD.

Special Achievement Award, Office of the Independent Counsel.

15. Published writings (list the titles, publishers, and dates of all books, articles, reports, or other published materials you have written):

Alex M. Azar II, Note, "FIRREA: Controlling Savings and Loan Association Credit Risk Through Capital Standards and Asset Restrictions," 100 *Yale Law Journal* 149 (1990).

Alex M. Azar II, "Recommended Reading: Antonin Scalia's *A Matter of Interpretation: Federal Courts and the Law," The Federalist Paper,* May 1997.

Alex M. Azar II, "The Appellate Corner," *Criminal Law and Procedure News,* Federalist Society for Law and Public Policy Studies Criminal Law and Procedure Practice Group, Fall 1996, Spring 1997, Fall 1997, Winter 1998, Spring 1999.

Alex M. Azar II, Letter to the Editor, "The Cipro Dilemma," *American Lawyer,* January 31, 2002.

Alex M. Azar II, "What a Food and Drug Lawyer Should Know About the Medicare Modernization Act," 59 *Food and Drug Law Journal* 217 (2004).

Alex M. Azar II, "Administrative Law Meets Health Law: Inextricable Pairing or Marriage of Convenience?", 49 *St. Louis University Law Journal* 35 (2004).

Alex M. Azar II, "The Role of Intellectual Property Protection in the United States to Yield Both Public Health and National Wealth: Customary Coordination Between the Private Sector and the U.S. Department of Health and Human Services Realizing the Common Good," The Forum for EU–U.S. Legal-Economic Affairs, Amsterdam Forum, The Netherlands (The Mentor Group, Boston, Mass.), May 2005, at 41.

Alex M. Azar II, "Cracks in the System: The Adequacy of the U.S. Health Care Regulation in a Global Age," 58 *Administrative Law Review* 551 (2006).

Alex M. Azar II, "Eating Today and Eating Tomorrow: Competition, Innovation, and Pricing for Modern Medicine," The Ripon Society's Congressional Advisory Board: Public Policies for Debate 2006 (The Ripon Society, Washington, DC), 2006, at 7.

Alex M. Azar II, "What is Your Health Worth to Your Bureaucrat?", The Forum for EU–US Legal-Economic Affairs, Vienna Forum, Austria (The Mentor Group, Boston, MA), 2006, at 1.

Alex M. Azar II, Panelist Remarks from Panel, "Intellectual Property: Does IP Harm or Help Developing Countries," Proceedings of the 2006 National Lawyers Convention, Engage, Vol. 8, Issue 2 (The Federalist Society for Law and Public Policy Studies, Washington, DC), 2006, at 80.

Alex M. Azar II, "Transparency in Health Care: What Consumers Need to Know," *Heritage Lectures,* No. 986 (The Heritage Foundation, Washington, DC), January 22, 2007, at 1.

Alex M. Azar II, "We Have to Innovate for Desired Patient Outcomes," *Medical News (www.medicalnews.md),* November/December 2007, at 5.

Alex M. Azar II, "Taking the Strain," Interview with Alex M. Azar II, *The House Magazine,* Tuberculosis Supplement, March 24, 2008.

Alex M. Azar II, "The Importance of HIT," *Prescriptions for Excellence in Health Care,* a Collaboration between Jefferson Medical College and Eli Lilly and Company, Issue 3, Spring 2008.

Alex M. Azar II, "Health Information Technology: A Priority for Patients, for Physicians, and for Lilly," *Prescriptions for Excellence in Health Care,* a Collaboration between Jefferson Medical College and Eli Lilly and Company, Issue 4, Summer 2008.

Alex M. Azar II, "Keeping the Patient in the Center of Health Reform," *Inside ALEC,* a Publication of the American Legislative Exchange Council. November/December 2008.

Alex M. Azar II, "Generic Medicines: The Gift of Innovation," reprinted in *Vital Speeches of the Day,* December 2008, at 559.

Alex M. Azar II, "Health Chief Can Make Her Mark by Prioritizing," *Indianapolis Star,* March 15, 2009, at B9.

Alex M. Azar II, "Generic Medicines: The Gift of Innovation," reprinted in *Contemporary American Speeches,* by Richard Johannesen, et al. (2011), at 36.

Alex M. Azar II, "A Letter," in *The 4 Disciplines of Execution: Achieving Your Wildly Important Goals,* by Chris McChesney, Sean Covey, and Jim Huling (Free Press 2012), at xxv.

Alex M. Azar II, "Inheritance From Hugo Chavez: How Not To Fix Healthcare," *Real Clear Markets, http://www1.realclearmarkets.com/printpage/?url=http://www.realclearmarkets.com/articles/2014/02/25/inheritance_from_hugo_chavez_how_not_to_fix_healthcare__100923.html,* February 25, 2014.

Alex M. Azar II, "If We Love U.S. Jobs, We Must Love Tax Competition," *Real Clear Markets, http://www.realclearmarkets.com/articles/2014/04/25/if_we_love_us_jobs_we_must_love_tax_competition_101019.html,* April 25, 2014.

Alex M. Azar II, "A Few Simple Fixes Could Unleash an Economic Boom," *Real Clear Markets, http://www.realclearmarkets.com/articles/2015/04/29/a_few_simple_fixes_could_unleash_an_economic_surge_101647.html,* April 29, 2015.

Alex M. Azar II, "What's Behind the Surge of Healthcare Consolidations?", *Real Clear Markets, http://www.realclearmarkets.com/articles/2015/06/29/whats_behind_the_surge_of_healthcare_consolidation.html,* June 29, 2015.

Alex M. Azar II, "Will Healthcare Experience a 'Retail Revolution'?", *Real Clear Markets, http://www.realclearmarkets.com/articles/2015/11/09/will_healthcare_experience_a_retail_revolution_101880.html,* Nov. 9, 2015.

Alex M. Azar II, "A Dose of Patience Needed to Make Personalized Medicine a Reality for All Patients,"; BIO Buzz Official Show Daily, June 8, 2016, at 10.

There may be older publications that I do not now recall or have copies of.

16. Speeches (list all formal speeches you have delivered during the past 5 years which are on topics relevant to the position for which you have been nominated):

Acceptance of the John J. McCloy Award, American Council on Germany 21st Annual McCloy Awards Dinner, New York, New York, June 11, 2013.

Opening remarks, American Council on Germany Policy Conference on "A Transatlantic Trade and Investment Partnership: Can the United States and Europe Lead the Way to Global Economic Recovery?", New York, New York, June 12, 2013.

Panelist, *Indianapolis Business Journal* Power Breakfast Series, "Health Care and Benefits," Indianapolis, Indiana, September 25, 2013 (no prepared remarks).

Keynote address, "Personalized Medicine: The Big Picture," MIT Sloan Bio-Innovations 2014, Precision Medicine and the Impact of Innovation on Targeted Care, Cambridge, Massachusetts, February 28, 2014. Video available at: *https://youtu.be/XqA8nPVuk64.*

Panelist, "The Rise of the Patient: Re-Imagining the Health Care Ecosystem," The Economist Health Care Forum 2014: A Global Business in Flux, Boston, Massachusetts, September 17, 2014 (no prepared remarks).

Panelist, "Bigger and Better? Horizontal Consolidation Within Sectors and Antitrust Enforcement," Solomon Center for Health Law and Policy at Yale Law School, New Haven, Connecticut, November 13, 2015 (no prepared remarks). Video available at: *https://youtu.be/7pfXioj9beY*.

Inaugural keynote address, "Succeeding on Purpose: Why Institutions That Provide Purpose to Their Staff and Customers Are Winning Today," Dr. Nicholas R. Blanchard Annual Healthcare Symposium, University of Maryland Eastern Shore, Princess Anne, Maryland, April 13, 2016. Video available at: *https://youtu.be/JQLvyLNhja4*.

Panelist, "Pharmacoeconomics: R&D Strategies in an Era of Drug Pricing Controversy," FierceBiotech Executive Breakfast at BIO2016, San Francisco, California, June 7, 2016 (no prepared remarks).

Panelist, "Educational Series on Affordable Medicines: Value-Based Payments and Financing Breakthrough Treatments," Bipartisan Policy Center, Washington, DC, June 16, 2016 (no prepared remarks). Video available at: *https://bipartisanpolicy.org/events/educational-series-on-affordable-medicines-value-based-payments/*.

Address, "Join Me on the Frontier," Leadership Dinner, American Legislative Exchange Council, Indianapolis, Indiana, July 26, 2016.

Case study presentation, "Using Behavioral Economics to Improve Patient Adherence," Center for Corporate Innovation, Inc., DC Healthcare Summit, Washington, DC, August 4, 2016 (no prepared remarks; PowerPoint provided).

Dinner address, "Succeeding on Purpose: Why Providing Purpose Is Key to Winning Today," Indiana Healthcare Executives Network, Indianapolis, Indiana, September 7, 2016.

Keynote presentation, "Demonstrating the Value of Medicines," Common Problems in Arrhythmia Management: A Case-Based Approach, Carmel, Indiana, September 23, 2016.

Panelist, "Health Law, Policy, Politics, and Progress: What Lies Ahead," Yale Law School Alumni Weekend 2016, New Haven, Connecticut, October 22, 2016 (no prepared remarks).

Keynote address, "Prescription for Value: Keeping Innovation Affordable for Patients," Manhattan Institute Health Care Symposium, New York, New York, November 3, 2016.

Panelist, "Large Biotech and Pharma Perspectives: Takeaways From Last Year," Boston Biotech Conferences, East/West CEO Conference, San Francisco, California, January 7, 2017 (no prepared remarks).

Discussion starter, "Medicare as a Public-Private Program: Lessons Learned," The Roles of Government and the Private Sector: Markets, Regulation, Responsibility and Risk, The Zetema Project, Chattahoochee Hills, Georgia, January 19, 2017 (no prepared remarks).

Guest lecturer, "Present and Future Directions of the U.S. Healthcare Ecosystem," Healthcare Initiative at Tuck, Tuck School of Business, Dartmouth College, Hanover, New Hampshire, February 9, 2017 (no prepared remarks).

Panelist, "Policy Outlook—ACA, CMS, PDUFA VI and the Trump Administration," BIO CEO and Investor Conference, New York, New York, February 14, 2017 (no prepared remarks).

Moderator, closing keynote, "Healthcare Debate Featuring Karl Rove and Howard Dean," MedImpact 2017 Annual Conference, Coronado, California, March 10, 2017 (no prepared remarks).

Keynote, "Industry Perspective, a Fireside Chat," Veeva Global Commercial and Medical Summit, Philadelphia, Pennsylvania, May 8, 2017 (no prepared remarks). Video available at: *https://www.veeva.com/resources/industry-perspective-fireside-chat-matt-wallach-and-alex-azar/*.

Keynote Address, "Specialty Pharmacy: The Bridge to the Patient in a Rapidly Evolving Healthcare Ecosystem," 5th Annual National Association of Specialty

Pharmacy Annual Meeting and Educational Conference, Washington, DC, September 19, 2017 (no prepared remarks; PowerPoint provided).

Dinner address, "Leadership Lessons From a Life in Law, Government, and Business," Class of 2016 Current Issues in the Business of Medicine Speaker Series, Business of Medicine Physician MBA Program, Indiana University Kelley School of Business, Indianapolis, IN, October 13, 2017 (no prepared remarks).

I have not included informal remarks and discussions and internal Lilly presentations.

17. Qualifications (state what, in your opinion, qualifies you to serve in the position to which you have been nominated):

I would be deeply honored to return to the U.S. Department of Health and Human Services to help lead the dedicated team there. In 2001, I became the General Counsel of the Department of Health and Human Services. In that role and in my subsequent role as Deputy Secretary of Health and Human Services, I developed a deep sense of mission and purpose to help people live longer, healthier, happier lives. With almost 6 years of experience at the highest levels of HHS playing key roles during the attacks on September 11th, the subsequent anthrax attacks, public health preparedness for potential smallpox attack, the SARS and monkeypox crises, implementation of Medicare Part D and the Medicare Advantage program, the Hurricane Katrina response and recovery, the Office of Refugee Resettlement of Americans from Lebanon, the global public health preparedness efforts, the creation and implementation of Project Bioshield and other efforts to develop and acquire chemical, biological, radiological, and nuclear countermeasures, public health emergency preparedness and planning efforts in the United States, and the pandemic avian influenza preparedness program, as well as the day-to-day operations of HHS, I would bring a unique level of experience and knowledge to the role of Secretary. I believe this deep knowledge and experience at HHS, combined with my years of experience in the private sector leading large organizations and delivering results would enable me to help HHS and its dedicated career professionals deliver on their critical mission of improving the lives and well-being of every American.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

Yes.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next presidential election, whichever is applicable? If not, explain.

Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

The U.S. Office of Government Ethics ("OGE") and the HHS Ethics Office have reviewed my financial holdings, outside positions, and my existing agreements and arrangements. I have agreed to take all of the actions that they have requested in order to resolve any actual or apparent conflict of interest. The specific actions I agreed to take are detailed in the ethics agreement I have signed and submitted to the HHS Designated Agency Ethics Official ("DAEO").

I will follow the law and the administration's conflict of interest policies and recuse myself as required. I will consult with the HHS Ethics Office as needed and will follow the advice of the HHS DAEO, a career civil service employee, regarding my recusal obligations.

2. Describe any business relationship, dealing, or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

The U.S. Office of Government Ethics ("OGE") and the HHS Ethics Office have reviewed my financial holdings, outside positions, and my existing agreements and arrangements. I have agreed to take all of the actions that they have requested in order to resolve any actual or apparent conflict of interest. The specific actions I agreed to take are detailed in the ethics agreement I have signed and submitted to the HHS DAEO.

I will follow the law and the administration's conflict of interest policies and recuse myself as required. I will consult with the HHS Ethics Office as needed and will follow the advice of the HHS DAEO regarding my recusal obligations.

I was employed by Eli Lilly and Company or its U.S. affiliate, Lilly USA, LLC, for most of the past 10 years, leaving at the end of January 2017. I continue to participate in the Eli Lilly and Company Defined Benefit Plan, which has both qualified and nonqualified components; however, I am owed no other payments, participate in no other benefit programs, and hold no equity interests in Eli Lilly and Company. I have agreed to take all of the actions that OGE and the DAEO have requested in order to resolve any actual or apparent conflict of interest regarding Lilly, which are set forth in my ethics agreement. I will consult with the HHS ethics office as needed and will follow the advice of the DAEO regarding my recusal obligations.

Since October 2016, I have been a member of the board of directors of HMS Holdings, Inc., which provides cost containment solutions in health care to help payers improve performance. As set forth in my ethics agreement, I will resign from the board of HMS Holdings, Inc., and divest my equity interests in HMS. I will consult with the HHS ethics office as needed and follow the advice of the HHS DAEO regarding my recusal obligations.

From January 2017 to present, I have been the chairman and founder of Seraphim Strategies, LLC. I am the only member and employee. If I am confirmed, this LLC will be inactive during the period of my appointment and will not advertise. I will not perform any services for this entity, except that I will comply with any requirements involving legal filings, taxes, and fees that are necessary to maintain the entity while it is in inactive status. I will consult with the HHS Ethics Office as needed and will follow the advice of the HHS DAEO regarding my recusal obligations.

Through Seraphim Strategies, LLC, I was retained to provide a modest amount of consulting advice to UCB, Inc., Edwards Lifesciences, and the National Pharmaceutical Council. In addition, through Seraphim Strategies, LLC, I was retained by my speaker's bureau, World Wide Speakers Bureau, to deliver paid speeches or host debates at meetings held by MedImpact, the National Association of Specialty Pharmacy, and Veeva Systems. Also through Seraphim Strategies, LLC, I was independently retained by CCI, Inc., to deliver paid remarks. As to each of these entities, I will have no continuing relationship or financial connection, and I will consult with the HHS Ethics Office as needed and follow the advice of the HHS DAEO regarding my recusal obligations.

As noted, I served on the boards of the Biotechnology Innovation Organization and the Healthcare Leadership Council and will consult with the HHS Ethics Office as needed and follow the advice of the HHS DAEO regarding my recusal obligations.

My spouse is an unpaid volunteer for three not-for-profit organizations. These organizations and her association with each are as follows:

Christamore House Guild: member (Fall 2001–present); board of directors (2015–2017).

The Policy Circle: member (Fall 2015–present).

Women for Riley (philanthropic group within Riley Children's Foundation): member (Fall 2017–present).

I will not participate personally and substantially in any particular matter involving specific parties in which I know any of the above three organizations is a party or represents a party, without first consulting with the HHS DAEO.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal Government need not be listed.

   As a senior executive of Eli Lilly and Company, I had occasions to meet with members of Congress, administration officials, Governors, and State officials regarding a variety of issues including, but not limited to, tax reform, patent reform, Medicaid, Medicare, coverage status of Lilly drugs, the 3408 program, FDA regulation, and prospective European and Pacific trade agreements. Some of these activities and contacts, which were a small portion of my responsibilities, related to particular legislative or administrative proposals such as the inclusion of biosimilar legislation in the ACA and for Medicare coverage of Amyvid, a tool to assist in the diagnosis of Alzheimer's disease, while others focused more broadly on topics such as U.S. global tax policy and reform, patent reform, and drug pricing. While at Lilly, I also on occasion met with foreign government officials and worked on issues related to the reimbursement of Lilly medicines in foreign countries and regarding reforms and designs of foreign health systems and drug reimbursement systems.

   In addition, as a senior executive of Lilly and as a member of the boards of various trade associations, I have been involved directly in monitoring (and at times formulating positions regarding) various health policy proposals, primarily at the Federal level but also at the State and local level.

   As a board member at HMS, I have been involved in discussions regarding how to get CMS to enhance its efforts to use outside vendors to pursue waste, fraud, and abuse in the Medicare and Medicaid programs, how to get the Federal Government to enhance dependent eligibility verification in the FEHBP, and other similar areas of business focus for HMS. I also had brief discussions with individuals in the new administration regarding ideas HMS had come up with to save taxpayer money (regardless of the vendor used) through rooting out waste, fraud, and abuse.

   Over the past couple of years, but particularly since leaving Lilly, I've spoken publicly about the Affordable Care Act, drug pricing, specialty pharmacy, and FDA regulation. Some of these speeches and appearances have touched on existing legislative proposals while others have recommended various government actions to address drug pricing or other policy issues.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items.

   The U.S. Office of Government Ethics ("OGE") and the HHS Ethics Office have reviewed my financial holdings, outside positions, and my existing agreements and arrangements. I have agreed to take all of the actions that they have requested in order to resolve any actual or apparent conflict of interest. The specific actions I agreed to take are detailed in the ethics agreement I have signed and submitted to the HHS Designated Agency Ethics Official ("DAEO").

   I will follow the law and the administration's conflict of interest policies and recuse myself as required. I will consult with the HHS Ethics Office as needed and will follow the advice of the HHS DAEO, a career civil service employee, regarding my recusal obligations.

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

   No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county, or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

No.

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

   In November 2004, an employee of the FDA purported to sue pro se the Secretary and several other senior and junior officials of HHS for issues arising out of his employment with the New York District Office of the FDA. His claim against me was that my office (the Office of the General Counsel at the time) allegedly gave advice to agency managers that could "revoke, restrict, or chill" his first amendment rights. The complaint did not allege that I had any knowledge or personal involvement in the matters at issue. The Justice Department defended me and the case was dismissed by the court on September 8, 2005, 2005 WL 2207011 (S.D.N.Y.), No. 04 Civ. 9318 (VM).

   On February 13, 2005, my wife and I filed an administrative appeal of the January 2005 property tax assessment on our then residence by the State of Maryland. The appeal was with the Maryland Department of Assessments and Taxation, Montgomery County, Real Property Appeals, and was identified by Notice Number 266512, Control Number 7250, Account Number 0700601307. I do not recall any further proceedings and believe our appeal was denied.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

   No.

5. Please advise the committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

   None.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

   Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

   Yes.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. ALEX MICHAEL AZAR II

QUESTIONS SUBMITTED BY HON. ORRIN G. HATCH

MEDICARE HOSPITAL INSURANCE (HI) TRUST FUND

Question. The most recent Medicare Trustees report projects that Medicare's Part A trust fund will be officially bankrupt in 2029, at which time the Medicare program will no longer be able to pay full benefits for seniors.

Assuming current law remains unchanged, the Medicare trustees also estimate that the Medicare Part A total unfunded obligation over 75 years is $3.3 trillion. Using the CMS Actuary's alternative projection, which looks at Medicare's financial footing using more realistic assumptions, the Part A unfunded obligation over 75 years climbs to $9.4 trillion. In your view, what program reforms or changes are necessary to ensure that Medicare continues to provide appropriate access to high quality services and remains affordable for both beneficiaries and taxpayers?

Answer. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. By improving how we operate the program, I believe we can stretch out the resources to make Medicare more sustainable and allow it to better serve more beneficiaries as the baby boomer generation ages into the program. We need to make sure Medicare has long-term sustainability, and if confirmed, I will work with CMS, Congress, and other stakeholders to make sure we come up with the right approaches to work towards this goal.

ACCOUNTABLE CARE ORGANIZATIONS (ACOS) AND CARE COORDINATION

Question. I and Senator Wyden formed a bipartisan, full Finance Committee chronic care working group, co-chaired by Senators Isakson and Warner. After over 2 years of collaborative work with Finance Committee members, MedPAC, CMS, and CBO, we introduced bipartisan legislation aimed at increasing care coordination in the Medicare program without adding to the deficit. It goes without saying that this is a topic that is of great importance to me and to the members of this committee. That said, I understand that delivering health-care services to beneficiaries living with multiple chronic conditions is a challenging task. Private health plans like PPOs and HMOs can create preferred networks of providers where beneficiaries are charged lower cost-sharing if they seek medical services in network. ACOs and other alternative fee-for-service Medicare payment models do not operate the same way. Given this restriction in Medicare fee-for-service, it appears our options to strengthen care coordination services are somewhat limited to, for example, changing the provider payment structure. Because ACOs are not allowed to navigate their patients to specific providers, how effective do you believe ACOs will ultimately be at coordinating care and lowering costs?

Answer. Accountable Care Organizations are a tool in the toolbox to help ensure high quality, low-cost health care for beneficiaries. Of course, they are not a silver bullet to all of our country's delivery system challenges. If confirmed, I plan to work with CMS Administrator Verma to ensure, as we move forward, that we learn from the results of ACOs and chart a path forward based on an understanding of what is and what is not working. I look forward to working with you, if confirmed, to think about ways the ACO program can be made even more robust as a vehicle for transformation of our health-care system.

CARE COORDINATION FOR THE CHRONICALLY ILL

Question. As the population ages, an increasing number of Medicare beneficiaries have multiple chronic conditions. In your view, is Medicare well designed to appropriately and efficiently provide care to these beneficiaries? If not, what more must be done?

Answer. The Medicare program is more than 50 years old, and the needs of the beneficiaries it serves have evolved since its creation. As you note, beneficiaries are living longer, and more have multiple chronic conditions, like diabetes and heart disease. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. If confirmed, I will work closely with CMS and other Department components to ensure that we are creating programs that work well for Medicare beneficiaries and deliver higher quality care at a lower cost.

CMS PREVIOUS GOAL TO TIE 50 PERCENT OF FFS MEDICARE PAYMENTS TO APMS BY 2018

Question. In 2015, Secretary Burwell announced the Obama administration's goal of tying at least 50 percent of traditional, fee-for-service Medicare payments to the use of alternative payment models by 2018. While recent ACO demonstrations have shown some promise, these payment initiatives are still relatively new. Many providers are not yet ready or willing to take on two-sided risk and write checks to the government when they exceed their spending targets. Perhaps Secretary Burwell's intention was to have as many ACOs as possible, with as many Medicare beneficiaries placed in them as possible, to meet this goal—even if all the ACOs are not producing evidence that they have and will continue to improve quality and significantly reduce Medicare spending over the long-term. If confirmed, how would you quantify success in this area? Will you act to streamline alternative payment models that fail and promote the ones that are most successful?

Answer. If confirmed, I look forward to reviewing the actions taken by health-care providers and CMS to achieve this goal in order to determine what has worked and what we can improve upon going forward. ACOs are an important tool, but every approach needs to be evaluated and refined as we learn more about what delivers higher quality care and lower costs. I believe firmly in value-based purchasing models and their potential to incentivize higher quality care and lower costs, and if confirmed, I will work closely with CMS and other Department components to ensure that we are creating programs that work well for Medicare beneficiaries and deliver higher quality care at a lower cost.

MEDICARE DELIVERY SYSTEM CHANGE AND "BENDING THE COST CURVE"

Question. Many observers believe that the health care delivery system must change if we are to bend the spending curve over time. What is Medicare's role in helping to bring about such changes to the entire health-care system? As Secretary, how would you use Medicare demonstrations to explore health care delivery system alternatives and promote the ones that prove successful?

Answer. As I said during my opening statement to the committee, we must make health care more affordable, more available, and more tailored to what individuals want and need in their care. I also made clear that using Medicare as a vehicle for helping to transform our health-care system to a more value-based system would be one of my four key priorities as Secretary. If confirmed, I look forward to working with CMS to explore payment models that reduce costs and increase quality for Medicare beneficiaries.

CMS recently issued a Request for Information seeking feedback on a new direction for its Center for Medicare and Medicaid Innovation (CMMI) to promote patient-centered 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. This new direction includes a focus on voluntary models with defined and reasonable control groups or comparison populations, to the extent possible, and models that reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality health care to their patients. If confirmed, I look forward to reviewing the comments received and working on the new direction for CMMI.

IMPACT ACT IMPLEMENTATION

Question. In 2014, I worked closely with Senator Wyden—and leaders from the House Ways and Means Committee—to enact a bipartisan, bicameral law called the Improving Medicare Post-Acute Care Transformation or "IMPACT" Act. The IMPACT Act serves as a critical building block to achieve future Medicare post-acute quality measurement and payment reform. Specifically, the IMPACT Act requires the collection of standardized data to help Medicare not only compare quality across the different post-acute care settings, but also improve hospital and post-acute discharge planning.

Our goal was to produce data-driven evidence that Congress can use to debate the best ways to align Medicare post-acute payments that improve patient outcomes and save taxpayer dollars. Our intention is to ensure that beneficiaries are receiving the highest quality post-acute care services in the right setting at the right time. Will you commit to working with me, members of Congress, and the post-acute provider community on the implementation of the IMPACT Act?

Answer. Yes. If confirmed, I plan to fully implement all laws passed by Congress, including the Improving Medicare Post-Acute Care Transformation Act. I look forward to learning more about this legislation and working with you, your colleagues and CMS to see that it is implemented correctly.

OPIOIDS

Question. Mr. Azar, we hope a major focus of yours will be on efforts to combat the opioid epidemic which is ravishing communities throughout Utah and the Nation. From my perspective, it is obvious that we must work in a united, coordinated approach to address prevention, appropriate treatment, research, and reimbursement.

For treatment, we have learned that there are a myriad of large challenges, including Medicare and Medicaid reimbursement, geographical disparities in trained providers, and the lurking shadow of stigma. But I want to highlight an example of a more subtle barrier.

As you may be aware, I was one of the lead sponsors of the DATA 2000 law, along with then Senators Biden and Levin. That law allowed doctors to prescribe a new medication—buprenorphine—in their offices, instead of patients having to travel to a methadone clinic. Experts agree that DATA 2000 really changed the treatment paradigm, making more therapy options available to patients.

Fast forward to 2018. It is an exciting time in medicine; a number of new addiction treatment therapies and opioid alternatives are in development, many with collaboration from the NIH. But for these therapies to help patients—they must reach patients. The Controlled Substances Act is silent on whether such provider-

administered therapies may be delivered to the doctor through a specialty pharmacy—rather than under the "buy and bill" system which requires the practitioner to purchase the product first.

As you are well aware, there are other issues which can challenge effective treatments, including Medicare and Medicaid coverage. But, the reason I bring this one issue up is that it is a timely example of ways we should work to forge a better prevention and treatment system. So, my question is simple: may we count on you to be sensitive to removing barriers and forging both an intra-departmental and inter-departmental collaboration which works to the betterment of patients and communities?

Answer. Yes. If confirmed, I am committed to working both internally at HHS and with other Federal agencies to ensure that we are bringing everything we have to bear to fight this epidemic. The opioid crisis will remain one of the top priorities at the Department, and I look forward to looking at governmental barriers that can be removed to ensure we are best addressing the opioid crisis.

WHA

Question. Infectious diseases do not recognize national borders, thus protecting global health requires inclusions of all relevant partners. The World Health Assembly (WHA), the decision-making body of the World Health Organization (WHO), serves as an opportunity to address health issues around the world requiring international coordination to effectively combat. Congress has passed legislation supporting Taiwan's participation in WHA in the capacity of an observer. With the support of the United States and other like-minded countries, Taiwan was invited to attend WHA since 2009. However, Taiwan was excluded from WHA in 2017 for the first time in recent years. As the head of U.S. delegation to WHA, how do you renew the efforts to affirm observer status for Taiwan at future WHAs?

Answer. I fully agree with you that global health security requires all countries to help prevent, detect, control, and fight such outbreaks of infectious diseases. I agree with you that Taiwan is a valuable ally in the global health arena and deserves to be treated as such. If confirmed, I commit to working with the World Health Organization (WHO) leadership to affirm Taiwan's observer status at future World Health Assemblies.

BARDA

Question. In early 2014, the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) approached the U.S. manufacturer of INSCOP (Intra-nasal scopolamine)—a repurposed version of a proven military product—for civil population protection against a Sarin attack. This U.S. manufacturer holds the proprietary intra-nasal formulation of INSCOP. Following a series of meetings and conversations with BARDA, a proof of concept study was undertaken with a Missouri-based independent not-for-profit research organization. Data from the evaluation—conducted from June 2016 to October 2016—showed INSCOP significantly increasing survival in sarin-exposed animals. Following completion of all evaluations suggested by BARDA, a one-on-one meeting with BARDA was held to provide the proof of concept data. BARDA specifically stated its interest in INSCOP as a chemical defense product and emphasized the potential use of varying doses of INSCOP in civilian use (pediatric to geriatric). Concurrently, the U.S. manufacturer of INSCOP was made aware of a proposal request (RTORCHEM–1003; issued April 13, 2017) from BARDA for evaluating the efficacy of intranasal scopolamine to increase survival of guinea pigs exposed to sarin. The U.S. manufacturer was surprised to learn that BARDA had issued such a RTOR without consulting with the only company possessing the advanced intra-nasal product. On September 8, 2017, BARDA awarded a $420,989 contact to a foreign company from The Netherlands (Nederlandse Organisatie Voor Toegepast-Natuurwetenschappelijk Onderzoek or TNO) to evaluate the effectiveness of intranasal scopolamine against sarin in a guinea pig model. The amount of the award to this foreign entity is significantly higher than that proposed by the U.S. team, which continues to own the proprietary formulation of INSCOP. BARDA's charter is to encourage and leverage industry developments in the service of public health, rather than to glean concepts and applications from industry and to then develop its own products. How did BARDA select a foreign entity, and why were U.S. manufacturers and research organizations, which significantly underbid the foreign entity for this effort, not selected for this award?

Answer. Not having been at HHS, I am not aware of why BARDA selected a foreign entity in this instance. If confirmed, I would be happy to look into the matter and speak with you about this in the future.

REPORT TO CONGRESS

Question. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 directed HHS to report to Congress regarding obstacles to legitimate patient access to controlled substances and issues with diversion of controlled substances, among other things. That report was due more than a year and a half ago. Will you commit to making completion of the report a priority for the Department? And, if confirmed, will you please notify me which agency within HHS is taking the lead on the report?

Answer. If confirmed, I look forward to getting briefed on the status of the report and will commit to providing you an update on its status.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

GLUCOSE MONITOR COVERAGE

Question. A constituent recently reached out to me about coverage determinations in regard to glucose monitors.

It was with great excitement that I read about the FDA approval of a CGM device to be used to make diabetes treatment decisions without confirmation by a traditional fingerstick in December of 2016.

My constituent raised concerns that his CGM device is not covered. He states that the device was covered by commercial insurance prior to his enrolling in Medicare.

My question is, what steps are being taken at FDA (for approval for use) and CMS (approval for payment) for other technologies in this space?

Answer. FDA continues to work with product developers to advance and approve devices that improve the lives of those living with chronic diseases, including further "first-in-class" products. The agency offers multiple expedited pathways to approval for devices which are truly cutting edge, and we look forward to seeing other products receive approval in the coming days and months and years that contribute to an improved standard of living.

Medicare was first established more than 50 years ago, at a time when promising advanced technologies that help so many, like continuous glucose monitors, did not exist. Medicare has evolved since its creation, and if confirmed, I would be happy to work with Congress to make sure the program appropriately covers and pays for technologies that do not fit clearly into one of the existing parts of the program so that Medicare beneficiaries can benefit from the latest in prevention, cures, and treatments. In general, the Medicare statute covers items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. This includes numerous items and services critical to beneficiaries with diabetes. However, the items and services are required by Medicare statute to be within the scope of a Medicare benefit category.

My understanding is that CMS determined that a path to coverage under the Medicare program is available for additional products used for the delivery of insulin for the treatment of diabetes. On January 5, 2018, CMS announced that, consistent with the Part D policy to allow coverage of certain insulin delivery devices, Part D sponsors may provide coverage of products such as Omnipod under Part D as "medical supplies associated with the injection of insulin."

If confirmed as Secretary, I will work with the CMS team to ensure that Medicare beneficiaries, particularly those with diabetes, have access to items and services reasonable and necessary for diagnosis and treatment as required by the Medicare statute.

ORTHOTICS AND PROSTHETICS

Question. Medicare currently administratively includes them as part of DME even though orthotics and prosthetics have very different purposes and qualities than DME.

Over the past 3 years CMS has released proposed rules concerning orthotics and prosthetics. The first, on off-the-shelf/minimal self-adjustment orthotics, and then on

qualified providers for orthotics and prosthetics, which both received thousands of comments. Unfortunately, rather than promulgating final rules, CMS instead withdrew the proposed rules in their entirety. There are legislative proposals in both the Senate and House (S. 1191/H.R. 2599) that underscore and reinforce the important issues these withdrawn proposed rules cover.

Does HHS have an agenda for the orthotics and prosthetics sector to ensure fraud and abuse is addressed in a common sense manner, to protect the safety of patients and quality of care and that recognizes both the uniqueness of this sector and the needs of the amputees, disabled, and mobility impaired patients served by this sector?

Will you work to finalize the proposed rules regarding orthotics and prosthetics?

Answer. If confirmed, I look forward to learning more about this issue, and working with our CMS teams as well as other stakeholders to understand the potential benefits and costs. As you mention, there are various concerns at stake here: Medicare program integrity, ensuring that we do not jeopardize the needs of those who rely on orthotics and prosthetics, and reducing burden on suppliers and providers of those devices. I take these concerns very seriously, and, if confirmed, I will work with CMS to ensure the Department carefully evaluates this proposal.

LYMPHEDEMA

Question. With cancer survivorship on the rise, more and more Medicare beneficiaries are suffering from a secondary diagnosis called lymphedema. Senator Cantwell and I have introduced legislation to provide coverage for compression garments and help beneficiaries manage this chronic condition. Our Senate bill has 51 cosponsors; the House companion bill has 304 cosponsors (S. 497/H.R. 930).

We would like to work with you on this initiative, which we believe CMS has existing authority. In October, Senator Cantwell and I wrote to Acting Secretary Hargan, bringing this issue to his attention. If nominated as HHS Secretary would you work with us to help close this coverage gap?

Answer. Medicare was first established more than 50 years ago, with a siloed approach to determining what would and would not be covered. It is important to make sure that we are not being short sighted and failing to cover a treatment or item that will improve health and save money simply because it does not fit into a category in Medicare. If confirmed, I would be happy to work with you and with CMS to explore whether separate coverage of and payment for compression garments is possible under the Medicare Part B benefit categories established in the statute.

NATIONAL CLINICAL CARE COMMISSION (DIABETES)

Question. As you may know, the University of Iowa is home to the Pappajohn Biomedical Institute, which houses the Fraternal Order of Eagles Diabetes Research Center. The University is also home to the Stephen A. Wynn Institute for Vision Research. Among other things, these premier institutions are conducting cutting edge research on the neural complications of diabetes in the eye and brain. I could not be more proud of the innovative work taking place in Iowa to help combat diabetes, a disease affecting more than 30 million Americans.

Given the increasing prevalence of diabetes and its staggering cost to the American people, in terms of both dollars and quality of life, it is necessary to coordinate and leverage Federal programs in order to improve treatment options for patients. The National Clinical Care Commission Act passed the Senate by Unanimous Consent. In November 2017, President Trump signed it into law. The commission created by this legislation will do the important work to find solutions for diabetes.

As Secretary, you would be responsible for appointing non-government experts to serve on the commission alongside leaders from a variety of Federal health agencies. In working on this critical piece of legislation, Congress felt it important to include on the commission physician specialists that play a role in the treatment and prevention of diabetes and its complications, such as severe vision loss, blindness, and other neural complications. I hope in constituting the commission, you and your staff will call upon the many talented individuals performing lifesaving and cutting edge work in this area, in Iowa and across the country.

Will you work with me and my colleagues to prioritize the establishment and success of this new commission and to ensure it includes a diverse group of members with clinical and research expertise in a variety of medical specialties?

Can you provide a status update on the agency's timeline for constituting the commission, including when you will call for applications for appointment to the commission?

Answer. Diabetes prevention and treatment is critically important. If confirmed, I look forward to working with you and your colleagues on this issue. I commit to ensuring that the commission is set up and consists of members that will bring diverse expertise to this work. I would be happy to provide a status update on constituting the committee, if confirmed.

QUESTION SUBMITTED BY HON. MIKE CRAPO

Question. In 2016, the American Medical Association (AMA) passed a resolution recommending that pharmaceutical lawsuit advertisements come with a warning that patients should consult with a physician before discontinuing their medications. One AMA Board member noted, "[t]he onslaught of attorney ads has the potential to frighten patients and place fear between them and their doctor. By emphasizing side effects while ignoring the benefits or the fact that the medication is FDA approved, these ads jeopardize patient care. For many patients, stopping a prescribed medication is far more dangerous, and we need to be looking out for them." It has also been noted that "between $100 and $300 billion of avoidable health care costs have been attributed to nonadherence in the U.S. annually, representing 3 to 10 percent of total U.S. health care costs."

In light of the AMA resolution indicating that lawsuit advertisements targeting pharmaceuticals are triggering patient nonadherence to medications and the corresponding evidence that nonadherence imposes significant costs on the U.S. healthcare system, will you work with the agencies within Health and Human Services, including the Food and Drug administration and the Centers for Medicare and Medicaid Services, to ensure patient medication adherence is not inappropriately impacted by certain advertisements?

Answer. I agree that patient adherence to prescribed medications is critically important, and we must do all we can to ensure that individuals are encouraged to follow the directions of their physicians. If confirmed, I commit to working with the relevant HHS agencies on this issue.

QUESTIONS SUBMITTED BY HON. PAT ROBERTS

Question. CMS recently issued guidelines to expedite the approval process for 1115 Waivers and State Plan Amendments. What steps do you think CMS can take to reduce the unnecessary administrative burden on States that does not provide a benefit to patients? If confirmed, how would you work with CMS to ensure waivers provide maximum flexibility to States who are working to both control costs and provide the highest level of care to patients, but also ensure guardrails to preserve appropriate services, so no matter where an individual resides they are assured access to essential services under Medicaid?

Answer. State-driven innovation must be a top priority for the Department. States, as administrators of the Medicaid program, are in the best position to assess the unique needs of their respective Medicaid-eligible populations and to drive reforms that result in better health outcomes. If confirmed, I will work closely with CMS to ensure the continued support and the timely review of all State waivers received by HHS, and to make the waiver approval process more transparent, efficient, and less burdensome.

Question. The current and previous administrations have provided flexibility to providers as they have started data collection and worked toward implementing the Medicare payment reforms under MACRA (Pub. L. 114–10). However, small, private practice and rural providers are still concerned about how they will fit into the new system and MedPAC has shared some concerns and suggestions as well. If confirmed, will you commit to working with our medical community on solutions to drive value in Medicare?

Answer. Yes. If confirmed, one of my top four priorities will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. In pursuing that goal, we must pay careful attention to how MACRA and other payment policies will impact providers of all types, in par-

ticular those in small, private, and rural settings. I look forward to working with you to emphasize value in Medicare with this in mind.

Question. Last year, CMS requested public comment on a new direction for the Center for Medicare and Medicaid Innovation (CMMI). I see this as an opportunity to hopefully put in place some appropriate guardrails and limitations on the center to ensure beneficiaries are being protected. If confirmed, how would you direct CMS to utilize CMMI?

Answer. As I mentioned above, one of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. CMMI will be a critical part of these efforts. Of course, we must exercise the power of CMMI and other authorities in ways that are open and transparent, and that seek out collaboration and input as much as possible. As you note, CMS recently issued a Request for Information seeking feedback on a new direction for CMMI to promote patient-centered 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. If confirmed, I look forward to working with CMS to review the input that stakeholders submitted in response to the RFI, and the opportunity to chart a new direction for CMMI that puts patients first.

Question. Would striking the non-interference clause under Medicare Part D save the government, or patients, money? What impact could it have on access to new innovative therapies?

Answer. My understanding is that the Congressional Budget Office and others have concluded that removing the non-interference clause would not generate lower prices than those obtained by prescription drug plans, and that it would have a negligible effect on Medicare drug spending. Access to new and innovative therapies could be impaired if we removed the market-oriented incentives that have made the Part D program a success for beneficiaries. As I stated at my Senate HELP hearing a few weeks ago, Part D plans are actually negotiating today with the three or four biggest pharmacy benefit managers that in turn negotiate prices with drug manufacturers and actually secure the best net pricing of any players in the commercial system. If confirmed, I would like to think about how we can take the lessons from Part D to improve the rest of Medicare.

Question. CMS recently proposed and then backed away from significant policy and payment changes to the Medicare home health benefit. In addition, we have seen regulatory burdens on this sector increase with face-to-face documentation requirements and the pre-claim review demonstration. If confirmed, will you work with Congress to ensure appropriate payments are in place to maintain access and incentivize quality care for seniors, as well as find ways to reduce regulatory burdens on providers?

Answer. Yes. One of the goals of this administration that I welcome and support is ensuring that regulatory burdens that make it costly or difficult for Americans to access the providers of their choice are reduced or eliminated. If I am confirmed, I look forward to working with Congress to promote access to quality health care and remove undue burdens on health-care providers.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

Question. The Independent Payment Advisory Board (IPAB), created in the Affordable Care Act, empowers a small, unelected group to decide on Medicare spending cuts.

While I have serious concerns about Medicare's current spending path, I believe that IPAB is the wrong approach to address these concerns, could override the will of Congress, and could instead jeopardize access to care for the over 50 million Americans that rely on Medicare. This is why I have led legislation in the Senate which would repeal IPAB.

The health reform law also specifically prohibits the IPAB from making recommendations that would "ration health care" or "otherwise restrict benefits." Would you agree that provider payment rates can be cut so low that this ultimately

leads to rationing of care? As Secretary, what options would be available to you to prevent this Board from harming Medicare beneficiaries?

Answer. I share the concerns that you, many of your colleagues, and doctors and providers have expressed regarding the Independent Payment Advisory Board (IPAB). Congress should play an important role in any changes that alter Medicare, and the IPAB would rely on an unelected group to make decisions about a program that serves millions of beneficiaries. I agree that providers must be fairly and adequately reimbursed for the care they are providing, and significant cuts could make it difficult for Medicare beneficiaries to access care.

I think one of the best ways to drive down costs without harming beneficiary access to care is to improve how we operate Medicare using a more value-driven approach. By running the program more efficiently and effectively, I believe we can stretch out the resources to make Medicare more sustainable and allow it to better serve more beneficiaries as the baby boomer generation ages into the program. We need to make sure Medicare has long-term sustainability, and if confirmed, I will work with CMS, Congress, and other stakeholders to make sure we come up with the right approaches to work towards this goal.

DISASTER/PANDEMIC PREPAREDNESS

Question. In the last decade, the CDC has been called upon to address emerging public health threats such as Ebola, Zika and West Nile Virus. Many times, Texas has been the frontlines of combating these diseases, as we've seen in the aftermath of Hurricane Harvey; and I've seen firsthand the role of local communities, but we also need a whole government response.

Mr. Azar, under your leadership as Secretary of HHS, could you give us your thoughts on the role the CDC will play in defending Americans from disease both at home and abroad? What do you think should be done moving forward with regard to the U.S. response to these public health threats?

Answer. If confirmed, I commit to working with the CDC and others within HHS to ensure that our Nation is prepared to address all potential public health threats. The CDC is well equipped to work in concert with State and local governments to provide surveillance and early detection of possible diseases. Through CDC assets deployed across the globe, we will ensure that the same level of surveillance and early detection are utilized to help prevent the spread of foreign diseases. Moving forward, I believe we need to ensure that our surveillance systems, and those of our international partners, are optimized in order to provide timely information that allows us to identify these public health threats as early as possible, so that we can proactively address them.

GENERIC DRUGS

Question. For the past 3 decades, the Hatch-Waxman Act created a successful marketplace for generic drugs. Today, however, the generics industry is facing a number of market and public policy challenges that could undermine competition and decrease access to affordable medicines for patients.

Recently, both the FDA and the FTC have convened day-long public meetings/workshops to examine marketplace dynamics that are impacting generic drug sustainability. If confirmed as Secretary, what steps would HHS take to ensure that the generic marketplace remains vibrant and competitive?

Answer. FDA Commissioner Gottlieb is already working on ways to increase generic competition, by encouraging the development of generic drugs and speeding approval of such drugs. FDA has unveiled a drug competition action plan, which will increase competition and help keep drug prices down. If confirmed, I will work with FDA to help bolster this effort, and I look forward to working with him to ensure that increased competition for drugs leads to lower list prices and other approaches to reducing cost-sharing for patients.

PHYSICIAN-OWNED HOSPITALS

Question. According to CMS's own quality ratings programs enacted as part of the ACA, physician-owned hospitals are consistently outperforming non-physician owned hospitals (POH) in terms of quality and patient satisfaction. Yet the ACA directly penalizes them by making it virtually impossible to expand their treatment capabilities if they want to continue to participate in the Medicare program.

Will you support efforts in Congress to repeal the prohibition on physician-owned hospitals and amend the expansion criteria in such a way that it would allow reasonable growth for physician-owned hospitals that have demonstrated higher quality?

Answer. The Affordable Care Act imposed additional restrictions on physician ownership and investment in Medicare-participating hospitals, banning new physician-owned hospitals (POHs) and limiting the expansion of existing POHs. CMS does, however, have the authority to grant exceptions to the expansion prohibition for certain applicable hospitals and high Medicaid facilities. My understanding is that CMS included a Request for Information on this topic in the 2018 IPPS/LTCH PPS Proposed Rule in April 2017. This RFI requested information regarding physician-owned hospitals, and sought public comment on the appropriate role of physician-owned hospitals in the delivery system and on how the current scope of and restrictions on physician-owned hospitals affects health-care delivery, particularly regarding Medicare beneficiaries. If confirmed, I look forward to working with CMS to use this feedback to ensure beneficiary access to high-quality care, and to working with you on this issue.

HOME HEALTH MORATORIUM

Question. Texas currently has a statewide moratorium on any new home health agencies. While moratoriums can be a useful tool for fraud and abuse, this type of far reaching approach could keep bad actors in the system and stop competition which provides higher quality and more access. Can you commit to working with Congress to find a more targeted way of applying CMS moratoria authority?

Answer. Fighting waste, fraud, and abuse is a top priority across CMS programs and an important part of efforts to increase the sustainability of the Medicare program. However, we must also examine efforts made in this area, like the moratorium authority, to make sure they do not have unintentional consequences such as stifling innovation, overburdening legitimate providers, or limiting beneficiary access to high-quality care. As I mentioned during the hearing, if confirmed, I look forward to hearing ideas from Congress and other stakeholders to guide our work and make sure our programs are meeting their goals and appropriately balancing concerns related to program integrity and patient access.

EPIPEN—PATENT GAMING

Question. During the hearing, you mentioned one of the steps you would take to lower drug prices would be to take steps to prevent drug companies from taking advantage of extensions of exclusivity, as well as fostering competition through the generic market. The EpiPen stands as an example of a product that has seen massive increases in price, even with an introduced generic version. What steps would you take to address the prices of a product like the EpiPen?

Answer. I have made clear my concerns with those companies that game or "evergreen" patents and exclusivities by branded companies under Hatch-Waxman and other provisions of the Food, Drug, and Cosmetics Act. If confirmed, I will 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. As we discussed in the hearing, 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. In addition, the Food and Drug Administration Reauthorization Act of 2017 (FDARA), which was signed in to law earlier this 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.

CTSA GRANTS

Question. The National Institutes of Health (NIH), specifically, the National Center for Advancing Translational Sciences (NCATS)/Clinical and Translational Science Awards (CTSA) programs have been a major component of the Nation's ef-

forts to support impactful clinical research. As NCATS maintains the existing support structure, including maintaining the number of CTSA hub awards, will you support awards to remain at no less than 64, in addition to continue funding CTSA hub awards for 5 years?

Answer. I understand that under NCATS's leadership, the CTSA Program, which represents a national network of medical institutions, works to improve the translational research process to get more treatments to more patients more quickly. I recognize that Congress has significant interests in this Program and its success. If confirmed, I look forward to working with the NIH Director Dr. Francis Collins and NCATS Director Dr. Christopher Austin to ensure that the CTSA Program continues to catalyze innovation in training, research tools, and processes to meet the needs of the research and patient communities.

CMS GUIDANCE ON MEDICARE CONDITIONS OF PARTICIPATION FOR INPATIENT HOSPITALS

Question. On September 6th, CMS issued a memo that changed the Medicare Conditions of Participation for inpatient hospitals. The new criteria are not unreasonable, but they are effective immediately and were issued without any input from patients or hospitals. The new rules risk closing 35 high-quality hospitals in my State that serve a critical need by providing care to more than 500,000 patients annually and employing more than 4,000 Texans. Will you work with me to ensure that the concerns of my Texas hospitals are addressed and provide these hospitals with at least 12 months to comply with these surprise changes so that access to care is maintained in my State?

Answer. It is my understanding that CMS is taking steps to evaluate and streamline regulations and guidance with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience through their Patients over Paperwork initiative. If confirmed, I will work with CMS to make sure their programs achieve a balance between protecting patient safety and avoiding undue burden on providers as they seek to comply with the Conditions of Participation, and with you to ensure the concerns of Texas are addressed. If confirmed, I will certainly review this issue and its impact on Texas carefully and promptly to make sure your constituents' concerns are appropriately considered.

CAR–T THERAPY

Question. Several companies have recently received approval for a very promising new type of immunotherapy, known as CAR–T cell therapy, which relies on modifications to a patient's own immune cells to fight cancer. This is truly a breakthrough in cancer care, and holds the promise of saving the lives of patients who would not otherwise survive their cancer. But these CAR–T therapies are very complex, require careful monitoring of the patient after administration, and raise reimbursement challenges for the handful of centers that are qualified to administer them. Will you commit as Secretary to working with CMS to make sure that these uncertainties are addressed in short order, so that we can be sure that eligible patients are able to access these truly life-saving new therapies?

Answer. Medicare and Medicaid were first established more than 50 years ago, at a time when promising advanced technologies that help so many, like CAR–T cell therapy, did not exist. Innovations like this reinforce my belief that current health care payment systems need to be modernized in order to ensure access to new high-cost therapies, including therapies that have the potential to cure the sickest patients. Improving payment arrangements is a critical step towards fulfilling President Trump's promise to lower the cost of drugs and therapies. If confirmed as Secretary, I will work with the CMS team to ensure that Medicare and Medicaid beneficiaries, particularly those with cancer, have access to technologies that are reasonable and necessary for diagnosis and treatment as required by statute.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. Since the inception of electronic health records, feedback from the hospital and physician community resoundingly indicate that the burdens of compliance associated with electronic health records negatively impacts hospitals and doctors. Many of my colleagues on the committee and I have worked on solutions to mitigate some of the persistent problems in this space through legislation that would eliminate the requirement for the Secretary of HHS to make meaningful use more stringent over time and remove the all or nothing approach to the program that fails

a provider for missing one measure, among other things. Is this something you would support as Secretary? What is your vision for ensuring that electronic health records and other health IT tools are assets rather than burdens for doctors and patients alike?

Answer. As I said in my opening statement, we can better channel the power of health information technology and leverage what's best in our programs and in the private competitive marketplace, to ensure that the individual patient is at the center of decision-making and his or her needs are being met with greater transparency and accountability. I am committed to partnering with health-care providers and stakeholders to harness the potential of health IT, while reducing burden on providers and ensuring high-quality care for their patients. If confirmed, I look forward to working with Congress and stakeholders to determine what is working and what is not working, as well as what is duplicative, and what we may be missing to help us move in the right direction and more fully realize the promise of EHRs without placing unnecessary requirements on clinicians.

Question. Following last year's budget hearing with then-Secretary Price, I asked him about how the Department of Veterans Affairs' change in its electronic health record system would impact the Indian Health Service, which utilizes the same system. I was assured that IHS had formed a working group to examine its current platform and that the two departments would continue their collaborative relationship. If confirmed, will you commit to continuing that relationship and ensuring that IHS' EHR system does not fall behind in this transition?

Answer. If confirmed, I look forward to working with the Indian Health Service to ensure the IHS EHR system meets the needs of hospitals and health centers serving American Indians and Alaska Natives.

Question. HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) has been developing guidelines to recognize hair testing as a federally accepted testing method since the early 2000s. Transportation industry stakeholders have expressed support for these guidelines, stating they would provide employers with a longer detection window than the standard urinalysis, as well as being easier to collect and harder to adulterate. Regrettably, SAMHSA has delayed the development of these guidelines. In 2015, Congress endorsed the accelerated development of the guidelines in section 5402 of the FAST Act (Pub. L. 114–94), which required the Secretary of HHS to issue guidelines for hair testing within 1 year of enactment.

As Chairman of the Senate Committee on Commerce, Science, and Transportation, who oversaw this provision in the FAST Act, I am particularly interested in getting these guidelines in place. If confirmed, will you commit to expeditiously completing the required technical guidelines that could pave the way for more employers to use this testing method and potentially identify a greater number of safety-sensitive employees who violate Federal drug testing regulations?

Answer. If confirmed, I look forward to learning about the work currently underway at HHS to develop these guidelines and commit to working with you on this issue.

QUESTION SUBMITTED BY HON. JOHN THUNE AND HON. ROB PORTMAN

Question. The hospital community and health systems in South Dakota and Ohio have expressed significant concerns regarding CMS's recent changes to Medicare reimbursement for separately payable drugs in the 340B program. The feedback we've received is that the reduced reimbursement will impact hospitals' ability to continue serving the most vulnerable. Will you commit to working with Congress on ensuring the sustainability of the 340B program in the long-term?

Answer. I understand that CMS recently finalized a change for 2018 to the Medicare payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. The reduced payments on 340B purchased drugs would better align with hospital acquisition costs and directly lower drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments by an estimated $3.2 billion over ten years. Certain hospitals are exempted from this Medicare payment reduction for 340B drugs such as rural sole community hospitals, prospective payment system-exempt cancer hospitals and children's hospitals. Additionally, all critical access hospitals are not affected by this policy because they are

not paid under the outpatient prospective payment system. If confirmed, I will faithfully implement any laws related to the 340B program as passed by Congress and I look forward to working with Congress and stakeholders to ensure that the 340B program is putting patients first.

QUESTION SUBMITTED BY HON. ROB PORTMAN

Question. According to the CDC, the number of new HIV infections in the United States has remained flat around 50,000 cases per year for the past few decades. What existing authorities do you believe that the Department of Health and Human Services has to further advance efforts against these stagnant rates? What further actions do you believe are necessary to make progress in the fight against HIV?

Answer. If confirmed, I am committed to ensuring HHS remains a world leader in HIV/AIDS prevention and treatment strategies and research. I look forward to reviewing both the National HIV/AIDS Strategy, as well as the National Viral Hepatitis Action Plan, and working with stakeholders to reduce new infections and improve access to care and treatment outcomes. I look forward to reviewing the Department's current work in this area and determining what additional steps should be taken to address HIV incidence.

QUESTION SUBMITTED BY HON. PATRICK J. TOOMEY

Question. One of the great health-care challenges our Nation faces is the growing prevalence of Alzheimer's disease. Over 5 million Americans are estimated to be already living with the disease, and if current trends continue unabated, that number could triple by 2050. Significantly, Alzheimer's disease is the most deadly disease in our Nation without an effective means of treatment.

In the private sector, you were part of a team that invested heavily in trying to meet this unmet need, giving you a rare and valuable perspective of the current challenges in developing an effective therapy. As Secretary of Health and Human Services you will have an opportunity to address this problem in a way afforded to few others. What will you do to improve our Nation's response to Alzheimer's disease?

Answer. I share your interest in pursuing effective therapies for Alzheimer's disease. It affects too many Americans, and its impact will only continue to grow unless we make advances in treatment and prevention. We need to review our current research and identify where gaps exist. We also need to leverage partnerships with the private sector to bring our collective resources to this great challenge. If confirmed, I commit to working on this issue and ensuring that the agency is working collaboratively to address this disease.

QUESTIONS SUBMITTED BY HON. DEAN HELLER

ADDRESSING NEVADA'S OPIOID EPIDEMIC

Question. Like many States, the opioid epidemic has hit Nevada hard. According to the Centers for Disease Control and Prevention (CDC), there were 665 deaths in Nevada due to drug overdose in 2016.

That is why it is critical that Congress has taken steps to help States address this crisis, and State officials have made combatting this issue a priority. In fact, last October, Nevada's Attorney General appointed our first statewide opioid coordinator to assist law enforcement and victim services coordinate responses to this crisis.

If confirmed as HHS Secretary, how will you assist States like Nevada confront the opioid crisis?

Answer. The opioid crisis is impacting every State differently, and we need to support each State in its unique fight against this epidemic. I know that HHS has distributed more than $800 million in funding to States through the State Targeted Response to the Opioid Crisis grants program. We can support the States by providing technical assistance and help with their surveillance efforts. In addition, the new Policy Lab that was created by the 21st Century Cures Act will be critical in identifying evidence-based programs and practices that can be utilized by the States

for prevention, treatment, and recovery. If confirmed, I commit to working with you to address the specific needs Nevada is facing with the opioid crisis.

CADILLAC TAX

Question. As you know, Obamacare increased taxes on the American people by $1.1 trillion dollars. One of the worst taxes was the 40-percent excise tax on employee health benefits, commonly referred to as the "Cadillac tax."

Across America, nearly 178 million workers who currently enjoy employer sponsored health care will experience massive changes to their care by the year 2020.

Hardly anyone in Nevada will be shielded from the devastating effects of the Cadillac tax. These are public employees in Carson City, service industry workers on the Strip in Vegas, small business owners and retirees across the State.

That is why I have worked tirelessly to repeal this bad tax alongside Senator Heinrich and have worked with my colleagues on a bipartisan basis to successfully delay its implementation until 2020.

Do you believe that this tax will increase already high out-of-pocket health-care costs for working families and hit working families with a new unfair tax?

Can I have your commitment to work with me to provide consumers relief from the devastating impacts of the Cadillac tax?

Answer. I share your concern regarding the many additional taxes created by the Affordable Care Act. Ultimately, changes to the Cadillac Tax or other ACA taxes will need to come from Congress. We need a health-insurance system that is responsive to the needs of individuals and their families, and the current system is not working as well as it could or should. We must address these challenges for those who have insurance coverage and for those who have been pushed out or left out of the insurance market by the Affordable Care Act. I look forward to working with Congress on the best way to achieve the goal of ensuring that all individuals have access to health care.

QUESTIONS SUBMITTED BY HON. RON WYDEN

OPIOID OVER-PRESCRIBING

Question. In your opening testimony, you highlighted the need to address the opioid epidemic, including the need for "aggressive prevention, education, regulatory, and enforcement efforts to stop over-prescribing and overuse of these legal and illegal drugs." In the hearing, Senator Scott asked for your views on development of alternative pain treatments and abuse deterrence. "Abuse-deterrent" formulations are pharmacologically no different from conventional opioid medications and have not been proven to be less addictive.

What specific measures will you advocate to reduce inappropriate prescribing of all forms of opioid medications, be they conventional or abuse-deterrent formulations? For example, would you support funding for Pain Management and Substance Use Disorder education initiatives for primary care providers and subspecialty providers such as oncologists and cardiologists?

Answer. Overprescribing of opioids is still a major problem, and I know that HHS is currently ramping up its efforts to address the problem from both the provider and the patient side. For instance, CDC has developed guidelines for providers, while at the same time has launched a media campaign targeting patients. SAMHSA provides educational tools to help providers identify signs of prescription drug abuse or doctor shopping. In general, I support these education efforts and look forward to learning more about the programs underway at HHS. Payers such as Aetna and retailers such as CVS Health have started to implement safety edits to incentivize best practices, and that's the crux of the matter. When appropriate checks are put in the system, at the provider, payer, and retailer level, we will start to see more and more progress.

OPIOID TREATMENT

Question. In your opening testimony concerning the opioid epidemic, you also stated that ". . . we need compassionate treatment for those suffering from addiction."

What specific measures will you take to ensure that health-care providers in rural and underserved communities have access to timely consultation with pain and pal-

liative care experts for patients in the midst of a national opioid crisis? For example, would you support the expansion of the use of Telemedicine to increase access of patients to pain management and addiction specialists?

Answer. As I mentioned during the hearing, addressing the opioid epidemic will be one of my top four priorities, if confirmed. I share your concern about the specific needs of the rural and underserved communities facing this crisis. In general, I am supportive of telemedicine and believe it can be an effective tool to connect more rural communities to physicians. If confirmed, I look forward to working with you on how we can expand this resource to meet the needs of rural and underserved communities.

NURSING HOME EMERGENCY PREPAREDNESS REGULATION

Question. Hurricanes Irma and Harvey brought to light the challenges of protecting frail seniors under disaster conditions from harm or death. As many as 12 nursing home patients in one Florida nursing home may have died as a result of inadequate care in the aftermath of Irma. In September 2016, the Centers for Medicare and Medicaid Services (CMS) promulgated a rule establishing requirements for emergency preparedness for Medicare and Medicaid participating providers and suppliers, including nursing homes (long-term care facilities). Under the terms of the 2016 regulations, nursing homes were not required to be in full compliance with those regulations until November 15, 2017, after Irma and Harvey occurred.

If confirmed, will you commit to implement these new regulations? What additional measures will you advocate to ensure that there are adequate protections for seniors in CMS-regulated nursing homes in the event of natural disasters?

Answer. Patient safety is always a top priority for the Department, and, if confirmed, I will work closely with CMS and other departmental agencies to ensure we are taking appropriate actions to protect patients. As you noted, CMS updated and improved its existing emergency preparedness requirements for nursing homes and other providers participating in Medicare and Medicaid by issuing an Emergency Preparedness Final Rule.[1] It is my understanding that the new standards became effective on November 15, 2016 and surveys began verifying facility compliance with these regulations in November 2017. If confirmed, I will work with CMS as they monitor the results of these surveys to make sure facilities are meeting CMS requirements to ensure preparedness for emergencies and natural disasters.

DISCLOSURES TO CONGRESS

Question. While you were General Counsel at HHS, your office took the position that legal protections for HHS employees who make disclosures to Congress—protections which are codified in statute and in appropriations bills—were not binding on the Department. In September 2004, GAO concluded that they were in an opinion related to efforts by HHS to prevent disclosures by the CMS actuary. More recently, in September 2016, GAO again upheld the application of appropriations language prohibiting agencies from interfering with employees making disclosures to Congress albeit with regard to a different agency—the Department of Housing and Urban Development. The whistleblower provisions in question have been in appropriations laws every year since 1978 according to GAO.

Will you commit, as Secretary, to ensure that HHS employees who make disclosures to the Congress will not be impeded in doing so, nor retaliated against for making those disclosures?

Answer. Yes. While HHS will determine who speaks for the agency in matters of interest to the Congress, HHS employees who make disclosures to the Congress on their own behalf will not be impeded from doing so, nor retaliated against for making such disclosures.

PATIENT ASSISTANCE PROGRAMS

Question. The U.S. Department of Justice recently concluded two settlements with drug manufacturers which included allegations of anti-kickback violations related to their participation in third-party Patient Assistance Programs (PAPs). PAPs generally seek to ameliorate the effect of high drug prices and co-payments on patients. Co-payments, in turn, have long been considered a tool for reducing overall health care costs and there are significant restrictions on providing co-payment assistance for Federal health programs. (As discussed in the committee's pre-hearing due dili-

[1] *https://www.gpo.gov/fdsys/pkg/FR-2016-09-16/pdf/2016-21404.pdf.*

gence questions, one of these settlements involved a Lilly USA drug—Adcirca—although it was marketed by a company other than Lilly.) More recently, a lawsuit was filed against the Department of Health and Human Services and the Inspector General challenging the Department's ability to regulate communication and coordination between pharmaceutical companies and PAP sponsors which could lead to such abuses.

What role did you play in approving Lilly USA's participation in PAP programs, and what are your views on the role PAPs do and should play in pharmaceutical manufacturers' pricing policies?

Answer. I believe Lilly USA, LLC's contractual arrangements with third-party Patient Assistance Programs in the United States were created, managed, and maintained out of the U.S. Medical Division of Lilly USA, LLC, which is part of the global medical affairs function at Eli Lilly and Company. Funding to support grants made by the U.S. Medical Division to patient assistance programs pursuant to these arrangements would have come through the budgeting processes of each respective business unit, so I would have been involved in making funds available to support grants to patient assistance programs by the U.S. Medical Division with respect to biomedicines business unit products. The question regarding pricing policies is not one that I have studied.

RESPONSIBILITIES AS PRESIDENT OF LILLY USA, LLC

Question. You were president of Lilly USA, LLC from January 2012 to January 2017. As discussed at the hearing, during this period you were chairman of the unit's pricing, reimbursement, and access steering committee. According to the company's 2016 integrated summary, list and net prices of Lilly's U.S. product portfolio increased each and every year during this period.

For some products within the biomedicines division that you headed, product prices more than doubled during this period.

Please describe your roles and responsibilities while in the position of president, Lilly USA, LLC., including any executive committees or responsibilities of Eli Lilly and Company, and your role in pricing Lilly products in the United States.

Answer. In late 2009, Eli Lilly and Company adopted a global business unit structure. As part of this change, three global business units were created with responsibilities for pharmaceutical sales in the United States: the diabetes, oncology, and biomedicines business units. Each of these business units is headed by a global president. These business units own the profit and loss accountability for their medicines, the budget planning and forecasting for their business, the hiring, reorganization, termination, sizing, and organization of the sales forces, brand marketing teams, and payer marketing teams for their brands, and the sales, marketing, payer, and pricing strategies for their brands. The biomedicines business unit does this with respect to all non-diabetes and non-oncology medicines in the United States. In addition, the biomedicines business unit had the responsibility to "host" the two other business units in the United States, Canada, Japan, Australia, and Europe, providing infrastructure and operations support to them. Thus, as president of Lilly USA, LLC, I directly led the biomedicines business unit in the United States with all of the above-mentioned roles with regard to non-diabetes and non-oncology products in the United States (which primarily encompassed the areas of neuroscience, cardiovascular health, men's health, musculoskeletal, pain, autoimmune disease, and Alzheimer's disease). I reported directly to the global president of the biomedicines business unit. There was similarly a vice president of the U.S. diabetes business unit, who reported directly to the global president of the diabetes business unit, and a vice president for North America for the oncology business unit, who reported directly to the global president of the oncology business unit. Both of these individuals were members of the board of managers of Lilly USA, LLC. In addition, in my hosting capacity, I chaired the board of managers of Lilly USA, LLC, the legal entity for the sales and marketing organization in the United States, and supervised the sales, marketing, and payer operations, which provided support to all three business units. Payer operations, led by the Managed Healthcare Services organization, represents Lilly's U.S. business units in negotiating to secure appropriate patient access to Lilly products and resources through population-based decision makers at private and public insurers, pharmacy benefit managers, hospital systems, wholesale distributors, retail pharmacies, specialty pharmacies, oncology practices and purchasing organizations, group purchasing organizations, and senior care facilities and purchasing organizations, as well as the management of those arrangements. Sales and marketing operations included services such as managing

the fleet of cars for sales representatives, managing the production, warehousing, and distribution of marketing and sales materials, sample integrity and accountability systems, supervision of the customer information quality system for approval of marketing materials, and administration of the sales incentive systems per parameters and goals set by the respective business units for their teams. I also served as chair of the Lilly USA, LLC, pricing, reimbursement, and access steering committee, as a member of the Eli Lily and Company Corporate Compliance Committee, and at some point was a member of a corporate manufacturing quality and patient safety committee. I do not recall if I was a member of any other executive committee in this role.

With respect to pricing, as described above, in late 2009, Eli Lilly and Company adopted a global business unit structure. For the first couple of years of my tenure as President of Lilly USA, LLC, in my capacity as chair of the Lilly USA, LLC, pricing, reimbursement, and access steering committee, that role approved pricing recommendations from the diabetes and oncology business units (although launch pricing was approved at the relevant global business unit level), as well as recommendations regarding biomedicines business unit prices. Recommendations from the profit and loss accountable diabetes and oncology business unit leaders were expected to receive and did receive deference since they owned the budget planning and forecasting for their business, the payer marketing teams for their brands, and the payer and pricing strategies for their brands. In 2014, Lilly's governance processes were regularized to recognize the business unit structure, and the vice presidents of the diabetes and oncology business units were formally given the approval authority for pricing of their medicines in the United States.

MARKETING PROGRAMS AT ELI LILLY

Question. Allegations have been made in a qui tam lawsuit that Eli Lilly improperly provided services of financial value to U.S. prescribers of Lilly drugs, such as nurse educator and reimbursement support services, to serve as inducements to prescribe Lilly drugs. These are alleged to have occurred, in part, through Lilly-sponsored nurse educator programs such as the Diabetes Interactive Network and Forteo Connect. Forteo was a Lilly drug marketed by the biomedicines business unit, which you headed. Lilly is alleged to have made arrangements through four companies to provide these services: HealthSTAR Communications of Mahwah, NJ; VMS BioMarketing of Indianapolis, IN; Covance of Princeton, NJ (a subsidiary of Laboratory Corporation of America); and UBC (a subsidiary of Express Scripts of St. Louis, MO.)

In your capacity as a senior executive at Lilly USA, did you ever negotiate, oversee, manage, or approve contracts or business relationships with any of these firms to assist in the marketing of Lilly drugs in the United States? If so, please describe those actions and when they occurred.

Answer. By way of background, each of these referenced programs related to Forteo (injection training, Forteo Connect, and patient reimbursement support) existed to assist patients who had already been prescribed Forteo in having a safe and positive patient experience with Forteo. Any promotional activity by individuals involved in these programs to encourage prescribing of Forteo would have been contrary to Lilly policies. These programs were to educate and train largely elderly patients to use a daily, self-injectable, cold-chain storage specialty medicine, to help them navigate a difficult reimbursement environment with payers, and to assist them in adhering to their medicines once started. These programs would have been vetted and reviewed by counsel periodically to ensure compliance with all relevant laws, regulations, and industry practices.

While these programs operated within the biomedicines business unit, I believe any business contractual relationships with the above-referenced firms would normally have been negotiated and contracted by Lilly's global procurement organization on behalf of those who were responsible for managing these programs within the biomedicines business unit in the United States.

With regard to the specific above-referenced entities, I do not recall knowing of HealthSTAR Communications. I know of VMS BioMarketing, but in the context of providing meeting planning services to Lilly. I do not currently recall VMS being involved in the Forteo injection training program. UBC provided patient support HUB services (services offered to patients, at their request, through the Internet and/or telephone in connection with an already-prescribed specialty medicine) at various times for Forteo, and perhaps other products that I do not now recall. I believe in 2015 the Forteo patient support HUB services were moved from UBC to

Covance. My memory is that at some subsequent point other brand patient support HUB services were consolidated to Covance. Patient support HUB services are administered as non-promotional programs within the Managed Healthcare Services function of Lilly USA, LLC, for all business units. As noted above, I believe any such business relationships are negotiated and contracted by Lilly's global procurement organization on behalf of the Managed Healthcare Services team that manages these programs.

Question. In your capacities as a senior executive at Lilly USA, did you ever oversee, manage, or approve nurse educator programs, such as Forteo Connect, or reimbursement services for providers?

Answer. The Forteo injection training program was offered during my tenure as president of Lilly USA, LLC, and I believe before my tenure. As indicated above, in my role as president, I led the biomedicines business unit, which included Forteo. I believe this program was administered within what was originally called the Musculoskeletal Health Business Unit within the biomedicines business unit and later called the Specialty Business Unit within the biomedicines business unit. I do not recall whether a similar injection training program was offered for any other biomedicines business unit products during my tenure. I would have to refer you to Lilly regarding details of any nurse educator programs in the diabetes or oncology business units.

HUB services for Forteo and any other brands of any business unit are managed within the Managed Healthcare Services organization, which I directly led from April 2009 through December 2011, and which reported to me as president of Lilly USA, LLC, from January 2012 through January 2017.

The patient reimbursement support services non-promotional field-based team was managed for all business units within the Managed Healthcare Services organization, which reported to me as president of Lilly USA, LLC, from January 2012 through January 2017 (this function did not exist when I was the vice president of Managed Healthcare Services). This function was to assist patients prescribed specialty medicines, at their request, in navigating through the benefit investigation process, ensuring their physicians have any needed prior authorization forms, and, depending on the brand, providing support to patients should they need to appeal the denial of coverage by their payer/specialty pharmacy, and generally attempting to assist patients in securing appropriate coverage of a medicine they have already been prescribed. These are all support programs intended for the benefit of patients already prescribed a medicine. These programs operate similarly to the patient support HUB services programs described above, except that these individuals work in-person, rather than over the Internet or telephone. Any promotional activity by individuals involved in these programs to encourage the prescribing of a medicine would have been contrary to Lilly policies. These programs would have been vetted and reviewed by counsel periodically to ensure compliance with all relevant laws, regulations, and industry practices.

WORLD HEALTH ASSEMBLY

Question. With the support of the U.S. Congress and international partners, Taiwan was invited to participate as an observer in the World Health Assembly (WHA)—the World Health Organization's (WHO) decision-making body—between 2009 and 2016. My position has long been that the fight against infectious disease is a global one and will require the participation of global partners, regardless of political considerations. Like many Senators, I was disappointed to see Taiwan excluded from the WHA in 2017, and I believe continued exclusions will only make it more difficult to provide solutions to global health challenges. If confirmed, how would you renew the Department's efforts to secure observer status for Taiwan at future WHA meetings?

Answer. I fully agree with you that global health security requires all countries to help prevent, detect, control, and fight such outbreaks of infectious diseases. I agree with you that Taiwan is a valuable ally in the global health arena and deserves to be treated as such. If confirmed, I commit to working with the World Health Organization (WHO) leadership to affirm Taiwan's observer status at future World Health Assemblies.

HUMAN SERVICES

Question. The President's budget proposed eliminating funding for the Social Services Block Grant (SSBG), a flexible funding stream for social services programs such as substance use disorder treatment services, child protection, elder protection,

services for the elderly like Meals on Wheels, and other critical safety net programs. It also helps fill in financial gaps for overburdened State foster care systems which are facing an increased strain in light of the opioid epidemic.

In light of increased demands on State human services programs brought on by the opioid epidemic, do you support this elimination?

If so, where do you suggest States turn to make up for the loss of these flexible SSBG dollars if funding is eliminated? Please be specific in terms of which programs you believe would fill the void left by SSBG.

Answer. The opioid crisis is one of the top priorities I will be working on if confirmed as Secretary. If confirmed, I plan to ensure that all components of the Department are dedicated to advancing the five-point strategy developed to address this issue. If confirmed, I will work with the Administration for Community Living to advocate for and enhance OAA programs within the budget constraints of the current fiscal environment. Also, I believe the use of innovation and evidence-based practices will be critical to meeting the needs of our growing population of older Americans and of those with disabilities.

Question. The Temporary Assistance for Needy Families (TANF) program has not had a substantive reauthorization since 2005. If confirmed, what would be your policy priorities for a TANF reauthorization?

Answer. If confirmed, I look forward to working with the leaders of the Administration for Children and Families to build upon what they have learned and to ensure the Temporary Assistance for Needy Families (TANF) program is as successful as possible. Responsible reforms should focus on reducing burdens and inefficiencies and should recognize that States, which have been the laboratories for innovation in social welfare programs, are in a better position than the Federal Government to operate programs that best meet the needs of their citizens. I see the Federal Government's role as a catalyst for engaging all sectors of the community to develop and implement a shared vision to grow the capacity and reduce the dependency of economically and socially vulnerable populations.

Question. Do you believe the 1996 welfare law was a success and upon what outcomes—particularly those specifically attributable to the law and not external factors—do you base that determination?

Answer. After enactment of the 1996 welfare reform law, the employment rate of single mothers rose from an average of 58.6 percent in the 5 preceding years (1991–1995) to an average of 70.2 percent in the 5 years after reform (1997–2001).[2] As a result, the official poverty rate among single mother-led families fell from 44.0 percent in 1994 to 33.0 percent in 2000 and was still well below pre-welfare reform levels in 2016 (35.6 percent).[3] More than 20 years later, I see opportunities to revitalize the law's goals and to improve the efficiency and effectiveness of our welfare programs to the benefit of recipients and taxpayers. If confirmed, I will work across the Department to prioritize reforms that maintain an emphasis on national values of work, community engagement, and personal responsibility.

Question. The President has repeatedly stressed his desire to promote employment. And the administration recently signaled that the Department will approve unprecedented section 1115 Medicaid demonstration waivers that would allow States to condition receipt of Medicaid for otherwise eligible individuals on meeting certain work requirements. As you know, TANF is the primary program under HHS's jurisdiction aimed at helping poor parents find employment and escape poverty. States are expected to use these flexible funds to help connect disadvantaged populations to employment. Yet at a time when the administration is telling States they can require recipient of essential health care under Medicaid to meet burdensome work requirements, the President's budget has proposed deep cuts to TANF.

Do you support these proposed TANF cuts?

What do you view as the policy rationale for these proposed cuts?

Answer. If confirmed, I look forward to working with the leaders of the Administration for Children and Families to build upon what they have learned and to en-

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[2] ASPE tabulations from the Current Population Survey, Annual Social and Economic Supplement.

[3] U.S. Census Bureau, Historical Poverty Tables, Table 4, *https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-people.html.*

sure the Temporary Assistance for Needy Families (TANF) program is as successful as possible and that funds are used in the most efficient and effective manner.

Question. The Maternal, Infant, and Early Childhood Visitation program (MIECHV) is a program that members on both sides of the aisle have championed due to the demonstrated success of its models in improving the health and well-being of mothers and children. MIECHV's innovative model has well-established goals, outcomes and metrics.

At current funding levels ($400M/year), the Department of Health and Human Services estimates that only 3 percent of the eligible population receives MIECHV services. I believe Congress and the administration should work to expand this important program. Instead, the program's authorization expired at the end of the fiscal year.

If confirmed, will you work with me and members on both sides of the aisle to ensure the continuation and expansion of MIECHV?

Answer. If confirmed, I look forward to working with members of Congress from both sides of the aisle on the reauthorization of the Maternal, Infant, and Early Childhood Home Visiting Program.

Question. The United States is the only industrialized country without paid maternity leave.[4] The President has endorsed such leave for new mothers.

Do you support a governmental paid parental leave program?

If confirmed, how might you lead the Department to help support the goal of expanding access to paid parental leave? Please be specific about resources and expertise that may be available at HHS, including in such areas as benefit design, eligibility determination, IT systems, and program access.

Answer. If confirmed as Secretary, I will support the work of the administration to enact family-friendly policies, and will strive for HHS to be a place that is supportive of working parents.

Question. A recent article in *Health Affairs* looked at the connection between opioid prescriptions and foster care entries. While the article is specific to Florida, national data and data in many States indicate that as the opioid epidemic has expanded, the foster care system is coming under increased strain. According to the article:

> Based on the full sample estimates, a one-standard-deviation increase in the statewide opioid prescription rate was associated with over 2,000 additional Florida children being removed due to parental neglect. The resulting fiscal cost was roughly $40 million, which did not include the psychological and physical effects and health care costs for affected children. For instance, neonatal abstinence syndrome primarily affects infants exposed to opioids. The syndrome's incidence rate in Florida per 1,000 hospital births increased from 0.4 in 1999 to 6.3 in 2013; 39 nationwide, the syndrome was responsible for approximately $1.5 billion in hospital charges in 2012. Many of these children will require ongoing psychiatric and physical care, which compounds our cost estimates.[5]

Are you aware of these trends in foster care?

If confirmed, would you support efforts to increase services and supports to children and families, including grandparents and other potential relative caregivers, to help safely prevent foster care entries?

Answer. With the opioid crisis, supporting grandparents and relatives who act as primary caretakers in their families is an emergent need and one that the Substance Abuse and Mental Health Services Administration (SAMHSA) is committed to addressing in its programs and policy initiatives. If confirmed, I will encourage SAMHSA to collaborate with the Administration for Community Living to ensure complementary efforts. However, older adults raising children and youth have concerns that affect all areas of their family lives: education, transportation, primary health care, behavioral health care, financial stability, and for some, juvenile justice. Working together with our Federal partners, including the Department of Edu-

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[4] *http://www.oecd.org/els/family/PF2_5_Trends_in_leave_entitlements_around_childbirth.pdf.*

[5] Quast et. al., "Opioid Prescription Rates and Child Removals: Evidence From Florida," *Health Affairs* 37, No. 1 (2018): 134–139.

cation, the Department of Justice, and the Department of Housing and Urban Development, we can help ensure that any programs and policy initiatives address the full range of needs grandparents and other caregiving relatives may have. Close coordination will ensure all efforts leverage the full range of resources across the Federal government in ways that are non-duplicative and financially efficient.

Question. I am concerned about the potential discriminatory impacts of recent efforts undertaken at HHS to promote "religious liberty." For example, HHS's new draft strategic plan and the recent HHS Request for Comment on "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding" may serve as a signal to Federal contractors that they have a license to discriminate against the children and families they serve, using the justification of religious beliefs. I am not alone in holding these concerns. Numerous child welfare organizations and children's advocates indicated in their comments to HHS in November very serious concerns about how children will be harmed if HHS allows adoption and foster care providers to discriminate under the guise of liberty.

For example, the American Academy of Pediatrics stated: "We urge HHS to not make policy changes that would enable possible discrimination against children in the child welfare system or prospective foster or permanent families. Regardless of whether a specific HHS grant or contract is supporting child welfare services, HHS should not provide grants and contracts to entities involved in child welfare services that engage in discrimination against children or families based on sexual orientation, gender identity, marital status, or faith."[6] The Children's Defense Fund said: "Allowing an organization to deny the application and licensure of certain individuals—like those who identify as LGBT, individuals not married, or people of certain religious faiths—would create additional strain on an already overtaxed system looking for foster and adoptive families with the best interest of the child the uppermost concern."[7]

I share these concerns that federally funded foster care and adoption agencies will interpret "religious liberty" as permission to restrict the types of families they place children into based on religion, marital status, sexual orientation, or other factors unrelated to the best interests of the child, and thus drastically limit the number of homes open to children who need them.

If confirmed as Secretary of HHS, what will you do to ensure that children are not denied access to qualified homes based on irrelevant factors that do not put the interests of the child first, but rather the personal beliefs of the contractor?

Answer. If confirmed, I will work with the leadership of the Administration for Children and Families to ensure the foster care and adoption programs continue to have at the forefront the best interests of the children needing these important services.

Question. A 2014 study of the foster care system in Los Angeles found that 19 percent of foster youth over the age of 12 identify as lesbian, gay, bisexual, or transgender.[8] If child welfare agencies do not provide culturally competent care, children suffer harm. The American Academy of Pediatrics has said in comments to HHS, "Policies that single-out or discriminate against LGBTQ youth are harmful to social-emotional health and may have lifelong consequences." And the Center for Study of Social Policies reported in comments to HHS that "[c]hildren and youth who identify as lesbian, gay, bisexual, transgender, queer (LBGTQ) are disproportionately involved with child welfare and experience worse outcomes than their peers *due to trauma they often experience while in State care*"[9] (emphasis added).

HHS's 2014–2018 strategic plan included the following goal: "Support the safety, well-being, and healthy development of children and youth, including children and youth who have been maltreated, who have disabilities, who are integrating into U.S. society, and who are experiencing homelessness, including lesbian, gay, bisexual, and transgender (LGBT) youth and other vulnerable populations." That goal was *removed* from HHS's draft 2018–2022 strategic plan, as were all mentions of health and human services disparities experienced by LGBT people and almost all

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[6] *https://www.regulations.gov/document?D=HHS-OS-2017-0002-12098.*
[7] *https://www.regulations.gov/document?D=HHS-OS-2017-0002-11661.*
[8] *https://www.acf.hhs.gov/sites/default/files/cb/pii_rise_lafys_report.pdf.*
[9] *https://www.familyequality.org/equal_family_blog/2018/01/04/2302/child_welfare_agencies_to_hhs_no_licensetodiscriminate_it_hurts_children.*

mentions of health and human services disparities experienced by other minorities. That removal is of grave concern.

Will you commit that HHS will promote the health and well-being of all youth, including LGBT youth, and will work to ensure that LGBTQ youth receive culturally competent care, whether they are foster youth, are unaccompanied refugee minors, or are other youth served by HHS programs?

Will you commit that HHS will ensure that LGBTQ youth in their care are placed in affirming and accepting homes and families?

Will you commit that LGBTQ minors will not be placed in homes or settings where they will be subjected to harmful conversion therapy, a medically discredited practice to change the sexual orientation or gender identity of an LGBTQ person—which has been outlawed for minors in nine States, including Oregon?

Answer. If confirmed, I will work with the leadership of the Administration for Children and Families to ensure the foster care and adoption programs continue to have at the forefront the best interests of the children needing these important services. My mission, if confirmed, will be to enhance and protect the health of all Americans, and this would most certainly include the children supported through HHS programs. Part of that mission is to ensure that everyone is treated with respect, especially in the provision of human and health services.

Question. Research has shown that both in TANF and outside it, individuals who receive targeted career and technical education, including having the opportunity to acquire credentials, participate in "career pathways" programs, and serve apprenticeships, are the most likely to get and keep good jobs. Under current TANF work participation calculations, States that use these evidence-based strategies widely are disadvantaged. For this reason, Governor Kasich of Ohio applied to HHS for a waiver of TANF's restrictions on career and technical education several years ago.

Do you support allowing States to improve access to career and technical education without penalty, so that low-income parents can get and keep good jobs?

If so, what legislative proposals would you make to address this ongoing problem with TANF?

Answer. If confirmed, I look forward to working with the leaders of the Administration for Children and Families to build upon what they have learned and to ensure the Temporary Assistance for Needy Families (TANF) program is as successful as possible. Responsible reforms should focus on reducing burdens and inefficiencies and should recognize that States, which have been the laboratories for innovation in social welfare programs, are in a better position than the Federal Government to operate programs that best meet the needs of their citizens. I see the Federal Government's role as a catalyst for engaging all sectors of the community to develop and implement a shared vision to grow the capacity and reduce the dependency of economically and socially vulnerable populations.

HEALTH CARE

Measuring Success at Lowering Prescription Drug Prices

Question. President Trump has repeatedly promised the American people he will lower prescription drug prices. During his first year in office, there has been no progress. Mr. Azar, during your confirmation hearing you acknowledged that "drug prices are too high" and committed to fulfilling the President's promise to lower drug prices. I am hopeful you can change the direction of the administration and make real progress.

In order to know if that is occurring, what metrics would measure success in this area?

In January 2019—a year from now—what should we look at to measure whether or not you and the administration have been successful at making prescription drugs more affordable for the American people?

Answer. As I said during my opening statement to the committee, drug prices are too high. The President has made this clear. I would like to work to ensure that there is adequate competition, which would lead to lower pricing. Additionally, Commissioner Gottlieb is already working on ways to increase generic competition, by encouraging the development of generic drugs and speeding approval of such drugs. FDA has unveiled a drug competition action plan, which will increase competition and help keep drug prices down. If confirmed, I will work with FDA to help bolster

this effort, and I look forward to working with him to ensure that increased competition for drugs leads to lower list prices. This is a metric that would indicate success in addressing drug pricing.

Pharmaceutical Supply Chain

Question. U.S. spending on prescription drugs is growing rapidly, and evidence suggests that rising drug costs can be attributed to a broken pricing system involving multiple actors. As a former pharmaceutical executive, you have insight into this broken system.

If confirmed, what specific reforms would you pursue for each actor in the supply chain to lower the cost of drugs?

What would you do to bring down prices set by drug manufacturers?

What specific reforms would you pursue regarding Pharmacy Benefit Managers and Wholesalers?

What would you do to reform health plans?

Answer. As I said at my confirmation hearing, drug prices are too high. The existing system for pricing and reimbursement of drugs works for many of the players in the system, but not for patients who have to pay high out-of-pocket costs for their drugs because of lack of insurance, high deductibles, or high cost sharing. Drug pricing is informed by a multitude of factors including the list price, competitive market dynamics, government rebate programs, insurer market power, discounts to the list price, and research and development costs, to name a few. If confirmed, I will work to make sure that patients benefit from lower drug costs.

PBMs

Question. During the hearing, you testified about the significant negotiation power that pharmacy benefit managers (PBMs) have in Medicare Part D to secure "the best rates of any commercial payers" for the Medicare program.

You also proposed applying principles from Medicare Part D to how the Medicare program pays for Part B drugs, which you suggest could lower costs for both beneficiaries and the Medicare program.

In your view, what specific principles from Medicare Part D should be applied to how Medicare pays for Part B drugs?

Please describe in detail how those Part D principles would be applied to Part B under your proposal.

During the HELP hearing, you stated that "everyone shares blame" in the drug pricing system, making PBMs partially responsible for the high and rising costs of prescription drugs. To the extent that your proposal includes utilizing PBMs (or entities similar to PBMs) in Medicare Part B, please explain why you believe that PBMs would have the opposite effect—lowering drug prices—in Part B.

Answer. Through my experience helping to implement Part D and with my extensive knowledge of how insurance, manufacturers, pharmacy, and government programs work together, I believe I bring skills and experiences to the table that can help us address these issues, while still encouraging discovery so Americans have access to high-quality care.

The President has generally spoken about the desire to ensure that Medicare is negotiating and getting the best deal possible for drugs. As I stated at the hearing, Part D plans are actually negotiating today with the three or four biggest pharmacy benefit managers that negotiate and actually secure the best net pricing of any players in the commercial system. If confirmed, I would like to consider more ways to take the lessons from Part D to improve Medicare.

Question. You expressed support for using national emergency powers to provide the HHS Secretary with the authority to negotiate reduced pricing for Naloxone to address the opioid epidemic.

Why is direct government negotiation preferable to PBM negotiation under this circumstance?

What other circumstances or drugs present such a dire circumstance similar to the opioid crisis that direct negotiation by the government would result in lower prices?

Answer. As we fight this opioid epidemic, I believe access to naloxone is critical. I support efforts to assist in these purchases and, if confirmed, will review the cur-

rent efforts underway in this area. I am not aware of any authorities provided by the Public Health Service Act under a public health emergency, or by the National Emergencies Act under a national emergency, that would permit me, if confirmed, to negotiate reduced drug pricing for naloxone. If confirmed, I commit to looking into whether HHS has programs and funding whereby HHS could negotiate for and procure naloxone for use by public health emergency first responders. In addition, in an effort to expand access, I would like to work to ensure that there is adequate competition for naloxone, which would lead to lower pricing. FDA has indicated the agency is identifying ways to encourage OTC naloxone applications. Additionally, Commissioner Gottlieb is already working on ways to increase generic competition, by encouraging the development of generic drugs and speeding approval of such drugs. FDA has unveiled a drug competition action plan, which will increase competition and help keep drug prices down. If confirmed, I will work with Dr. Gottlieb and FDA to help bolster this effort.

MACRA Implementation

Question. Ensuring the successful implementation of the Medicare physician payment reforms included in the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) will be one of the most important issues faced by the new HHS Secretary.

In your view, what are the most significant challenges regarding successful implementation of the Merit-based Incentive Payment System (MIPS)—and how would you approach those challenges as HHS Secretary?

What about with respect to the Advanced APM track?

In your opinion, what have HHS and CMS done well in terms of MACRA implementation, and where do you see opportunities for improvement?

Answer. I agree with the goals of MACRA, and I commend Congress for taking action toward stabilizing Medicare Part B payments for clinicians. MACRA repealed the flawed Sustainable Growth Rate formula, which put clinicians in Medicare at the risk of recurring payment cuts, and replaced it with a new program that CMS calls the Quality Payment Program. However, like any new program requiring significant changes to the way clinicians are paid within Medicare, the Quality Payment Program has faced barriers to achieving the well-intended goals it was designed to accomplish. Most clinicians who receive Medicare Part B payments must participate in one of two tracks, and clinicians face unique challenges under each track. The Merit-based Incentive Payment System (MIPS), which adjusts clinician payment based on performance, requires reporting of different types of measures across numerous performance categories, and it has been challenging for clinicians to learn and understand these new program requirements. A key challenge under MIPS going forward will be to measure the quality of care in a meaningful way that does not require an unduly burdensome amount of time and resources.

Alternatively, clinicians may participate in one of several Advanced APMs, which allows clinicians with sufficient participation to earn a 5 percent incentive payment by going further in improving patient care and taking on risk. However, there are concerns there are too few Advanced APMs, and the process to develop new models is extensive and lengthy. It is my understanding that CMS released a Request for Information [10] seeking public feedback on a new direction for the Innovation Center and ways to promote patient-centered 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. If confirmed, I look forward to reviewing the comments received on the Request for Information as well as the Physician-Focused Payment Model Technical Advisory Committee's comments and recommendations on these proposals to help ensure CMS increases the number of available Advanced APMs.

It is my understanding that CMS is working closely with stakeholders to maximize clinician flexibility and to make the transition as smooth as possible, however much additional work lies ahead if this program is to achieve the goals of improved quality and improved value-based payment intended by the MACRA statute.

CMMI RFI

Question. In September 2017, under the Trump administration, the Center for Medicare and Medicaid Innovation (CMMI) issued a Request for Information (RFI) regarding a "new direction" for CMMI. The RFI hinted at specific policies under con-

[10] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*

sideration that would increase out-of-pocket costs for Medicare beneficiaries—including allowing physicians to balance bill Medicare beneficiaries and turning Medicare into a voucher program (*i.e.,* premium support).

If confirmed as HHS Secretary, will you commit to not pursuing any CMMI models that would allow doctors to balance bill Medicare beneficiaries?

Will you commit to not pursuing any CMMI models testing the use of vouchers in Medicare (*i.e.,* premium support)?

Will you commit to making all of the responses to the CMMI RFI publicly available?

Answer. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. CMMI will be a critical part of these efforts. Of course, we must exercise the power of CMMI and other authorities in ways that are open and transparent, and that seek out collaboration and input as much as possible. I am not familiar with any details or deliberative process behind the most recent actions cited in this question, but if confirmed, I look forward to exploring models that reduce costs and increase quality for Medicare beneficiaries, taking full advantage of the stakeholder input CMS receives through the recent RFI.

ASPE RFI

Question. On December 26, 2017, the Department of Health and Human Services (HHS) released the "Promoting Healthcare Choice and Competition Across the United States" Request for Information (RFI) on the Office of the Assistant Secretary for Planning and Evaluation (ASPE) website. The RFI solicits stakeholder comments on State and Federal laws, regulations, guidance, requirements, and policies that discourage or prevent the development and operation of a health-care system that provides high-quality care at affordable prices for the American people, the promotion of competition in health-care markets, and the limitation of excessive consolidation throughout the health-care system.

While the RFI refers to this comment solicitation as "informal," responses to the RFI's wide-ranging questions—addressing Medicare, Medicaid, and other sources of payment—may "lay the groundwork for future action." It is critical that HHS maintain transparency when exchanging information that may shape HHS' future policy decisions and actions.

If confirmed as HHS Secretary, will you commit to publishing all future RFIs in the Federal Register?

Will you commit to making stakeholder comments submitted in response to the "Promoting Healthcare Choice and Competition Across the United States" RFI publicly available in a timely manner?

Answer. I am firmly committed to ensuring that any regulatory actions taken by the Department comply with the Administrative Procedure Act (APA). If confirmed, I will review this issue and take any steps that are necessary to ensure that the Department complies fully with requirements for RFIs.

Medicaid Expansion and Mental Health

Question. In 2010, the Affordable Care Act (ACA) dramatically expanded coverage for needed mental health services by giving States the opportunity to extend Medicaid eligibility to low-income, non-elderly adults. Of the 11 million adults who subsequently gained coverage through 33 State Medicaid expansion programs (including the District of Columbia's), one in three beneficiaries had a substance use disorder, mental health condition, or both. As a result, over a million people with substance use disorders gained coverage for treatment under the Medicaid expansion.

This prominent role in expanding access to mental health and substance use disorder services has made Medicaid a vital tool in the national fight against the opioid epidemic. Today, Medicaid is the single largest payer of substance use disorder services in the Nation, covering one of every three Americans battling opioid dependence. States that have shouldered the brunt of the crisis have relied heavily on the Medicaid expansion to give people access to needed services. In Kentucky, Maine, Pennsylvania, Ohio and West Virginia, for example, Medicaid pays for 35 to 50 percent of all Medication-Assisted-Treatment.

In 2017, legislation was repeatedly introduced to roll back Federal funding for the Medicaid expansion and to eliminate States' authority to expand Medicaid eligibility

to low-income, non-elderly adults. Would you oppose future proposals to roll back or eliminate Medicaid expansion, understanding that such proposals would cripple the Nation's ability to combat the opioid crisis?

Do you agree that the Medicaid expansion has helped States address the opioid epidemic by connecting individuals to substance use disorder services? Please answer "yes" or "no."

Answer. Medicaid is a safety-net program that provides 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. For that reason, it is crucial for States to have the flexibility to tailor the Medicaid program to meet the needs of their constituents. If confirmed, I will work to ensure that States are empowered to tailor solutions that work for their citizens with substance use disorders and that they receive the proper supports from their Federal partner at HHS.

1115 Demonstration Projects

Question. Recent comments and guidance from the Centers for Medicare and Medicaid Services (CMS) indicate that the agency may be willing to approve proposed section 1115 demonstration projects that would restrict access to essential benefits and services through the Medicaid program. These include proposals to impose work requirements, time limits, mandatory drug testing, burdensome reporting requirements, and other onerous premium and cost-sharing requirements on Medicaid families. By limiting access to health care for beneficiaries, these restrictive conditions on eligibility run counter to congressional intent and the statutory objectives of the Medicaid program, which Congress created in 1965 to enable States to provide medical assistance and long-term care to those who lack the resources to obtain the services they need.

Will you commit to rejecting any proposed section 1115 demonstration project that undermines the objectives of the Medicaid statute by reducing access to health services and benefits, including proposals to impose work requirements on Medicaid beneficiaries? If not, please explain.

Answer. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. We need to customize our programs and benefits to the characteristics of our beneficiaries. While I have not been involved as a nominee in CMS efforts to allow States to implement work requirements in their Medicaid programs, I do believe there is significant evidence that one of the best ways to improve the long-term health of low-income Americans is to empower them with skills and employment, for those who are able to work. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

Section 1332 State Innovation Waivers

Question. Section 1332 of the Affordable Care Act (ACA) provides the Secretary of the Department of Health and Human Services (HHS) with broad authority to approve State waivers to certain ACA marketplace provisions. To obtain these State Innovation Waivers, States must satisfy substantive and procedural safeguards. Waivers must ensure that individuals get insurance coverage that is at least as comprehensive as provided under the ACA; the coverage offered is at least as affordable as it would be under the ACA; as many people are covered as would be under the ACA; and the waiver does not increase the Federal deficit. States must also take procedural steps to be eligible for a waiver, including: providing a public notice and comment period for the application; enacting a State law for the implementation of the waiver; and submitting a comprehensive application to HHS.

Describe the opportunities you see for States to use State Innovation Waivers. Specifically, are there particular State-led reforms that you think would enhance access to affordable, quality coverage?

What precautions would you put in place to ensure consumers are protected in States that choose to move forward with a section 1332 waiver application?

What steps would you take to implement this provision, as intended by Congress, to ensure it is not used to undermine the ACA?

Describe how you envision State Innovation Waivers working in conjunction with Medicaid and any corresponding Medicaid waivers. Specifically, what checks would

you put in place to ensure that individuals entitled to Medicaid receive the full benefits and protections afforded them under title XIX?

In 2017, multiple proposals were introduced to modify section 1332's substantive and procedural guardrails. Would you support legislative efforts to weaken these safeguards? If so, cite which guardrails, in your view, could be modified without sacrificing all consumers' access to affordable, comprehensive coverage.

Answer. State-driven innovation must be a top priority for the Department. The ACA has very stringent requirements related to 1332 waivers that limit State flexibility and significantly lengthen the waiver approval process. I support continued efforts to use CMS's statutory waiver authorities to test and evaluate demonstrations that can lower health-care costs or improve quality. These need to be approached carefully to avoid the potential for waste, fraud, and abuse, and preserve patient protections, but an unwillingness to examine these areas makes us penny-wise and pound-foolish too often. If confirmed, I will work closely with CMS to ensure the continued support and the timely review of all State 1332 waivers received by HHS, and to make the waiver approval process more transparent, efficient, and less burdensome to the extent authorized by law.

Association Health Plans and Short-Term Limited-Duration Plans

Question. As part of the administration's campaign to undermine the Affordable Care Act (ACA), the President issued an executive order on October 12, 2017 that directed the Departments of Health and Human Services (HHS), Labor, and the Treasury to expand the use of association health plans (AHPs) and short-term limited-duration insurance. On January 4, 2018, the Department of Labor (DOL) released proposed rules to expand the availability of AHPs and enable these plans to bypass certain consumer protections under the ACA, including the ACA's requirement that plans cover essential health benefits. If finalized, these rules would make it easier for small employers and individuals to buy cheap AHP plans substantially less comprehensive than policies offered under the ACA.

If finalized, DOL's recent AHP rule may destabilize the individual and small group marketplaces and drive up the cost of ACA-compliant plans. This is because AHPs will draw younger and healthier consumers out of those markets, leaving older and sicker individuals behind.

If this rule as proposed is finalized, how would you prevent this expansion of AHPs from driving up the cost of coverage for individuals with pre-existing conditions in the individual and small group marketplaces?

Despite AHPs' history of mismanagement and abuse, DOL's regulation would give the Federal Government greater oversight authority over self-insured AHPs. If this rule as proposed is finalized, how would you, as HHS Secretary, ensure that fraudulent AHPs do not expose consumers to inadequate coverage and medical debt?

Answer. Millions of consumers in too many State marketplaces have already lost the plans they liked and the doctors they liked under the ACA. Large employers often are able to obtain better terms on health insurance for their employees than small employers because of their larger pools of insurable individuals across which they can spread risk and administrative costs. Expanding access to Association Health Plans (AHPs), which can sell insurance across State lines, can help small businesses overcome this competitive disadvantage by allowing them to come together in larger groups to self-insure or purchase large group health insurance. This approach can reduce administrative costs, increase bargaining power, and create new economies of scale, administrative efficiencies, and better allocation of plan responsibilities to those with greater expertise designing and administering health benefits programs. Expanding access to AHPs will also allow more small businesses to avoid many of the ACA's costly requirements driving millions of Americans into the ranks of the uninsured, or keeping them there. Expanding access to AHPs would provide more affordable health insurance options to many Americans, including hourly wage earners, farmers, professionals who work as solo practitioners or in small groups, and the employees of small businesses and entrepreneurs that fuel economic growth. The status quo is not working for millions of Americans. If confirmed, I will continue to work within HHS, as well as with the Department of Labor and other components of the executive branch, to create an affordable, accessible health insurance system that is responsive to the needs of individuals and their families.

Question. The administration has yet to implement the executive order's directive to expand the availability of short-term limited-duration insurance. Like AHPs,

these plans would segment the market between healthy and sick consumers and drive up the cost of coverage for individuals with preexisting conditions.

If you are confirmed as Secretary, will you oppose efforts to expand the availability of short-term limited-duration plans?

Short-term limited-duration plans are permitted to charge individuals with preexisting conditions more for coverage. Do you think insurers should be permitted to charge these consumers higher premiums or cost-sharing requirements?

As HHS Secretary, how would you prevent short-term limited-duration plans from raising the cost of coverage for individuals with pre-existing conditions in the individual and small group marketplaces?

Answer. The ACA has already failed millions of Americans who have lost the plans they liked and the doctors they liked. 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 are. If confirmed, I will work, within HHS as well as with the Department of Labor 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 health-care system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them, including reliable association health plans and the option of short-term, limited-duration insurance. I will also work to ensure the least disruptive approach to implementing these policies, and to appropriately consider the concerns expressed by stakeholders during the rulemaking process.

Women's Health

Question. The Trump administration has put forth an agenda that directly undermines women's access to health care, including the reinstatement of the "Global Gag Rule" or "Mexico City Policy," the termination of funding for the Teen Pregnancy Prevention Program, restriction of access to birth control, and support for legislative proposals to end reimbursement for health services provided by Planned Parenthood.

I request your detailed response to the following:

On October 13, 2017, the administration published two interim final rules (IFRs) to allow for-profit employers to end coverage of birth control for their employees based on religious or moral objections, undermining the Affordable Care Act's (ACA) guarantee that women be able to access birth control at no out-of-pocket cost. This guarantee under the ACA is estimated to have saved women more than $1.4 billion in out-of-pocket costs on birth control per year.

Please answer "yes" or "no." Do you believe that all women should have access to the health care their doctor recommends for them?

Will you rescind these IFRs if you are shown evidence that they would curtail access to needed contraceptive services for women?

Will you reject any proposal that limits a women's access to contraceptive care or drives up the cost of birth control?

Will you advise the President to veto any bill that reduces guaranteed access to affordable contraceptive coverage?

Answer. I believe all women should have access to the care that they need. We can advance that goal while simultaneously following the many laws protecting the right of conscience in health care.

Question. In 2016, Planned Parenthood provided preventive care to over 2.5 million patients—including 1.5 million Medicaid patients. Over 90 percent of the care Planned Parenthood delivers are preventive health services, including 360,000 life-saving breast exams, 270,000 Pap tests, and 4.3 million tests and treatments for sexually transmitted infections. Over 54 percent of Planned Parenthood health centers are in health professional shortage areas or medically underserved areas.

Will you advise the President to veto any bill that rips access to care away from hundreds of thousands of families by ending Medicaid reimbursement for Planned Parenthood services?

Answer. Preventive care is important, and I believe women should have access to such care. If confirmed, I look forward to working with you to ensure that access to coverage for preventive care is available for all Americans.

LGBTQ Health Care

Question. LGBTQ individuals often experience exceptional barriers to care; health disparities associated with gender identity are partially driven by lower rates of insurance. Under the ACA, the LGBTQ population cannot be excluded from health plans due to pre-existing conditions such as HIV. Discrimination based on sex and gender identity is also prohibited for programs receiving Federal funds. Additionally, all insurance plans must offer the same coverage to married same-sex couples as is offered to opposite-sex couples. In terms of national health surveys, the ACA changed data collection requirements to include sexual orientation and gender identity, which supports future advocacy and research.

Will you maintain health-care protections for the LGBTQ community? Please explain.

Answer. If confirmed, I will do everything in my power to ensure that all Americans have meaningful access to medical care, including ensuring that the Department continues to empower patients and consumers so that they will have increased access to medical care, health, and wellness. Our Nation's health-care system is founded on the respect for the human person, evidence-based research, and effective medical treatment. It must be a system that treats each patient with the respect that they deserve, in compliance with the law.

The National Registry of Evidence-Based Programs and Practices

Question. It has been reported that the administration has frozen The National Registry of Evidence-Based Programs and Practices that provides professionals and community groups with access to a robust database of independently-assessed, evidence-based programs for treating mental illness and substance use. Given that we are in the midst of an opioid crisis that is taxing our mental health and substance use services systems, policymakers, community members, and providers are in tremendous need of knowledge regarding new, evidence-based interventions that are effective in treating mental health and substance use disorders such as opioid use disorder.

If confirmed, will you work to reinstate this important registry of evidence-based interventions including the addition to close to 90 reported programs that were reviewed and rated since September, but have not yet been added?

Additionally, if confirmed, what will you do to insure that the National Mental Health and Substance Use Policy Laboratory will make sure that impartial, nonpartisan, and trustworthy interventions are promoted by the agency to ensure policymakers, community members, and providers can benefit from the database in order to help address the opioid epidemic taking hold across the country?

Answer. I believe in the importance of evidence-based programs and policies and know that Dr. McCance-Katz, the Assistant Secretary for Mental Health and Substance Use at SAMHSA, shares this belief. I am not familiar with the particular reasons why the NREPP contract was discontinued, but you can be assured that I will maintain HHS's commitment to evidence-based programs and practices should I be confirmed.

CDC Guidelines

Question. In your testimony to the committee, you stated that addressing the opioid crisis would be a top priority for you if you are confirmed as Secretary. In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines for prescribing opioids for chronic pain unrelated to cancer, palliative care, or end-of-life care. While some health systems and payers have adopted the guidelines, many have not. For example, according to a Kaiser Family Foundation survey conducted last summer, the guidelines have been adopted by 23 States with fee-for-service (FFS) Medicaid programs. Just eight States that use managed care organizations (MCO) for Medicaid have required MCOs to adopt the guidelines.

What steps do you plan to take to increase adoption of the CDC guidelines?

Do you believe that it would be appropriate for the Department to issue guidance or regulations that would support the adoption of these guidelines?

Answer. I believe that education of providers is a key component to addressing the opioid crisis. If confirmed, I would ensure that CDC and HHS are doing all we can to raise awareness about the guidelines and encourage adoption of them. I am not sure that guidance or regulations would be needed to support the adoption of the guidelines, but I commit to reviewing this, if confirmed.

QUESTIONS SUBMITTED BY HON. DEBBIE STABENOW

Question. President Trump's recent executive orders would expand the use of Association Health Plans and short-term health insurance coverage, and these plans would not be required to cover the 10 essential health benefits.

Do you support finalizing these rules?

Do you believe that there should be a minimum set of benefits for anyone buying health insurance in this country? If not, which of the 10 essential health benefits do you believe should be optional?

Answer. The ACA has already failed millions of Americans who have lost the plans they liked and the doctors they liked. 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 are. If confirmed, I will work, within HHS as well as with the Department of Labor 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 health-care system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them, including reliable association health plans and the option of short-term, limited-duration insurance. I will also 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. Prior to the ACA, the vast majority of plans on the individual market did not offer maternity coverage, and those that did charged significantly more.

Do you believe that all health plans should be required to cover maternity and newborn care at no additional cost?

Answer. It is critical that every woman have access to high-quality prenatal care. If confirmed, I look forward to working with Congress on the specifics of any new proposals in order to hold States accountable to ensure patient access to high quality health care.

Question. Because of Medicaid expansion in Michigan, 660,000 people have insurance and uncompensated care has been cut by at least 50 percent. Thirty thousand jobs have been created and the State will end the year with $432 million more than it invested in the program.

Did you support the health-care repeal bill this summer that ended Medicaid expansion?

Do you support block-granting and cutting the Medicaid program?

Would you support cutting Medicaid by $1 trillion, as done in the current Republican budget?

Answer. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the

flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it.

Question. Last year, there were 55.5 million total Medicare beneficiaries, including nearly 2 million in Michigan.

Can you commit to my constituents in Michigan that you will not propose any cuts to the Medicare program or their benefits in any HHS budgets during your time as Secretary, if confirmed?

Answer. I take the President's commitment to Medicare beneficiaries seriously, and, if confirmed, I commit to putting patients first in whatever Medicare policies we pursue. I will note that any significant changes to the Medicare Program would need to be passed by Congress. If confirmed, I will faithfully execute the laws as passed by Congress.

Question. Throughout my career I have worked on both sides of the aisle to strengthen and grow our country's network of community health centers, which are uniquely designed to provide access to health care in the communities that need it most.

How do community health centers fit into your vision of a patient-centered health delivery system?

Will you work with me and members of this committee on both sides of the aisle to ensure that we sustain our investment in community health centers?

Can you share your thoughts about how we can shore up the health care safety net to ensure no one falls through the cracks?

Answer. It is vitally important that the U.S. health-care system provide meaningful access to quality medical care, health, and wellness for all Americans. I am committed to ensuring that community health centers continue to be funded, so that they can increase access to primary care. If confirmed, I will work with all members of Congress to highlight programs like Community Health Centers that can increase access to quality health care for all. If confirmed, the Department will work to reduce costs of medical care by increasing the options that patients and consumers have so that they can be in charge of their own futures when it comes to their medical care.

Question. CMS recently finalized a new Medicare billing code—code 99483—that physicians and other clinicians can use to be reimbursed for providing care planning and related services for persons with cognitive impairment, including Alzheimer's disease and related dementias.

Now that this code is active, as Secretary, how would you ensure that providers are aware of the code and provide care planning services to their patients?

Answer. Assessment and care planning for Medicare beneficiaries with Alzheimer's disease and other cognitive impairments are critically important given the challenges facing these individuals. In 2017, Medicare began making separate payments for physicians and other practitioners to perform these valuable services. If confirmed, I look forward to learning more about the education and outreach efforts with the physician community and other stakeholders who are involved in these services.

Question. Would you consider examining how cancer hospitals are reimbursed, particularly the PPS exempt hospitals and consider adding new facilities that already meet the criteria?

Answer. I understand that the cancer hospital designation under Medicare is a payment provision specified in statute that, under current law, excludes hospitals that met specific criteria at a specific point in time from the Inpatient Prospective Payment System (IPPS). If confirmed, I stand ready to work with Congress on legislation to address issues related to the treatment of cancer hospitals under Medicare.

Question. Recent actions by the FDA in implementing DQSA have created instances in which 503B compounding facilities are producing copies of approved drug products. Left unresolved, this issue has the potential to create marketplaces of inadequately regulated compounded medications that run counter to the intent of the law. This activity is concerning for patients in Michigan and for patient safety across the country considering past history of compounding contamination.

What steps will you take to protect patient safety while also ensuring access to safe and accessible compounded products for patients with medical needs not being met by marketed products?

Answer. I appreciate your expressing your support for drugs which have been through the FDA review and approval process and therefore receive certain exclusivity protections. It is my understanding that FDA continues to advance guidance on this and other issues which were mandated under the 2013 Drug Quality and Security Act, and I will work with Commissioner Gottlieb to advance these regulations quickly.

QUESTION SUBMITTED BY HON. DEBBIE STABENOW AND HON. BENJAMIN L. CARDIN

Question. Nearly one in five adults has a mental illness, yet over 60 percent of people with mental illness do not receive treatment. Mental health parity protections benefit 103 million people today, a critical step forward. The essential health benefit protections build on parity by requiring that mental health and substance abuse treatment are covered by insurance companies.

Do you believe that mental health and substance abuse treatment should be a guaranteed benefit in all health insurance plans?

What regulations would you pursue, or eliminate, related to Federal standards for mental health coverage?

Do you support the changes to the Essential Health Benefits regulations to allow States to choose less comprehensive coverage for mental health and substance use services?

Answer. It is critical that all Americans suffering from mental health and substance abuse disorders have access to the care they need. If confirmed, I plan to review the laws in place on mental health parity and ensure they are carried out faithfully. Although the Department of Labor has the primary role in enforcement of the law, I will be sure to coordinate with them.

QUESTIONS SUBMITTED HON. MARIA CANTWELL

Question. In my office we discussed using Medicare to advance delivery system reform across the entire health sector. Washington State health-care providers are paid about $2,000 less per Medicare patient per year when compared to national averages, according to Centers for Medicare and Medicaid Services (CMS) fee-for-service data compiled by the Kaiser Family Foundation. I have long held that Washington State health providers are essentially penalized for doing a good job. You have previously said "We need a next-generation payment system that rewards innovation, quality, prevention, and improved patient outcomes—with incentives for good care, not just more care." To help me understand what you mean, will you describe at least one specific example of a current Medicare payment model that you think shows promise toward achieving those outcomes?

Answer. If confirmed, one of my priorities will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. The CMS Innovation Center is testing many payment and service delivery models that aim to reduce expenditures and preserve or enhance the quality of care furnished to beneficiaries. The Innovation Center's Next Generation Accountable Care Organization (ACO) Model is one example of a current model that has early promising results. Net savings to the Medicare Trust Funds was more than $63 million for the first performance year of the model. In the first year, all Next Generation ACOs successfully reported on all 33 quality measures and received a 100-percent quality score.

Question. How will you encourage new Medicare payment and delivery models to be equitable to physicians and clinicians in low-cost States like Washington, when the benchmark for success in many of these models is tied to historical fee-for-service spending?

Answer. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system

that pays for quality and outcomes. It is my understanding that CMS recently issued a Request for Information seeking feedback on a new direction for its Center for Medicare and Medicaid Innovation to promote patient-centered 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. If confirmed, I look forward to working with CMS as they gather feedback from Congress and other stakeholders and use it to inform their efforts in developing payment and service delivery models that meet these goals, including models that reward providers who are already providing high-quality care at lowered costs.

Question. As you know, in 2015 Congress passed and President Obama signed into law the bipartisan Medicare Access and CHIP Reauthorization Act (MACRA). In implementing MACRA, how will you work with CMS and the provider community to expand participation in Advanced Alternative Payment Models (A–APM's)?

Answer. I understand CMS is working to implement MACRA in a way that ensures meaningful measurement of value and quality while promoting better patient outcomes and supporting a simplified pathway to participation in Advanced Alternative Payment Models (APMs). In the final rule with comment period for the second year of the Quality Payment Program, CMS updated policies to further encourage and reward participation in APMs and established policies to further reduce burden and simplify the program. In addition, it is my understanding that CMS released a Request for Information[11] seeking public feedback on a new direction for the Innovation Center and ways to promote patient-centered 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. If confirmed, I look forward to reviewing the comments received and working on the new direction for the Innovation Center and increasing the number of Advanced APMs available to clinicians.

MACRA also established the Physician-Focused Payment Model Technical Advisory Committee (PTAC), to review and assess physician-focused payment models, a type of APM, based on stakeholder proposals submitted to the committee. If confirmed, I look forward to reviewing PTAC's comments and recommendations on these proposals as part of my work in facilitating CMS's efforts to promote provider participation in Advanced APMs.

Question. One example of delivery system reform we discussed is "rebalancing" individuals who require long-term services and supports (LTSS) from institutional care settings, such as nursing homes, to home- and community-based settings. I believe that advancing such rebalancing policies holds the promise to improve quality of life for patients and save billions of dollars. In Washington State, evidence shows that 15 years of rebalancing work in our State's Medicaid program has yielded more than $2.5 billion in savings. I also believe that Federal incentives can help States accelerate rebalancing policies. I helped secure the Balancing Incentive Program in the Affordable Care Act, which 18 States have used to successfully lower their rates of institutional long-term care for their Medicaid beneficiaries. In addition, Senator Portman and I recently introduced legislation (S. 2227) to reauthorize the Money Follows the Person (MFP) demonstration program for 5 years and make improvements in the program. According to an HHS report, the MFP program has already saved approximately $1 billion in Medicare and Medicaid expenditures in recent years by helping States to rebalance Medicaid beneficiaries. If confirmed, will you work with me, my office and other interested members and stakeholders to advance these rebalancing policies?

Answer. Yes, I look forward to working with you and your office on these important efforts to support home and community-based care. I believe that the use of innovation and evidence-based practices will be a critical part of meeting the evolving needs of older Americans by supporting programs that provide long-term services and supports in community-based settings. If confirmed, I will remain deeply committed to ensuring access to high-quality, community-based supports and services so that older adults have more and better options about how and where to receive the services they need. Maintaining the Department's ongoing efforts through the Centers for Medicare and Medicaid Services and Administration for Community Living to work with States in ensuring the right balance of public funding for home and community-based options for older adults and people with disabilities will be a priority for me. To do that most effectively and efficiently, we have to work to-

[11] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*

gether across all levels of government and with all potential partners to establish innovative strategies for meeting these goals.

Question. On October 23, 2017, I wrote a letter with Senator Grassley to Acting Secretary Hargan regarding Medicare Part B coverage for people with lymphedema. Our letter requested that HHS use its discretionary authority to cover compression therapy supplies for Medicare patients with lymphedema, or provide us with an explanation for HHS's inability to do so. On November 30, 2017, CMS Administrator Verma replied to me indicating that CMS staff was in the process of exploring whether such coverage was possible under Medicare Part B. If confirmed, will you work with CMS to provide me and Senator Grassley a clear and detailed explanation for the decision that CMS ultimately reaches?

Answer. Medicare was first established more than 50 years ago, with a siloed approach to determining what would and would not be covered. It is important to make sure that we are not being short sighted and failing to cover a treatment or item that will improve health and save money simply because it does not fit into a category in Medicare. If confirmed, I would be happy to work with you and Senator Grassley and with CMS to explore whether separate coverage of and payment for compression garments is possible under the Medicare Part B benefit categories established in the statute.

Question. The vast majority of Washington State counties are primary care or mental health Professional Shortage Areas (HPSA's) according to HHS's HRSA. In response to an aging population and impending physician shortages, two new medical schools have opened in Washington, each focused on training more physicians to practice in shortage specialties and in medically underserved communities. Do you agree with an established body of research illustrating that the United States faces a major doctor shortage?

Answer. The Federal Government has invested in workforce training and is committed to continuing its work in this area. If confirmed, I believe it is critical that we look at ways to better address the workforce shortages.

Question. Given your experience in health-care policy, what is your view of the role the Federal Government should play to promote an adequate and balanced physician workforce in the United States?

Answer. As mentioned above, I believe addressing the workforce shortage is critically important. If confirmed, I commit to reviewing the budget and ensuring that the programs in place are effective and meet the goals we set forth.

Question. Medicare's GME program was created in 1965, when we had a very different health care delivery system than we do today. In what ways should GME funding programs adapt to the evolving nature of medical education and care delivery?

Answer. Under the Medicare program, teaching hospitals or hospitals that train residents in approved medical allopathic, osteopathic, dental, or podiatry residency programs receive direct graduate medical education payments that reflect the direct costs of operating approved residency training programs. Within the statutory parameters of these payments, there are programs designed to support physician training in areas with primary care shortages. For example, the Rural Training Track programs allow urban and rural hospitals to partner to train resident physicians in rural areas. If confirmed, I look forward to working with Congress to support health workforce training that develops practitioners in professions with pronounced shortages and in underserved areas. I would also look forward to speaking with you further about your insights regarding ways in which the program may not have kept up with the evolving nature of medical education and care delivery.

Question. In recent years some States have sought permission from CMS to exclude high-quality family planning providers from their Medicaid programs for ideological reasons. What is your view of whether the Federal Medicaid statute and regulations permit such exclusions?

Answer. If confirmed, I would work closely with CMS and the Office of General Counsel to review the relevant statutory and regulatory Medicaid participation requirements invoked in your question. As a general matter, if confirmed, I will work to promote a health-care system that will provide access to quality care while ensuring patients are able to make decisions that work best for them. Additionally, I will also work with States to help them achieve their goals with as much flexibility as possible, within the parameters and confines of the law.

Question. Will you commit to providing me and my office timely and responsive technical assistance on any future legislation I author or on which I seek assistance?

Answer. Yes, I will commit to working with my staff to facilitate their provision of appropriate technical assistance on future legislation.

QUESTIONS SUBMITTED BY HON. BILL NELSON

Question. I want to get your perspective on some of the policies supported by your predecessor, Secretary Price. Please answer with a "yes" or "no."

Do you support raising the Medicare eligibility age, forcing seniors to wait longer for benefits they earned during their working years?

Do you support turning Medicare into a voucher program? According to CBO estimates, privatizing Medicare would increase premiums paid by seniors by 30 percent.

Do you support allowing Medicare providers to enter into private contracts with their patients? This would place seniors on the hook for the difference between what an insurer pays and what a provider charges, potentially resulting in higher out-of-pocket costs for patients.

Answer. The mission of HHS is to enhance and protect the health and the well-being of all Americans, through programs that touch every single American in some way, every single day. As Secretary, my job would be to lead HHS in its work towards this mission.

Ultimately, the direction of Medicare is up to Congress and, if confirmed as HHS Secretary, I will follow the laws as passed by Congress and implement them accordingly.

Question. In Florida, over 3.5 million people, including children, seniors, and those with disabilities rely on Medicaid and CHIP. Another 800,000 would have gained access to Medicaid services had Florida expanded Medicaid.

Medicaid is particularly important to hurricane recovery efforts. As it is currently structured, Medicaid can respond to public health emergencies and natural disasters. As needs go up in a State, Federal funding goes up automatically in response. After going through three hurricanes in a matter of weeks, I am really worried about how Florida, Puerto Rico and the U.S. Virgin Islands will fare under "entitlement reform." Puerto Rico's Medicaid program is already subject to a block grant that won't adjust for the greater demand as the island recovers from the hurricane, and they're expected to run out of money in a month. To me, there is no better example of why block granting Medicaid just won't work.

How do block grants and caps provide States with enough funding to respond to natural disasters like Hurricanes Irma or Maria? Block grants provide a fixed dollar amount and caps provide a fixed about of funding per individual. What happens when more people need health coverage or costs rise on a per-beneficiary basis?

Answer. I am certainly aware of the unique challenges that the Puerto Rico Medicaid program faced even before the hurricane. Of course, these challenges are compounded following such a serious storm.

As I noted before the committee, the details around financing and flexibility are key to evaluating any block grant reform approach, including those proposed last year. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste, and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it.

Question. I introduced a bill that, similar to steps taken following Hurricane Katrina, has the Federal Government pick up 100 percent of Medicaid costs temporarily so that Puerto Rico and the U.S. Virgin Islands can recover from the hurricanes. The islands have limited ability to cover their share of Medicaid funds needed to draw down Federal dollars, and my bill would help them in their hour need.

Would you recommend that HHS support such a policy?

Answer. I am certainly aware of the unique challenges that the Puerto Rico Medicaid program faced even before the hurricane. Of course, these challenges are compounded following such a serious storm. Much of the Medicaid funding can only be addressed by Congress, and, if confirmed, I stand ready to assist Congress.

Question. My office has heard multiple reports that the FDA is not only seizing prescription drugs ordered by Floridians from outside of the United States, but is also raiding Florida storefronts that reportedly provide mostly seniors in-person assistance with buying necessary prescription medications from Canada and other countries.

While I appreciate that the importation of foreign prescription drugs is illegal under most circumstances to control the safety of our supply the chain, the Federal Government announced in 2006 that it would stop seizing small amounts of prescription drugs ordered from Canadian pharmacies.

That announcement was put in place at my urging, and it has allowed U.S. residents—again, mainly seniors—to save on the cost of their prescription drugs by ordering them online from pharmacies in Canada, instead of filling them at pharmacies in the United States.

To the best of my knowledge, no new FDA policies have been announced, yet these reports suggest a major shift in policy. I appreciate the need to keep dangerous drugs like fentanyl and counterfeit pharmaceuticals out of our country, but my constituents are confused about why they're receiving a seizure notice instead of their necessary medications.

Are you aware of this issue? Is there anything HHS can do to help shed light on what's going on in Florida?

Do you know if there has been a change in policy? I sent a letter to the FDA last month asking that same question, and I have yet to receive a response.

Do I have your commitment that, if confirmed, you will help get to the bottom of this?

Answer. I appreciate your bringing this issue to my attention. If confirmed, I will work with the FDA to provide answers to your questions.

Question. The opioid crisis is devastating families across the Nation. In Florida alone, 5,275 opioid-related deaths were reported in 2016—35 percent more than reported in 2015. Fentanyl killed 1,390 Floridians, nearly double the 705 Floridians killed by fentanyl a year before. I've long said that we need a comprehensive approach to prevent and treat the opioid epidemic before more lives are lost. But we can't do that without investing sufficient resources so that our communities can fight back.

As the President's chief advisor on issues like these, would you advise him to work with Congress to ensure that State and local governments receive the funding they need to fight the opioid crisis?

Answer. I know that the President is committed to fighting the opioid epidemic. He has made it a top priority of the administration, and I look forward to working with him and Congress to ensure that State and local governments are equipped with the tools they need to fight the opioid crisis.

Question. I am an original cosponsor of the Combating the Opioid Epidemic Act, which would appropriate about $45 billion to address the opioid epidemic. This is the same amount of funding proposed by Senate Republicans as part of the ACA repeal. Do you believe that more Federal funding assistance is necessary to improve the response to the epidemic?

Answer. If confirmed, I look forward to working with Congress to ensure that we are well-equipped to fight the opioid epidemic.

Question. What actions will you take, if confirmed, to improve the agency's response to the epidemic?

Answer. The opioid epidemic is a top priority at the Department. If confirmed, I look forward to being briefed on all the activities already underway and learning what we need to do to work more collaboratively and push forward solutions to this crisis.

Question. The Affordable Care Act includes a number of provisions designed to help improve and increase treatment for individuals addicted to opioids. For example, it requires health plans offered through the ACA marketplace to cover substance use disorder treatments as an essential benefit. The law also prohibits insurers from discriminating against folks with pre-existing conditions, including addiction. Yet my Republican colleagues tried repeatedly to undermine these protections as part of larger ACA repeal efforts. Do you support these provisions?

Answer. I believe that Americans should have access to the health care they need. I defer to Congress on how this should be achieved. As I have said, I believe that individuals with opioid use disorder should have access to treatment and recovery services. If confirmed, I look forward to ensuring that the Department is doing all it can to promote and advance treatment for individuals addicted to opioids.

Question. The ACA also expanded Medicaid, the single largest payer of substance abuse services in the country; an action that the State of Florida refuses to take despite the fact that it could help over 800,000 Floridians and bring billions to the State's economy.

Expansion aside, Medicaid plays a critical role in the fight against the opioid epidemic. Changing the Medicaid program through block grants or caps will shift costs to States, eliminate critical Federal protections, and hurt the more than 3.5 million Floridians who rely on the program, including those addicted to opioids.

Do you support these cuts to the Medicaid program through block grants, caps, or other proposals? If those cuts are made, how do you propose States like Florida provide the necessary services to help individuals with substance use disorders?

Answer. As I said above and before the committee, the details around financing and flexibility are key to evaluating any block grant reform approach, including those proposed last year. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for individuals with substance use disorders and all Americans who rely on it.

Question. Over 5,613 cases of Zika virus have been reported across the U.S. States and territories. No State has been hit harder by the Zika outbreak than Florida. The State has seen more than 1,708 reported cases of the Zika virus to date and reported 239 new cases of Zika in 2017. Last year, I fought to secure funding to address the Zika crisis. Unfortunately, the administration's 2018 proposed budget slashed many of the very programs Congress voted to fund in 2016 so they could help prevent, control, and research the spread of Zika.

The administration is expected to release a new budget for 2019 in the coming months. I want to know whether you support the cuts to programs and agencies critical to defending our constituents from the Zika virus, and other vector-borne diseases in 2018? Would you recommend that the administration make similar cuts in its 2019 proposed budget?

It took months since President Obama made his initial request for Congress to strike a deal to provide $1.1 billion to fight Zika. That delay is simply unacceptable, and we know better than to expect infectious diseases to stop with Zika.

Last year, I joined Senators Cassidy and Schatz in introducing a bill to fund the nearly empty Public Health Emergency Fund through mandatory appropriations designated as emergency spending modeled after FEMA's disaster relief fund.

Do you support the creation of an emergency health fund to provide mandatory appropriations to fight Zika and other infectious diseases? Do you have a better so-

lution to respond to these threats and to avoid the months of partisan roadblocks we encountered?

Answer. I was not at the Department during the development of the FY 2018 President's budget, so I am unable to comment on the basis for the budget decisions that are embodied in that document. Likewise, with respect to the FY 2019 President's budget, if the schedule for preparation of the budget is similar to the schedule followed when I was Deputy Secretary, most of the decisions with respect to the FY 2019 budget have already been made, given that it is likely to be released early in February of this year, so even if confirmed, I am unlikely to have any opportunity for input on the FY 2019 budget. I do understand that developing the 2018 budget required the Department to make tough choices about HHS programs and administration priorities. The 2018 budget proposed to support priority activities within an overall lower level that reflected a new approach to long-term fiscal stability across the Federal Government. It is also my understanding that the FY 2018 President's budget proposed a Federal Emergency Response Fund to enable the Department to address emergency situations, including to prevent, prepare for, or respond to an emerging infectious disease—the very situation that you identified. I understand that the FY 2018 budget also included a proposal for an enhanced transfer authority in emergencies, so that the Department would not need to wait for an emergency supplemental appropriation before it could begin responding to the emergency situation.

Question. I have long been a supporter of the Maternal, Infant, and Early Childhood Visitation program (MIECHV). The MIECHV program, enacted as part of the Affordable Care Act, aims to help States have the capability to provide in-home visits to at-risk parents and families to ensure that families remain united and children's developmental and early education needs are met. The program was last reauthorized for 2 years in 2015, and its authorization expired on September 30, 2017.

In Florida, the MIECHV program is implemented through public-private partnerships, with 27 sites around the State. They receive $11 million annually to support home visiting programs.

There have been bipartisan efforts to extend the funding for MIECHV, including S. 1829, of which I am a cosponsor. Reauthorization language has also been introduced in the House, however House Republicans have been advocating for several problematic policy changes including a State match requirement. This would put States on the hook for funding part of the program and many may be unable to meet this obligation, putting the program at risk should States not have enough funding to keep it going.

Do you support preserving this important evidence-based program and ensuring families have access to it?

If confirmed, would you oppose efforts to require States to provide matching funds in order to access Federal MIECHV dollars?

Answer. If confirmed, I look forward to working with members of Congress from both sides of the aisle on the reauthorization of the Maternal, Infant, and Early Childhood Home Visiting Program.

Question. The ACA reauthorized the Minority Centers of Excellence (COE) program, housed within the Department of Health and Human Services. The Florida Agricultural and Mechanical University (FAMU) Pharmacy, located in Florida, is a grantee. COE supports curriculum-based initiatives for increasing minority and underrepresented individuals to become health professionals.

Do you support preserving important programs like COE, Health Careers Opportunities Program, and Area Health Education Centers?

Answer. Encouraging minorities and other underrepresented individuals to become health professionals is an important piece of helping to address the shortage of health professionals across the health-care spectrum. If confirmed, I look forward to being briefed and learning more about these programs and others aimed at increasing minority health professionals.

Question. In 2015, the Precision Medicine Initiative (PMI) was launched, a research effort designed to advance biomedical discoveries and accelerate the development and delivery of optimal, tailored treatments to all patients. The All of Us Research Program (formerly Precision Medicine Initiative Cohort Program) will build a national research cohort of at least 1 million volunteers who will participate in a longitudinal effort to identify the factors that contribute to disease.

In September 2015, the Precision Medicine Initiative Working Group of the Advisory Committee to the Director recommended that NIH consider how to best incorporate necessary safeguards to ensure appropriate enrollment, retention and protections for children and other special populations.

In July of 2017, NIH launched the Child Enrollment Scientific Vision Working Group (CESVWG), which was charged with supporting the program's efforts to develop the approach for including pediatric populations. The CESVWG was tasked with releasing a report, which is pending. In September that same year, the CESVWG sought public input to inform its work. The CESVWG is the first of two groups; the second work group will examine the practical considerations of child enrollment and data collection involving children.

If confirmed, will you work with NIH to provide a timely update regarding the following:

- The date for the release of the report from the Child Enrollment Scientific Vision Working Group;
- The expected date for impaneling the second work group on child enrollment and data collection involving children;
- The targeted number of children for enrollment in the All of Us Research Program; and
- How enrollment will include participation from pediatric health systems with experience in pediatric clinical trial enrollment?

Answer. Yes, I commit to working with NIH to provide you with updates on these issues.

Question. For the past several sessions of Congress, I have introduced the Resident Physician Shortage Reduction Act of 2017 (S.1301), which would increase the number of residency positions eligible for Medicare GME support. The legislation would increase the number of residency slots nationally by 3,000 each year, from 2019 through 2023, for a total of 15,000 slots. The creation of these slots would ensure that America remains at the forefront of biomedical research and medical education. Senator Heller and I have introduced this bill in a bipartisan manner.

Medicare funding for training doctors has historically been stable and reliable, and should remain so. Our teaching hospitals and the pipeline of physicians are too important to put at risk. In fact, we need to pass S. 1301 and increase the level of support for GME in this country.

Can you describe how, as Secretary of Health and Human Services, you would ensure that funding for GME and America's teaching hospitals is protected and expanded?

Answer. Under the Medicare program, teaching hospitals or hospitals that train residents in approved medical allopathic, osteopathic, dental, or podiatry residency programs receive direct graduate medical education payments that reflect the direct costs of operating approved residency training programs. Within the statutory parameters of these payments, there are programs designed to support physician training in areas with primary care shortages. If confirmed, I look forward to working with Congress to support health workforce training that develops practitioners in professions with pronounced shortages and in underserved areas.

Question. Mr. Azar, last year, CMS proposed a new payment model for Medicare's home health patients. The proposed model from CMS, called the Home Health Groupings Model, has never been piloted or demonstrated. I, along with many other Senators and House members, wrote to CMS to let them know that we had heard from stakeholders who were concerned that the proposed rule lacked enough information to allow home health agencies to accurately estimate the model's impact. Thankfully, the Department did not finalize the policy as proposed, citing a need for more stakeholder input.

Are you familiar with the importance of home health in our Nation's health-care system, and can you commit to moving forward with the stakeholder involvement process?

Answer. Providing Medicare beneficiaries access to quality care in a setting that works best for their individual needs is an important priority for the program and for me. If confirmed, I look forward to working with stakeholders to better understand their perspective on CMS regulations, in particular those affecting home health care.

Question. Amyotrophic Lateral Sclerosis or ALS is a progressive disease that gradually leads people to lose control of their muscles. They may stop walking, speaking, eating, moving, or even breathing. To date, there is no effective treatment or cure for ALS. Most important is that the incidence of ALS in the military is twice that of civilians. It affects as many as 30,000 Americans, and 5,000 new cases are diagnosed each year.

The Centers for Disease Control and Prevention (CDC) is home to the ALS Registry, which was created by the bipartisan ALS Registry Act of 2008 signed into law by President Bush. The Registry serves several critical purposes, including alerting patients with ALS to clinical trials, as well as fostering collaboration within the Federal Government. The ALS Registry has received bipartisan support and is funded with an appropriation of $10 million. Without the registry, research on ALS would be set back considerably.

Can you provide reassurance that you will do all you can to support the Registry by requesting funds in the President's 2019 budget?

What else do you think CDC and/or the Department of Health and Human Services can do to support the fight to find a cure and treatments for ALS?

Answer. ALS is a serious disease, and I commit to working with the Department on the registry and finding cures and treatment.

Question. More than 650,000 Americans have ESRD—which occurs when the kidneys are no longer able to work at a level needed for day-to-day life—and require dialysis treatment. These individuals typically have many health problems, are at a higher risk of hospital readmissions, and receive fragmented care. Individuals with ESRD, regardless of age, are eligible for Medicare in most cases. In 2012, ESRD beneficiaries accounted for 1.1 percent of the Medicare pool, but 5.6 percent of total Medicare spending.

Late last year, I joined Senators Young, Heller, and Bennet in reintroducing S. 2065, the Dialysis Patient Access to Integrated-care, Empowerment, Nephrologists, Treatment, and Services (PATIENTS) Demonstration Act, which would establish a 5-year pilot program where groups of eligible providers would form an integrated care model to serve as the medical home for ESRD Medicare beneficiaries.

If confirmed, would you support patient centered models of care that allow people with ESRD to receive holistic health coverage, like the model we have created in the PATIENTS Act?

Answer. We share the goal of improving Medicare by empowering providers to be creative and developing payment models that best suit the unique needs of their patients to ultimately improve patient care. If confirmed, I would look forward to working with CMS and Congress in examining these alternative approaches. As I said in my opening statement to the committee, we must make health care more affordable, more available, and more tailored to what individuals need in their care, including those with very serious chronic conditions such as ESRD. If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

Question. The dialysis facilities were the first to agree to a value-based performance system and worked closely with the Congress and CMS to make sure that it worked for patients, physicians, and providers. However, it is my understanding that the number of quality programs has expanded to include a duplicative five star reporting system that uses a different methodology for assessing quality performance and different measures than the QIP program. Patients have raised concerns that the dueling programs are confusing and make decision-making more difficult. MedPAC has urged CMS to eliminate the five star program and rely upon the Congressionally mandated, publicly reported QIP.

What will you do to address this problem and reduce the confusion that patients experience?

Answer. Dialysis Facility Compare on the *Medicare.gov* website provides information about the quality of dialysis facilities and publishes data on thousands of Medicare-certified dialysis centers across the country. It is my understanding that CMS added the five star ratings in 2015 to Dialysis Facility Compare with the goal of improving the usefulness of quality information for consumers. Star ratings are intended to enhance and supplement existing publicly reported quality information, which will continue to be available. Star ratings can help consumers quickly identify

differences in quality when selecting a dialysis facility, as well as help existing patients understand how CMS measures quality for this program.

It is important that Dialysis Facility Compare and the Five Star Rating system meet the needs of individuals with kidney disease and their caregivers, groups and individuals who advocate on behalf of kidney patients, health-care providers, and others who may be involved in helping a patient have a better understanding of the care they receive. It is my understanding that CMS is continually working on improvements to Dialysis Facility Compare and the Five Star Rating system and welcomes stakeholder feedback. I believe patients need access to high quality, accurate and informative quality data. If confirmed, I will work with CMS to ensure that beneficiaries can easily access clear information on the quality of dialysis facilities.

Question. The Department of Health and Human Services has a special responsibility to ensure that survivors of the Holocaust receive the specialized care they need.

If confirmed, will you commit to working with me to better support Holocaust survivors? Also, will you commit to support funding of the Holocaust Survivor Assistance Fund at a level sufficient to address survivors' unique needs?

Answer. I am not familiar with the current state of the Holocaust Survivor Assistance Fund, but I look forward to working with you to ensure adequate support for Holocaust survivors.

Question. CT colonography (CTC), also known as virtual colonoscopy, are diagnostic medical tests, which produce detailed images of the colon by using a combination of 2-dimentional x-rays and a 3-dimentional computer views. They have the ability to identify lesions and tumors on the kidneys and other organs and blockages in the coronary arteries.

Currently, Tricare and all major private payers in the majority of States (37) cover CT colonography/virtual colonoscopies for colorectal cancer screening, but Medicare does not.

Will you use your authority as Secretary to consider the addition of CT Colonography/virtual colonoscopies as a colon cancer screening option for Medicare beneficiaries?

Answer. If confirmed as Secretary, I will work with Congress and the CMS team to ensure that the coverage determination process works well to ensure that Medicare beneficiaries have appropriate access to items and services reasonable and necessary for diagnosis and treatment of colorectal cancer.

Question. During the public comment period for the FDA's tobacco deeming rule, the Small Business Administration's Office of Advocacy filed concerns that the economic impact analysis conducted by the FDA was "deficient" and should be recalculated. Small business premium cigar retailers in my State have expressed the same concern to me. To date, the FDA has taken no action to address these concerns.

Do you believe additional review of the costs of this regulation should be conducted before any additional implementation?

Answer. That previous analysis was conducted under the prior administration. While I can't speak to their analysis, if confirmed, under my leadership the Department and our agencies will ensure our analysis is complete and incorporates the true impact regulations will have. I certainly support the steps Commissioner Gottlieb has taken regarding the regulation of nicotine in cigarettes, and I believe he shares my view that such regulations must be done in a reasonable way. Further, it is my understanding that the agency is in the process of evaluating prior regulatory proposals on premium cigars, and I commit to updating you on the analysis, if confirmed.

Question. Mr. Azar, as you know the Health Insurance Tax has been suspended in the past, and could be suspended again. Should you be confirmed as Secretary, how will you ensure that any savings from any further suspensions or changes to the tax are fully passed on to policyholders, including beneficiaries in the Medicare Advantage program?

Answer. I understand that the Internal Revenue Service is responsible for the collection of the Health Insurance Tax, but Congress will ultimately decide whether or not the Health Insurance Tax remains in effect. If confirmed I stand ready to implement the laws as passed by Congress.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Do you believe that repealing the Affordable Care Act without a workable plan in place is a responsible course of action?

Answer. The President has supported various efforts to replace the ACA system with other systems that would make insurance more affordable, available, and tailored to the needs of the individual. 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. However, any changes to the Affordable Care Act would need to come from Congress. My role as HHS Secretary, if confirmed, would be to faithfully implement the laws as passed by Congress. If confirmed, I will work, within HHS as well as with the Department of Labor and across the executive branch, to create a health insurance system that is more affordable and responsive to the needs of individuals, where they can choose the type of insurance coverage that works best for them.

Question. Are you aware of a document of options prepared by HHS for a March 23, 2017 meeting between then-Secretary Price and members of Congress? Are you aware of the document listing out ways the administration can undercut the Affordable Care Act? Is it the role of the executive branch to undermine existing law or to implement laws as passed by Congress?

Answer. I am only aware of the contents of this document from published press reports following Senator Casey's disclosure of the document. If confirmed, I would remain fully committed to implementing the laws and regulations that guide our Nation's health-care system. I look forward to working with Congress on the best way to achieve our shared goals.

Question. How will you, if confirmed, ensure people will have insurance that provides comprehensive coverage?

Answer. We must make health care more affordable, more available, and more tailored to what people want and need in their care. Under the status quo, premiums have been skyrocketing year after year and choices have been dwindling. An insurance card is no guarantee of access to quality care. We must address these challenges for those who have insurance coverage, and for those who have been pushed out or left out of the insurance market by the Affordable Care Act.

Question. In your testimony and during the hearing you indicated support for a model that will give consumer's choice, lower costs, and access to their choice of provider. What would that model of health care look like?

Answer. If confirmed, I will work, within HHS, as well as with the Department of Labor 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 health-care system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them including reliable association health plans and the option of short-term, limited-duration insurance.

Question. Do you believe charity care and community health centers can provide lower-income Americans the care they need to maintain their health and lead successful, productive lives? In fact didn't you say on the Fox Business Network in March, "That's one of the beauties and has been for the longest time of our system, that we really do take care of those who can't afford to have insurance. They still have access to care. Listen, it's still better for people to have insurance."

Rather than support people having access to preventive care, you think having those without insurance rely on charity care, community health care centers, is a better use of Federal resources?

Answer. If confirmed, I look forward to working to find ways to make health care more affordable, available, and tailored to what individuals want and need in their care. I will support community health centers that deliver comprehensive, affordable, high-quality primary health-care services, including preventive health services, to nearly 26 million people nationwide and make services available to residents of their service area regardless of ability to pay.

Question. As you may be aware, funding for Community Health Centers lapsed in September and the last CR provided temporary funding.

Do you support strong funding for health centers?

What will be your strategy to ensure they have the funding and support needed to continue to thrive in their communities?

Answer. I am committed to working with Congress to ensure that community health centers continue to be funded, so that they can increase access to primary care. If confirmed, I look forward to working to find ways to make health care more affordable, available, and tailored to what individuals want and need in their care.

Question. You previously criticized the ACA's Medicaid expansion. The Medicaid expansion was critical to expanding health care coverage to millions of Americans, including over half a million in New Jersey.

Do you have a workable solution to provide coverage to the millions of Americans who will lose their coverage if Medicaid expansion is repealed?

Do you think, especially with the changes to the tax bill, that charity care can fill that gap nationwide?

Answer. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. We need to customize our programs and benefits to the characteristics of our beneficiaries. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

Question. The Affordable Care Act remains the law of the land—will you ensure that law if followed or will you work to undermine it and rip health insurance away from millions of Americans.

Answer. Any significant changes to the Affordable Care Act would need to come from Congress. If confirmed, I will faithfully execute the laws as passed by Congress with the goal of making insurance as affordable, available, and tailored to the needs of the individual as is possible within the statutory constraints of the ACA. As I have said previously, we need a health insurance system that is responsive to the needs of individuals and their families, and the current system is not working as well as it could or should.

Question. The Autism CARES act has provided invaluable research funding for autism. This bipartisan legislation expires soon and I plan on reintroducing the bill in the coming weeks. In that vein, I have several questions about the commitment of HHS to improving outcomes for those with autism and other developmental conditions.

The President's HHS budget for FY18 substantially reduced Federal funding authorized by the Autism CURES Act, which includes training programs, research, and State systems grants. Will you commit to funding these programs as Congress intended under the Autism CURES Act, and to address areas that have been historically underfunded, including services research?

New Jersey's autism rate is the highest in the country. For children from lower income families Medicaid, CHIP, and the ACA provide critical access to care. Do you believe a patchwork of safety net providers and charity care can adequately provide the services and support for families with children and adult children who have special needs?

Access to timely interventions has proven to mitigate autism's disabling symptoms. However, children of color still lag in their access to interventions. What will you do to address this?

Every year 50,000 children enter adulthood, losing their school-based services and aging into adult services funded by Medicaid.

How will you improve outcomes for transition-aged youth that address the different needs of each youth based on the severity of their autism?

Answer. I am committed to fully implementing the laws passed by Congress and would ensure any provisions enacted related to autism are properly implemented. I believe that all Americans should have access to the health care they need and look forward to working with Congress on policies that address this goal. I am committed to ensuring that our fellow citizens in historically disadvantaged communities, especially racial and ethnic minorities, have equal access to quality and affordable medical care, health, and wellness as required by law.

Question. I am deeply concerned about recent cuts to the Prevention and Public Health fund. It is estimated that half of the CDC Immunization Program budget

is funded with Prevention Fund dollars. Cuts to the Prevention Fund threaten the remarkable progress we have made in public health.

As Secretary, will you commit to support and protect vital public health programs such as immunization, "yes" or "no"?

New Jersey was heavily impacted by the 9/11 terror attacks. The health consequences of that national tragedy were not immediately apparent; many of those caught in the terror attack as well as our first responders have been impacted by the event. My Firefighter Cancer Registry Act of 2017 would establish a voluntary registry for firefighters at the CDC to track and collect cancer data. Can I count on you to work with me to ensure our first responders are able to get this registry and we can work to minimize the health consequences they suffer from due to their work?

What actions will you take to ensure that State and local health departments are properly resourced and equipped to handle routine immunization outreach and delivery efforts as well as respond to emergencies and disease outbreaks?

Answer. Vaccines are one of the greatest success stories in public health and are among the most cost-effective ways to prevent disease. I know the CDC plays a large role in supporting States, counties, and city and tribal health departments in their immunization infrastructure. If confirmed, I look forward to continuing this great work. I also would be happy to work with you on your bill related to a firefighter cancer registry.

Question. I am encouraged by provisions in the 21st Century Cures Act which require CMS's risk adjustment penalties in the Medicare Hospital Readmissions Reduction Program (HRRP) to account for the socioeconomic challenges of vulnerable patients. These changes represent an important step in ensuring equitable reimbursement for safety net hospitals. As HHS Secretary, how would you build upon the progress that has been made to better account for social risk factors in how Medicare pays hospitals?

Answer. Social risk factors play a role in health and health care, and the issue of how to account for social risk factors in value-based payment programs has been the subject of recent reports, including by the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services, the National Academies of Sciences, Engineering and Medicine, as well as a trial done by the National Quality Forum. Evaluation of this issue is ongoing, and I hope to review the research and work with stakeholders and Congress to determine the best and most equitable approach to this difficult issue. While we should hold providers accountable for achieving outcomes in value-based payment programs, we must ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible while ensuring that beneficiaries have adequate access to high-quality care.

Question. Mr. Azar, one of the important protections afforded families in the ACA is guaranteed maternity coverage. Do you support women having access to the maternity care they need regardless of income?

Answer. It is critical that every woman have access to high quality prenatal care.

Question. Do you feel HHS can take steps to address racial, ethnic, and socioeconomic disparities in health care? Will you commit to working with my office on these issues?

Answer. I believe that every person should have meaningful access to quality medical care. I am committed to ensuring that our fellow citizens in historically disadvantaged communities, especially racial and ethnic minorities, have equal access to quality and affordable medical care, health, and wellness as required by law. If confirmed as Secretary, under my leadership the Department will work to reduce unequal access to quality medical care through vigorous enforcement of our civil rights laws and through evidence-based analysis of health-care disparities and attention to the causes of such differences in people's health.

Question. Senator Grassley and I introduced our Maternal, Infant, and Early Childhood Home Visiting Program reauthorization bill last year and unfortunately the program's authorization lapsed after September. Can I count on your support for the MIECHV program?

Answer. If confirmed, I look forward to working with members of Congress from both sides of the aisle on the reauthorization of the Maternal, Infant, and Early Childhood Home Visiting Program.

Question. Mr. Azar, is *Roe v. Wade* the law of the land?

Answer. *Roe v. Wade* and its progeny, as currently interpreted by the Supreme Court of the United States, are controlling Federal precedents.

Question. Do you recognize that as Secretary of HHS you must apply the law and not what you wish the law to be?

Answer. Yes. If confirmed, I will consider the advice of the Office of the General Counsel when interpreting and applying the law.

Question. The Office of Refugee Resettlement has been in the news lately for their denial of access to those in their custody to reproductive services.

Will you commit to reviewing ORR policy to prevent undue delays for the individuals seeking to access reproductive health care services?

ORR Director Lloyd has personally intervened in these cases. Do you have concerns that his actions violate *Flores v. Reno*—which requires ORR to provide emergency health care and family planning services to those in their custody?

Can you commit to ensuring ORR is not wasting Federal resources to countermand established law? Can you commit to providing this committee an accounting of ORR resources and money being used by Mr. Lloyd in his personal interventions?

Again, can you put aside personal ideology and follow the law?

Answer. If confirmed as HHS Secretary, I will ensure that the Office of Refugee Resettlement is run in accordance with the Refugee Act, the Homeland Security Act, and the Trafficking Victims Protection Reauthorization Act of 2008, as well as other applicable Federal statutes and regulations.

Question. In your response to Senator Cardin's question regarding the Mexico City Policy, you stated that you were "not deeply familiar" with the implementation of the global gag rule during this administration as compared to previous ones. Under the previous iteration of the policy, roughly $600 million in global health assistance was at risk of being taken away. Now, under President Trump's version of the policy, nearly $9 billion in U.S. foreign aid is in danger of being denied to those in need for ideological and unscientific reasons. Do you believe that this policy best serves the interests of the United States to deny millions of people around the world access to health assistance?

Where do you believe there is room for you, as Secretary, to make an impact on our global health policy and ensure that these people receive the basic care that they need?

Answer. If confirmed, I will consult with the leadership of CDC and other HHS components who are implementing the expansion of the Mexico City Policy to all global health assistance and learn from them how it has been received by HHS's non-governmental global health grantees, including any challenges that may have arisen from the policy. I do not believe that President Trump's decision to modernize the Mexico City Policy to reflect the way family planning and global health assistance are integrated in our current foreign assistance structure, to the extent allowed by law, affects funding levels in any way, and that no patient loses access to critical HIV/AIDS services as a result.

If confirmed, I will continue the Trump administration's support for the Global Health Security Agenda because the American people are better protected from global health threats when other countries are able to detect, contain, and respond to them before they spread across international borders

Question. Of the funding put at risk by this new Global Gag Rule, roughly $6 billion is marked for HIV/AIDS programs across the globe, under the President's Emergency Plan for AIDS Relief (PEPFAR). This threatens the incredible progress that the global HIV community has made in combatting the epidemic over the past 15 years. What are your plans to ensure that all of the increases we have made in this fight will not be diminished?

Answer. I believe that the PEPFAR Program launched by President George W. Bush is one of the United States' most significant contributions to the public health of the American people and the world. The evidence of its success can be seen in the enormous numbers of lives saved by antiretroviral drugs and the prevention of new infections. I do not believe that President Trump's decision to modernize the Mexico City Policy to reflect the way family planning and global health assistance are integrated in our current foreign assistance structure, to the extent allowed by

law, poses a risk to the PEPFAR program. The policy is designed such that funding levels are not affected in any way, and that no patient loses access to critical HIV/AIDS services as a result. The policy includes reviewing implementation to ensure that these goals are met. If confirmed, I will work to implement the policy toward these goals as well, and to support PEPFAR and the Global Health Security Agenda so that the United States and the world are better able to prevent, detect, contain, and respond to the next big global health threat.

Question. As Secretary, what are your specific goals for HHS in combatting HIV/AIDS around the world and in the United States?

Answer. If confirmed, I am committed to ensuring HHS remains a world leader in HIV/AIDS prevention and treatment strategies and research. I look forward to reviewing both the National HIV/AIDS Strategy, as well as the National Viral Hepatitis Action Plan, and working with stakeholders to reduce new infections and improve access to care and treatment outcomes.

Question. A 2011 study by Stanford University found that the global impact of the Mexico City Policy led to increased abortions in African countries where U.S. global public health funding was cut the most. This was an unintended consequence of the lack of available family planning and contraceptive services that resulted from the cuts. Do you believe that the implementation of President Trump's Mexico City Policy will lead to fewer abortions in low-income countries around the world?

Answer. If confirmed, I will consult with the leadership of CDC and other HHS components who are implementing the expansion of the Mexico City Policy to all global health assistance and learn from them how it has been received by HHS's non-governmental global health grantees, including any challenges that may have arisen from the policy.

QUESTION SUBMITTED BY HON. ROBERT MENENDEZ AND HON. BILL NELSON

Question. In a December 22, 2017 letter we led with a bipartisan group of Senators, we asked CMS Administrator Verma to exercise her regulatory authority to address the immediate health-care needs of those residing in Puerto Rico. One item we emphasized in our letter was the importance of CMS recalculating Puerto Rico's Medicare Disproportionate Share Hospital (DSH) payments to account for the fact that DSH payments are based, in part, on the number of Medicare patients who are entitled to Supplemental Security Income (SSI) benefits and residents of Puerto Rico are ineligible for SSI. Will you work with our offices and the other offices on the letter to address the health needs of our fellow U.S. citizens in Puerto Rico?

In general, Medicare payments to Puerto Rico hospitals have historically been significantly lower than payments to hospitals in the States. This is particularly the case for Medicare Disproportional Share Hospital (DSH) payments. In light of the extreme hardship facing Puerto Rico hospitals at this time, would you be willing to revisit and reconsider the inclusion of low-income Puerto Rico Medicare beneficiaries when calculating Medicare DSH payments for Puerto Rico hospitals?

Answer. I am certainly aware of the unique challenges that Puerto Rico has faced even before the hurricane. Of course, these challenges are compounded following such a serious storm. If confirmed, I look forward to learning more about this issue, and working with Congress and CMS to address issues faced by Puerto Rico.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. In Medicare, Medicaid, and the private sector, health-care delivery and payment systems are seeing significant and accelerating change. Yet the Program of All-Inclusive Care for the Elderly (or PACE), which pioneered so many of the features we now seek to build into our health-care system, is being constrained by regulations that are almost a decade old. If confirmed, will you ensure that CMS updates these regulations quickly to provide more flexibility to PACE so that our medically frail seniors can have greater access to its gold-standard, proven and replicable model of integrated, community-based, and person-centered care?

Answer. It is my understanding that CMS is reviewing their existing regulations and taking steps to evaluate and streamline regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience

through their Patients over Paperwork initiative. If confirmed, I will work with CMS to make sure their programs achieve a balance between protecting patient safety and avoiding undue burden on providers. In addition, I look forward to hearing ideas from Congress and other stakeholders on how CMS can improve their programs to make sure beneficiaries have access to high-quality care that meets their needs.

Question. An important change in the proposed rule on PACE issued last August would explicitly allow physician assistants (PA) to be employees or contracted providers. While PAs currently manage patient panels across the Nation and provide high quality medical care to both Medicare and Medicaid beneficiaries with chronic care management, current rules exclude PAs from being an employee or contracted provider in the PACE program. If confirmed, will you continue work to strengthen the PACE program and ensure it is modernized in a way that effectively utilizes the PA profession?

Answer. I agree that Physician Assistants are a vital part of our health-care system. If confirmed, I look forward to reviewing the changes outlined in the proposed rule, and I will work with CMS to make sure we effectively utilize health-care professionals across its programs.

If confirmed, I also look forward to working with CMS, Congress, and other stakeholders to make sure beneficiaries with chronic conditions have access to high-quality care that meets their unique needs.

Question. Health information technology (health IT) is a rapidly developing field that is improving coordination and quality of care for millions of patients across the Nation, but also brings many challenges related to interoperability, security, data analysis and availability, and reporting requirements. As Secretary, you would oversee a Department that is not only responsible for modernizing our health IT infrastructure, via implementation of the 21st Century Cares Act, but also is a major public payor, and therefore can influence how other health-care stakeholders adopt next-generation health IT. In your view, how can the Department help accelerate interoperability in health IT, and improve the availability of specific data related to the Medicare program, which can help risk-based coordinated care providers, such as accountable care organizations, tailor their services to the specific needs of their patients and providers?

Answer. I agree that interoperable health information technology is one of the key enablers for improving cost, quality, and value in our health-care system. I believe that all individuals, their families, and their health-care providers should have appropriate access to electronic health information that facilitates informed decision-making; supports coordinated health care and case management; allows individuals and caregivers to be active partners and participants in their health care; and improves the overall health of the Nation. I also recognize that, as health information flows more freely through interoperable health IT to achieve these important goals, people need confidence that their health information is secure. I will be committed to working with HHS staff on both interoperability and information security, if confirmed as Secretary.

Question. You served at the Department of Health and Human Services during the initial implementation of the Medicare Part D program. That program has been successful ensuring that seniors have coverage for the medications that their doctors prescribe. In addition to covering to cost of drugs for seniors, the Part D law also included medication therapy management services to help seniors take their medications correctly and to obtain the greatest health-care benefit. Unfortunately, that part of the program has not been as successful as we had hoped. A recent report by the Medicare Payment Advisory Commission indicated that the medication therapy management programs are "falling short" of their goal to reduce unnecessary expenditures and improve quality. The report also indicated that physicians might be reluctant to accept recommendations on medication management from Part D drug plans.

Given that MTM in the Part D program isn't meeting its intended goals, what more should we do to help seniors use their medications effectively? Do you think we should do more to make sure proven medication adherence programs such as comprehensive medication management and medication synchronization are available to seniors in Medicare? How can we make sure that doctors and clinical pharmacists are collaborating to help Medicare beneficiaries take the right drugs in the right ways at the right times?

Answer. As I indicated my opening statement, one of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. The Center for Medicare and Medicaid Innovation will be a critical part of these efforts.

I understand that CMMI currently has an ongoing model, the Part D Enhanced MTM Model, which offers an opportunity and financial incentives for basic standalone Part D Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs in lieu of the standard CMS MTM model, aimed at improving the quality of care while also reducing costs. I believe CMS is also testing changes to the Part D program that aim to achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in MTM targeting and interventions. If confirmed, I look forward to coordinating with CMS as they work toward their goal of fostering an affordable, accessible health-care system that puts patients first.

Question. Secretary Sylvia Burwell laid out an ambitious goal to move our country's health-care system from a fee-for-service system that can result in waste and inefficiency to a value-based system to keep Americans as healthy as possible. Unfortunately, your predecessor took us in the wrong direction by dismantling Medicare programs that would reward health-care providers based on outcomes instead of the number of procedures performed.

How will you ensure that Medicare and Medicaid work together with our private health insurance system to increase efficiency, lower health-care costs, and improve health outcomes?

Answer. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. If we start from the principle of empowering patients and putting their needs first, we can reform our health insurance system to realize efficiencies, reduce health-care spending and improve patient care. If confirmed, I will strive to work with staff across HHS to make health care more affordable, more available, and more tailored to what individuals need in their care. I look forward to working with Congress and the staff at HHS to identify and execute reforms that will put patients and beneficiaries first and drive towards the value-based system you referenced and that we all desire.

Question. In the 2017 open enrollment period, almost 9 million Americans enrolled in health insurance plans through *HealthCare.gov,* demonstrating a clear need and interest in affordable health insurance plans as provided for under the Affordable Care Act.

How will you use the 1332 waiver program to provide States with additional flexibility to carry out the Affordable Care Act? How will you ensure that Americans will not lose their health insurance and that there is order and stability in the individual health insurance marketplace?

Answer. I would intend to use the 1332 waiver program to help States make insurance more affordable, available, and tailored to the needs of the individual. Our shared goal is to expand access to affordable insurance to as many Americans as possible and to ensure that this insurance is real insurance with access to real providers and that it meets their needs. State-driven innovation must be a top priority for the Department. I support continued efforts to use CMS's waiver authorities to test and evaluate demonstrations that can lower health-care costs or improve quality. These need to be approached carefully to avoid the potential for waste, fraud, and abuse, but an unwillingness to examine these areas makes us penny-wise and pound-foolish too often. If confirmed, I will work closely with CMS to ensure the continued support and the timely review of all State 1332 waivers received by HHS, and to make the waiver approval process more transparent, efficient, and less burdensome.

Question. Obesity, smoking, and social isolation are among our country's most persistent public health challenges, driving up mortality rates and resulting in more than half a trillion in health-care costs each year.

As the head of the Health and Human Services Department, how would you lower the rates of obesity, smoking and tobacco use, mental health illness, and substance abuse?

Answer. These are all complex public health issues that deserve our attention. I believe we must implement evidence-based programs and policies that are proven to make an impact in these areas. If confirmed, I look forward to working with the experts at CDC, NIH, FDA, and other agencies to learn about the work currently underway to address these public health issues. I commit to ensuring that we are leveraging our resources to the greatest extent possible to make advances in these areas.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

KIDNEY CARE

Question. Stabilizing the Medicare ESRD Payment Program. While the number of Americans living with kidney failure is relatively small when compared with other chronic diseases, the Federal Government has made a big commitment to ensuring that these patients have access to the highest quality care. Currently, patients have a choice as to whether to maintain private insurance at the onset of their disease for a period of time or enroll into Medicare immediately. This choice is important and should be preserved, but it also demonstrates that the Federal Medicare program is critically important to these patients who require 3–4 dialysis sessions per week to manage their chronic condition. These sessions may occur in dialysis facilities or in the home. The current Medicare payment system, however, does not cover the cost of providing these services. Since the inception of the program there have been concerns about dollars being removed from the program because of a flawed methodology for calculating the rate. I have called on CMS to fix this problem in my legislation, the Chronic Kidney Disease Improvement in Research and Treatment Act (S. 1890) as well. Can you describe how CMS will fix this problem to work to ensure that the rates are set in a manner to ensure adequate payment and protect access to these life-sustaining services?

Answer. I share your concern for patients suffering from ESRD, and, if confirmed, look forward to working with you in this area. My understanding is that, by statute, dialysis facilities are paid a single bundled payment for each dialysis treatment that will cover all renal dialysis services and home dialysis furnished to Medicare beneficiaries with ESRD. The bundled payment includes all renal dialysis services furnished for outpatient maintenance dialysis, including drugs and biologicals (with the exception of oral-only ESRD drugs until 2025) and other renal dialysis items and services that were formerly separately payable under the previous payment methodologies. The bundled payment rate is case-mix adjusted for a number of factors relating to patient characteristics. There are also facility-level adjustments for ESRD facilities that have a low patient volume, for facilities in rural areas, and for wage index. For high-cost patients, an ESRD facility may be eligible for outlier payments. In addition, facility payments for dialysis services are linked to how well the facility performs under the ESRD Quality Incentive Program (QIP). Under the ESRD QIP, payments to facilities under the ESRD PPS are reduced by up to 2 percent if facilities do not meet or exceed a minimum total performance score with respect to performance standards established by the Secretary with respect to certain quality measures for a given year. I believe significant changes to the payment structure of the program would require congressional action. If confirmed as Secretary, I will work with you, with CMS, and with stakeholders to ensure we are doing everything we can as a Department and an agency to ensure CMS reimbursement policies are structured in a way to maximize the quality of care provided to these particularly vulnerable beneficiaries.

EMERGENCY HEALTH SERVICES

Question. I led the effort in Congress in the mid- to late-90s to ensure Medicare and Medicaid provided coverage for emergency services without prior authorization and established a Federal "prudent layperson standard." This standard defines an "emergency medical condition" as one that manifests itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy, serious bodily functions, or serious dysfunction of any bodily organ or part. This important patient protection was extended to all Federal health plans by executive order in 1998 and through congressional action to ERISA [group and individual market] plans in 2010. Do you support this Federal policy?

Would you agree that we don't want patients trying to self-diagnose?

Will you ensure the Department of Health and Human Services continues to enforce the prudent layperson standard?

Answer. It is my understanding that the law requires that if group health plans and health insurance issuers cover any benefits with respect to services in the emergency department of a hospital that the plan or issuer must provide those benefits without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis. If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

DENTAL COVERAGE

Question. Each year American children, nursing home residents, and other adults die because of dental infections. OHA cites the case of 12-year-old Deamonte Driver of Maryland, who died of complications resulting from untreated tooth decay in 2007. If confirmed, what steps will you take to ensure all Americans, young and old, poor or rich, educated or non-educated, receive dental insurance to cover dental services such as exam, cleanings, fillings, and extractions?

Answer. The serious health risks and costs associated with untreated oral disease are increasingly apparent. Not only can poor oral health lead to serious pain and impact the types of foods seniors need to eat to stay healthy, tooth decay may exacerbate diabetes, arthritis, and heart disease. Additionally, dental disease may preclude, delay, or even jeopardize the outcome of medical treatments such as organ and stem cell transplantation, heart valve repair or replacement, cancer chemotherapies, and placement of orthopedic prostheses.

Many oral health complications, such as tooth decay, are largely preventable. Yet, tooth decay continues to be one of the most common chronic conditions among children, with the propensity to significantly impact a child's quality of life by causing pain and interfering with a child's ability to speak and learn. As such, it is critical that we protect children's access to high-quality pediatric dental care.

If confirmed, I would work with CMS, IHS, and other parts of the Department to ensure every single American has access to the coverage they want for themselves or their children and dependents. In addition, I would aim to provide States with flexibility in their Medicaid programs to provide both coverage and access to these services. I would also welcome ideas from Congress and other stakeholders regarding opportunities to encourage innovation in both the coverage and payment for these services.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN AND HON. DEBBIE STABENOW

Question. Under the Patient Protection and Affordable Care Act, dental coverage for children is categorized as an "essential health benefit." As a result, oral health is viewed as an integral part of overall health and 8 million children are guaranteed a dental benefit. What is your position on preserving pediatric dental as an essential health benefit?

Answer. It is important that every child has access to high-quality health coverage and that we make health care more affordable, more available, and more tailored to what individuals want and need in their care. Access to oral health care for children is indeed an integral part of that, as tooth decay continues to be one of the most common chronic conditions among children.

If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

Question. The Children's Health Insurance Program (CHIP) is a successful bipartisan-supported Federal program that provides dental coverage to children. Coverage under CHIP includes: dental visits, cleanings, fluoride, sealants, and fillings. The Senate Finance Committee passed S. 1827, the Keep Kids' Insurance Dependable and Secure (KIDS) Act of 2017 with bipartisan support. The Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) recently completed a preliminary estimate of the budgetary effects of extending funding for CHIP for 10 years using the parameters set out by the KIDS Act. The agencies estimate that enacting such legislation would decrease the deficit by $6 billion over 10 years. Do you support a long-term extension of funding for CHIP that provides 9 million chil-

dren and 370,000 pregnant women with affordable, age-appropriate health coverage, including a guaranteed dental benefit?

Answer. As I said above, it is important that every child has access to high-quality health coverage. CHIP plays an important role in accomplishing this objective. HHS should work with Congress and with States to ensure that the CHIP program provides the best possible coverage to children in each State.

Question. Over 55 million Americans rely on receiving health-care coverage through Medicare. In his announcement to run for President, President-elect Trump promised to "Save Medicare, Medicaid, and Social Security without cuts" and continued to make this promise throughout his campaign. Do you agree with President-elect Trump's statements, and what is your vision for the future of Medicare? Specifically, what changes do you believe are needed in Medicare and does your vision include the addition of an oral health benefit to improve the overall health of seniors?

Answer. Oral health is an important aspect of general health and well-being. My understanding is that Medicare pays for dental services that are an integral part either of a covered procedure (*e.g.,* reconstruction of the jaw following accidental injury) or for extractions done in preparation for radiation treatment for neoplastic diseases involving the jaw. Additionally, many seniors in Medicare Advantage plans receive additional dental benefits, depending on the structure of their plans. If confirmed, I will faithfully implement the law to ensure that Medicare covers medically necessary oral health care.

I think one of the best ways to drive down costs without harming beneficiary access to care is to improve how we operate Medicare using a more value-driven approach. We need to make sure Medicare can serve future generations, and if confirmed, I will work with CMS, Congress, and other stakeholders to make sure we come up with the right approaches to work towards this goal.

CMS VACANCY FOR CHIEF DENTAL OFFICER

Question. The Chief Dental Officer vacancy at the U.S. Centers for Medicare and Medicaid Services (CMS) is of significant concern to the oral health community because the chief dental officer is charged with providing oral health expertise and support for Medicaid and the Children's Health Insurance Program (CHIP). Ensuring that children who are eligible for Medicaid and CHIP have access to appropriate, comprehensive, and preventative dental care is vital to achieving healthy communities. Will you make it one of your top priorities to fill the vacant chief dental officer position at CMS?

Answer. I share your interest in bolstering access to dental care for all Americans, in particular children. If confirmed, I look forward to reviewing the staffing needs of CMS and maximizing the Department's resources to fulfill our mission.

GLOBAL HEALTH

Question. The United States is one of over 50 countries that have committed to the Global Health Security Agenda, which aims to help countries improve their capacity to prevent, detect, and respond to infectious disease outbreaks. As Secretary, what specific actions will you take to advance the Global Health Security Agenda?

Answer. I am very supportive of U.S. participation in the Global Health Security Agenda and believe this global work is critical to protecting the Nation's public health. I believe it is important to continue to build support for the GHSA by encouraging the participation of more countries and ensuring that existing members of the partnership are undergoing transparency and evaluation efforts pursuant to the framework to which we all agreed. If confirmed, I will work with leaders on this issue both at HHS and at other Departments and agencies to build upon the achievements to date.

Question. What role do you see for HSS in supporting and enhancing global efforts to detect, prevent, and respond to diseases internationally to prevent them from becoming a threat to the United States? How do you plan to coordinate these efforts with the efforts being undertaken at the Agency for International development to build capacity in developing countries along these lines?

Answer. Global health surveillance is critical to protecting the health of our citizens. With the expansion of international travel for instance, diseases can spread quickly between countries, including the United States. This fact requires all countries to take steps to provide adequate surveillance and put in place measures to

stop the spread of these diseases. If confirmed, I look forward to working with HHS's Office of Global Affairs and CDC, as well as with our partners at the Agency for International Development, to ensure that we are doing all we can to work with other countries to stop the spread of diseases internationally. This is a major goal of the President's Global Health Security Agenda.

Question. In your view, are we and our partners in the developing world any better off today in our ability to respond to another crisis, such as Ebola or Zika? If not, what steps are necessary to improve our readiness to respond to the next global health crisis?

Answer. I was not at HHS during the Ebola and Zika outbreaks, so I cannot speak specifically to the lessons learned during these crises. However, from my prior experience at HHS, I know that agency staff make it a practice to conduct a post-incident review—a "hotwash"—to review what happened and identify and act upon the valuable lessons learned from the incident and our response, so that we can better address the next crisis. We always have more to learn, and it is important to conduct a complete evaluation of any response so that we can build on our successes and address any shortfalls. If confirmed, I commit to working with individuals within HHS, including staff at CDC and ASPR, to understand what steps we need to take to improve our readiness to prevent, detect, and respond to the next potential global health crisis.

Question. The African Union and the United States signed a memorandum of cooperation in April of 2015 formalizing a collaboration between the African Union Commission and the Centers for Disease Control and Prevention in creating the Africa Centers for Disease Control and Prevention. The African CDC, headquartered in Addis Ababa, was officially launched in January 2017. What is your assessment of the capacity of the African CDC to undertake its mandate, which includes helping African countries to improve surveillance, emergency response, and prevention of infectious diseases, and build capacity to reduce disease burden on the continent?

Answer. I have not had the chance to review or assess the African CDC. However, as I mentioned above, I do believe it is critical to encourage the public health efforts of our global partners. If confirmed, I look forward to learning about efforts underway in Africa and ways in which our CDC can support the efforts of others around the world to increase their capacity to prevent, detect, and respond to public health threats.

Question. What actions do you believe the United States should take to help support the sustainability of the African CDC?

Answer. I have not had the opportunity to review the African CDC. However, I look forward to learning about it and taking steps to encourage the success of its work.

Question. U.S. global health and global health security assistance programs are vital for stopping outbreaks at the source, and U.S. leadership has been instrumental in catalyzing new funding from the private sector and other countries for countering biological threats. With the loss of Ebola supplemental funding for global health security in FY 2019, how will you support and ensure that CDC, and its deployed health security experts who are integral to our Nation's biodefense, remain well-equipped to extinguish outbreaks when they arise outside of the United States?

Answer. If confirmed, I look forward to assessing the current funding available and ensuring we are using the funds optimally in support of our Nation's biodefense. It is important to ensure that CDC is well-situated to provide surveillance of and support in extinguishing disease outbreaks. It is equally important that we encourage the efforts of our global partners to identify and manage these outbreaks as well.

Question. Will you protect and strengthen the existing CDC offices overseas experts, which are so important for stopping outbreaks at the source?

Answer. I believe it is important to have CDC officials overseas, and I look forward to learning more about where they are currently placed and ensuring our resources are used in the most optimal way. That said, I agree that the best security for the United States is when other countries are able to be strong partners in the Global Health Security Agenda, meeting the objectives of that partnership and building prevention, surveillance and response capacity. CDC is a key player in helping partner nations build that capacity.

Question. What actions will you take to maintain and build on existing U.S.-led efforts under the Global Health Security Agenda to identify gaps and leverage resources from the private sector and other countries?

Answer. I believe it is important to continue to build support for the GHSA here at home while also encouraging the participation of more countries. If confirmed, I look forward to learning more about the work HHS has already undertaken to promote global health security in the years since I led these efforts while at HHS. I am very supportive of efforts to engage the private sector in the important work of maintaining global health security and, if confirmed, look forward to partnering with other stakeholders.

Question. Reducing the threat of pandemics—whether naturally occurring, deliberately caused, or accidentally released—is inherently a cross-governmental function and a global security priority. How will you work with your counterparts, including within the Departments of State and Defense, to ensure close coordination and to continue to promote biosecurity as an integral component of the Global Health Security Agenda?

Answer. Collaboration internally and externally with other government agencies is critical to advancing global health security. I have experience working interdepartmentally, and I look forward to working closely with the Departments of State and Defense on these issues, if confirmed.

Question. What actions will you take to continue to promote the participation of national security officials within global health security-related activities sponsored by the U.S. Government?

Answer. As mentioned above, I believe it is critically important that all Federal partners are involved in global health security-related activities and believe that global health security issues can often become national security issues. If confirmed, I would work ensure that I have strong relationships with my counterparts at other Federal departments and agencies and will encourage HHS staff to do the same in an effort to secure participation from all necessary individuals as we advance global health security.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

MEDICAID, WORK REQUIREMENTS, AND THE DEFINITION OF "ABLE-BODIED ADULT"

Question. During your hearing, I asked you about what attributes define an "able-bodied adult." You responded that you haven't used this term and that it isn't something you don't have a definition for. Since that time, the Trump administration has released guidance to States on implementing work requirements within the Medicaid program—a proposal that is in direct contradiction to the objectives of the Medicaid program.

Do you agree with the administration's proposal to encourage and allow States to implement work requirements?

Answer. Yes, I believe that there is significant evidence that one of the best ways to improve the long-term health of low-income Americans is to empower them with skills and employment, for those who are able to work. I also believe that as States propose and experiment with solutions to encourage independence and work in their communities, we should ensure that program requirements are measured and conditioned on the particular individuals and their unique life situations. The goal is to lift people up out of dependency, and we can and should do this by applying common sense principles to improve people's lives. We still have a great deal to learn about how to best assist individuals seeking to move out of poverty. These waivers would empower States to adapt their Medicaid programs to the needs of their populations, and will provide valuable information to the rest of the country. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

Question. For the record, please define your interpretation of the phrase "able-bodied adult," as utilized by CMS in its recent guidance, to be used for differentiating between Medicaid recipients.

How would you define "able-bodied adult"?

Do you believe that an individual who has been diagnosed with cancer is, in your words, "able-bodied"?

Do you believe that an individual who has been diagnosed with severe mental illness is, in your words, "able-bodied"?

Do you believe an individual with a substance use disorder, such as opioid dependency, is "able-bodied"?

Do you believe an individual with an intellectual or developmental disability is "able-bodied"?

Do you believe a child aging out of the foster care system is "able-bodied" and should be required to work to continue to receive health-care benefits?

Answer. As I understand the CMS proposal, the agency has outlined a number of guardrails to ensure that the disabled and medically frail are not subject to work requirements. Importantly, States will still also need to abide by the Americans with Disabilities Act (ADA) and other civil rights laws. If confirmed, I look forward to ensuring that the work requirements and their associated guardrails are implemented with the goal of lifting people up and out of dependency and providing strong protections for those who are unable to work since these are important goals of this administration and the Medicaid program.

Question. Ms. Verma claims that this proposal is the Trump administration's way of responding to requests from Medicaid officials in several States that have expressed an interest in running demonstration projects to test work requirements. However, it was Ms. Verma who solicited applications from States to test work requirements in the first place (in an earlier guidance document). Do you think that this is an appropriate approach to changing a fundamental entitlement program?

Do you agree with Ms. Verma's assertion that work requirements are consistent with the goals of Medicaid, despite the Medicaid statute including no such element?

According to a recent analysis done by the Kaiser Family Foundation, approximately 60 percent of non-elderly Medicaid beneficiaries already work. Of those who are not employed, more than a third have a disability or illness, another third cares for young children, and approximately 15 percent are still in school. If confirmed as Secretary of HHS, will you support the continuation of this policy?

Answer. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. We need to customize our programs and benefits to the characteristics of our beneficiaries. While I have not been involved as a nominee in CMS's efforts to allow States to implement work requirements in their Medicaid programs, I do believe there is significant evidence that one of the best ways to improve the long-term health of low-income Americans is to empower them with skills and employment, for those who are able to work. As I said above, I also believe that as States propose and experiment with solutions to encourage independence and work in their communities, we should ensure that program requirements are measured and conditioned on the particular individuals and their unique life situations. The goal is to lift able-bodied adults up out of dependency and we can and should do this by applying common sense principles to improve people's lives. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

OPIOID EPIDEMIC AND FOSTER CARE

Question. Because of the addiction epidemic, many parents are unable to care for their children due to opioid use, long periods spent in treatment facilities, and the frequent drug relapses that are a part of this disease cycle. As a result, over the past 4 years, Ohio has experienced a 23 percent increase in the number of children served by the foster care system, and this number is expected to increase another 33 percent by 2020.

And it's not just the foster care system that's overburdened. Ohio's grandparents are also stressed—according to an article published in *The Columbus Dispatch* this past weekend, more than 100,000 grandparents are raising their grandchildren in Ohio—many because of the opioid epidemic. Ohio's child protection agencies are overwhelmed, families and grandparents are overwhelmed, and our children are suffering.

Given the way in which the Federal Government funds foster care, if confirmed as Secretary of HHS, what specific ways would you use your authority to address the drastic increase in the number of children that need foster care, kinship care,

and child welfare services, and prioritize keeping families together wherever possible?

What, if anything, will you do to change how current Federal programs and interagency efforts to address the foster care crisis work together to prioritize the needs of children, families, and communities?

How would you support grandparents and other relatives who have stepped-up to care for these children?

Answer. With the opioid crisis, supporting grandparents and relatives who act as primary caretakers in their families is an emergent need and one that the Substance Abuse and Mental Health Services Administration (SAMHSA) is committed to addressing in its programs and policy initiatives. If confirmed, I will encourage SAMHSA to collaborate with the Administration for Community Living to ensure complementary efforts. However, older adults raising children and youth have concerns that affect all areas of their family lives: education, transportation, primary health care, behavioral health care, financial stability, and for some, juvenile justice. Working together with our Federal partners, including the Department of Education, the Department of Justice, and the Department of Housing and Urban Development, we can help ensure that any programs and policy initiatives address the full range of needs grandparents and other caregiving relatives may have. Close coordination will ensure all efforts leverage the full range of resources across the Federal Government in ways that are non-duplicative and financially efficient.

MEDICATION ASSISTED TREATMENT

Question. During his tenure at HHS, Secretary Price said some concerning things about medication-assisted treatment (MAT), calling into doubt the science behind this type of treatment for substance use disorders. Beyond this specific example, many of us have found the Trump administration's general approach to scientific findings and scientific consensus concerning.

Mr. Azar, when evaluating the relative effectiveness of different programs and treatments, will you rely on scientific, evidence-based findings?

Answer. If confirmed, I commit to ensuring that HHS's work is based on scientific, evidence-based findings. That includes MAT, which is the gold standard in opioid addiction treatment.

Question. As you know, MAT is the use of medications (such as buprenorphine) in combination with behavioral therapy as a way of treating substance use disorders. A substantial body of literature supports the efficacy of MAT, and several of us on this committee—including my Ohio colleague Senator Portman—have worked together to increase access to MAT services as part of last Congress's CARA law.

Do you agree that, as part of a comprehensive strategy to address this epidemic, the government should do more to increase access to both the overdose reversal drug naloxone as well as products used for MAT services?

Given the data demonstrating that increased access to MAT leads to better outcomes for those individuals seeking treatment for a substance use disorder, Senator Markey, Senator Portman, and a number of other members worked hard to get a provision included in the CARA law that would allow certified physician assistants and nurse practitioners to obtain a waiver to prescribe buprenorphine to help treat opioid addiction.

Do you support HHS implementing this provision and, if confirmed, would you work to ensure implementation of this provision in a way that fully utilizes all eligible advanced providers, including as PAs and NPs, in providing MAT services?

If confirmed, what other specific actions would you take to expand access to naloxone and MAT?

Answer. I am supportive of expanding access to medication-assisted treatment (MAT). It is a critical piece of the strategy to address the opioid crisis, and HHS has recognized it as such. If confirmed, I look forward to working to ensure that MAT is available to those with substance use disorder.

THE COST OF ADDICTION TREATMENT

Question. As you have acknowledged in prior testimony, government-granted patent monopolies allow pharmaceutical companies to price-gouge consumers by taking

a decades-old product and jacking the prices up year after year. It happened with the EpiPen and it happened under your leadership at Eli Lilly, when you spiked the price of insulin. I have a bill—the Stop Price Gouging Act—that would prevent this sort of abusive practice by holding drug companies accountable for large price increases.

Pharmaceutical companies are also using this tactic when it comes to medications that can help individuals struggling with addiction. Take naloxone for example. Even though naloxone is a generic medicine that was first patented in 1961, the price for a pack of two auto-injectors in the United States more than doubled between 2015 and 2017, and now costs more than $4,000.

By all accounts, this should be a cheap and accessible drug—there are multiple generics on the market. Yet consumers continue to get price gouged, and pharmaceutical company greed has made this drug unaffordable, particularly for those who need it most. President Trump's Commission on Combating Drug Addiction and the Opioid Crisis has even recognized price as a barrier to naloxone access.

The price of a popular medication-assisted treatment therapy, buprenorphine, is no better. According to recent testimony in front of a House Judiciary Committee subcommittee, "the pricing of MAT medications by several pharmaceutical companies obstructs access to treatment for opioid addiction and overdose in America, and thus prolongs the scourge of heroin and prescription opioid addiction, and puts American lives at risk."

Mr. Azar, in your opening statement, you mention your experience at HHS during the post 9/11 anthrax attacks and their threat on our Nation's public health. Your boss at the time—then-HHS Secretary Tommy Thompson—publicly considered using his authority under a section of the United States Code, title 28 section 1498, that would have allowed the government to buy generic versions of an otherwise patented anti-anthrax drug at a steep discount. Mr. Thompson's threat of invoking title 28 section 1498 allowed the government to leverage a deal with the brand name manufacturer and cut the price of the anti-anthrax medication Cipro in half, saving taxpayer dollars and protecting public health.

Did you play a role in advising then-Secretary Thompson in threatening to invoke the authority behind section 1498, which led directly to cheaper medicines?

As you are aware, title 28 section 1498 is not the only authority HHS can utilize to force a pharmaceutical company to lower the price of a drug. The Secretary of HHS also has the power to authorize the purchase of low-cost generic versions of patented medicines and to leverage that authority to demand reductions in prices of lifesaving medicines developed with taxpayer dollars under the Bayh-Dole Act and so-called "march-in rights."

Under the Bayh-Dole Act (35 U.S.C. § 200–212) the U.S. Government retains specific rights when licensing federally owned inventions, such as NIH-developed drugs. For example, by statue, the government can employ march-in rights to license the patent to a third party when "the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use." "Practical application" is defined to include an obligation for reasonable pricing. Despite having this authority for nearly 40 years, NIH has never exercised its march-in rights.

Given the public health threat that the opioid epidemic currently poses, if confirmed, would you consider invoking the authorities given to the Secretary of HHS under the Bayh-Dole Act or under title 28 section 1498 in order to ensure access to life saving medications—whether it be naloxone, buprenorphine, or any other drug that remains out of reach for too many Americans?

Thirty-five U.S.C. § 201(f) defines "practical application: as making an invention "available to the public on reasonable terms." What do you consider reasonable terms? Should there be any limits on pricing for government funded drugs that earn billions of dollars in sales?

If confirmed, would you exercise the public's rights under the Bayh-Dole Act to lower the prices of medical technology that is based on federally owned or licensed patents if the price charged for U.S. residents is significantly higher than that for other high-income countries?

Answer. I was involved in the negotiations with Bayer to acquire ciprofloxacin in the aftermath of 9/11 and during the anthrax attacks. As I noted in a letter to the editor of the *American Lawyer*—Alex M. Azar II, "Letter to the Editor, The Cipro

Dilemma," *American Lawyer,* January 31, 2002—Bayer was never threatened with the use of section 1498, and it was my view and the view of the Department's attorneys that section 1498 would not authorize FDA to approve a product in violation of the market exclusivity provisions of the Hatch-Waxman Act. Section 1498 is not a regulatory provision that would allow the FDA to approve a product under the Food, Drug, and Cosmetics Act when that Act does not so permit. Section 1498 does not authorize the government or its contractors to engage in patent infringement, but rather provides a remedy in the event that that were to occur. If, for example, a suit were filed against a government contractor for infringement and various conditions were met, the government would step in, defend the suit, and ultimately pay. Section 1498 has never been used in a situation like this, does not automatically result in a lower drug price, and it is not a cost free option.

My understanding is that the Department has reviewed the Bayh-Dole Act and determined that the Act does not permit march-in on the basis of market price alone. If confirmed, I look forward to reviewing this legal analysis.

EVERGREENING

Question. During your testimony in front of the HELP Committee in November and again in front of the Finance Committee on Tuesday, you talked a lot about your work during your time at HHS to address evergreening, where a pharmaceutical company tweaks a tiny part of a product in order to extend its exclusivity. You claim that your efforts to limit evergreening resulted in a rule that was estimated to save consumers $34 billion over 10 years.

During your testimony in front of the HELP Committee back in November you said, and I quote: "We have to fight gaming in the system of patents and exclusivity by drug companies. I have always been an opponent of abuse and gaming of the patent systems by drug companies."

In the last few days, however, media reports have emerged that claim that during your tenure at Eli Lilly, the company was able to extend its patent on the erectile dysfunction drug Cialis by testing it for a rare muscle-wasting disease in pediatric patients.

Do you believe that loopholes in current law remain that allow pharmaceutical companies to engage in "evergreening" or "product hopping," especially in light of the emerging biosimilars market?

How do you respond to these media claims regarding "gaming" by Lilly?

If confirmed, will you commit to working with Congress to identify those existing loopholes, promulgate regulations designed to close them, and, if legislative action is necessary, provide the technical assistance necessary to improve and modernize the law and prevent future abuses for all types of drugs, including small molecule, biologic, and combination products?

In addition to targeting evergreening, what specific ideas can you propose for addressing patent "gaming"?

Answer. I have made clear my concerns with those companies that game or "evergreen" patents and exclusivities by branded companies under Hatch-Waxman and other provisions of the Food, Drug, and Cosmetics Act. If confirmed, I will 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. As we discussed in the hearing, 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 . In addition, the Food and Drug Administration Reauthorization Act of 2017 (FDARA), which was signed in to law earlier this 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.

Regarding the pediatric exclusivity program, pediatric studies resulting in exclusivity are only done if FDA sends a "written request" to a company for a pediatric

study and the company accepts that request and performs that study to the FDA's satisfaction. Definitively knowing what does not work for or in pediatric populations can be as valuable as knowing what definitively does work. The pediatric exclusivity incentives have over the years proven to be an invaluable tool to get companies to spend the tens of millions of dollars to study medicines in pediatric populations, where they would otherwise lack the economic justification to do so. With regard to this particular program and the inaccurate headline in Politico, I do not believe performing clinical trials at the request of FDA pursuant to a statute created by Congress to attempt to discover a therapy that might help children suffering from and dying from Duchenne Muscular Dystrophy is a game in any respect. That is the pediatric exclusivity statute working exactly as Congress intended.

DRUG REIMPORTATION

Question. During your hearing in front of the Senate HELP Committee, Senator Paul asked you to come back with ideas on how to make the reimportation of drugs from Canada and Europe "safe." Like Senator Paul, I believe that the safe reimportation of prescription drugs from countries with rigorous safety standards such as Canada and Australia represent steps that would significantly reduce drug costs.

As HHS Secretary, would you support drug reimportation? If no, why not? If yes, what "safeguards," if any, would you propose to put in place?

Answer. Congress has established a statutory framework which governs the importation of prescription drugs. Under this framework, HHS's statutory authority to promulgate regulations implementing an importation program becomes effective only if the Secretary certifies to Congress that the implementation of such a program will pose "no additional risk" to the public's health and safety and that it will result in "a significant reduction" in costs for American consumers. My understanding is that previous Secretaries have been unable to make this certification based, at least in part, on unacceptable risks to the public's health and safety that would result from opening the Nation's drug supply to unapproved drugs from sources that may be difficult to verify. If confirmed, I will ensure that I am briefed on the facts informing this assessment of the risk to the public's health and safety, including current non-public facts to which I do not currently have access.

One of the challenges to importation safety in the past has been the inability to connect the U.S. closed distribution system to Canada's (or another country's) closed distribution system. In addition, if confirmed, I commit to exploring whether any pilots or demonstrations might be utilized to see if a system could be set up in a way such that public health officials would support a determination of no additional risk to the public's health and safety and of a significant reduction in costs for American consumers, when appropriately scaled up to represent the likely level of importation.

PATENT EXCLUSIVITY

Question. Under our current system in the United States, pharmaceutical companies are able to develop a drug and charge as high a price as possible to the patient during the monopoly period, resulting in barriers to access and significant financial burdens for patients.

As HHS Secretary, would you support or encourage research into the feasibility of new business models to delink the cost of research and development to the price charged to patients?

In 2012, Robert A. Armitage, who was then Senior Vice President and General Counsel at Eli Lilly, testified in front of the House Judiciary Committee that the current system in the United States does not provide enough patent protection for American pharmaceuticals, advocating for a "prior user" defense.

Do you agree with your former employer that the pharmaceutical industry needs greater patent protections and longer patents for drugs?

Answer. If I am confirmed as Secretary, one of the critical areas I plan to focus my efforts on is to lower drug prices. I believe through my experiences in both the public and private sectors I can start working immediately at the Department of Health and Human Services to identify solutions to the drug pricing issue. I believe that we need to institute policies that lower the list prices of drugs while also maintaining innovative new research and development. I am interested in novel ideas to lower the price of drugs and look forward to working with you on this issue, if confirmed.

STOP PRICE GOUGING ACT

Question. The Stop Price Gouging Act (S. 1369), which I reference above in question 4, requires drug companies to report increases in drug prices, and to justify any increase above medical inflation. Additionally, the legislation penalizes drug companies that engage in unjustified price increases with financial penalties proportionate to the price spike.

As HHS Secretary, would you support such penalties for price spikes as a means to lower prescription drug costs? If no, how would you propose to change the incentives under the act.

Answer. As I said during my opening statement to the committee, drug prices are too high. The existing system for pricing and reimbursement of drugs works for many of the players in the system, but not for patients who have to pay high out-of-pocket costs for their drugs because of lack of insurance, high deductibles, or high cost sharing. Drug pricing is informed by a multitude of factors including the list price, competitive market dynamics, government rebate programs, insurer market power, discounts to the list price, global freeloading by international price-fixing behavior, and research and development costs, to name a few. If confirmed, I will work to fix this broken system, and use my knowledge and experience to reduce drug prices for patients.

BIOSIMILARS

Question. You have stated that you are interested in promoting innovation and fostering competition in drug development. I have introduced legislation in the past that would help achieve this by shortening the patent exclusivity period for expensive, brand-name biologic drugs and allow biosimilars to enter the market sooner. Biosimilars, which are equivalent in safety and efficacy to their reference biologics, have the capacity to lower drug prices and reduce out of pocket costs for patients. In fact, a recent RAND study projected that a robust biosimilar market could save America's patients $150 billion over 10 years.

Mr. Azar, can you please describe the importance of biosimilars in reducing prescription drug costs for patients and the Federal Government?

How will you, as Secretary of HHS, support the uptake of biosimilars in the United States?

What do you believe to be the FDA's role and CMS's role in educating patients, providers, and other stakeholders about biosimilars?

Can you discuss how inclusion of biosimilars in the Medicare Part D coverage discount program could reduce costs and cultivate the biosimilar market for all patients?

Under the Affordable Care Act (ACA), brand drug manufacturers are required to offer statutory discounts under the Medicare Part D coverage gap to offset the cost-sharing for beneficiaries who are required to pay the full price for prescriptions. Biosimilar manufacturers, however, are exempted from this requirement.

Do you believe the current coverage gap discount program could discourage the uptake of biosimilars in any way?

Answer. If confirmed, I look forward to working with both FDA's and CMS's senior leadership to ensure that we have clear regulatory and coverage policies in place that support patients having access to safe and effective medical products, including biosimilars, in a timely manner and that support the development of a competitive market among biosimilars and with innovator products. An important component of biosimilar development and integration into the marketplace will be education for providers and patients. If confirmed, I will work with FDA's leadership to ensure we are educating clinicians and patients about biosimilars generally, as well as information specific to any biosimilar approvals at the time of such approvals.

MEDICAID AND FAMILY PLANNING SERVICES

Question. Two-thirds of births from unintended pregnancies in the United States are paid for by Medicaid or the Children's Health Insurance Program (CHIP). Public funding in my home State of Ohio supported slightly more unintended pregnancies than the national average. In 2010, these unintended pregnancies cost a total of $21 billion dollars, including $824 million in Ohio. Publicly funded family planning allows families to prevent unwanted pregnancies, and it is estimated that investing in family planning services would have saved public funding of unintended preg-

nancies by a total of $15 billion, including $607 million for Ohio. That's striking—almost 75 percent of the money spent on unintended pregnancies is estimated to be saved.

Unfortunately, many States are seeking waivers that would allow them to discriminate against certain family planning providers, leaving women with far fewer options and denying them their provider of choice. Some States want to insert work requirements into their waivers. And you have expressed support for converting Medicaid to block grants. All of those steps would dramatically limit the resources that are available for providing health care to the Nation's poorest people and are likely to harm reproductive and maternal health.

Do you acknowledge the effectiveness of investing in contraception and the need to continue the Medicaid State option to expand family planning services?

How will you ensure that family planning services, included access to preferred contraception methods, will remain available to all women?

Would you support State waivers that attempted to exclude maternity care? If such waivers were to be granted, resulting in reduced access to care, how would you plan to ensure that all women receive the health care they need before, during, and after pregnancy?

Answer. I believe that all women should have access to quality, affordable health care and insurance coverage that works for them and that meets their needs. Patients must be empowered to decide what kind of coverage they need, rather than Congress or HHS mandating what they must purchase. If confirmed, I will also work with States to help them achieve their goals with as much flexibility as possible, within the parameters and confines of the law.

BIRTH CONTROL IFRS

Question. In October 2017, the current administration issued two Interim Final Rules to allow employers, universities, and insurers with religious or moral objections to contraception to deny their employees and students insurance coverage for birth control. These rules were issued as Interim Final Rules, forgoing the normal Notice of Proposed Rulemaking process. The rules have potential to impact thousands of women, who could lose the contraception coverage they have come to depend upon.

Do you agree with the idea that employers or insurance companies should be able to deny women birth control coverage based on their religious or moral "beliefs"?

Do you believe that it was necessary to issue these regulations as IFRs, instead of going through the normal rulemaking process?

Answer. I believe all women should have access to the care that they need. We can advance that goal while simultaneously following the many laws protecting the right of conscience in health care. If confirmed, I look forward to working with others at HHS as well as Congress to ensure that both can be achieved.

REPRODUCTIVE RIGHTS

Question. In the landmark *Roe v. Wade* decision that established abortion as a fundamental right for women, the Supreme Court declared that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn." This central holding has been consistently upheld and reaffirmed by the Supreme Court.

However, HHS's recently released 2018–2022 Draft Strategic Plan makes references to an American lifespan spanning from "conception" to "natural death," and vows to respect "the inherent dignity of persons from conception to natural death."

As HHS Secretary, would you retain this unconstitutional and non-medical definition in the HHS strategic plan? If yes, how would this definition alter existing HHS programs and policies, and how will you ensure women's access to other crucial and legal health care services, such as abortion, are not threatened by it?

Answer. The mission of HHS is to enhance the health and well-being of all Americans, and this includes the unborn.

ACA INDIVIDUAL MANDATE

Question. As you are aware, Congress recently passed a tax reform bill that was signed into law by President Trump. In addition to providing tax cuts for the

wealthy under the ruse of "trickle-down" economics, the bill repealed an important component of the Affordable Care Act: the individual mandate.

CBO has predicted that repealing the individual mandate will result in increased premiums averaging 10 percent each year. In your opinion, will a 10-percent increase in premiums year after year continue to destabilize the market and cause additional insurers to exit the marketplace?

It has been projected that 13 million Americans will lose access to health insurance due to the prohibitively high cost of premiums as a result of repealing the individual mandate. How do you propose to limit these annual increases and keep health care affordable for the millions of Americans who rely on the individual market as their only source of health insurance?

Answer. I believe it is important to note that the CBO clearly stated in November of this past year that it is revising its approach to evaluating the effect of the individual mandate, and that "the estimated effects on the budget and health insurance coverage would probably be smaller than the numbers reported in this document." In other words, the CBO has publicly confirmed that its estimates are likely overstated. As I said in my opening statement to the committee, we must make health care more affordable, more available, and more tailored to what individuals want and need in their care. The President has made clear that any replacement system must make insurance more affordable, have more choices, and be insurance that people want. In addition, any system must effectively address the issue of risk pooling, beyond mandates. I would look forward to working with Congress and States in examining these alternative approaches. If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

GLOBAL HEALTH AND TAIWAN

Question. Last spring, I sent then-Secretary Price a letter with 20 of my colleagues urging him to advocate for Taiwan's inclusion in the World Health Organization's annual World Health Assembly (WHA). As the SARS outbreak in 2002–2004 demonstrated, Taiwan's exclusion from the World Health Organization has real-world costs and borders alone do not stop the spread of infectious disease. Taiwan has been granted observer status at the WHA since 2009, but this invitation was rescinded last year at China's urging.

As the head of the U.S. delegation to the WHA, how will you work to have Taiwan included in next year's WHA? Should Taiwan continue to be excluded from the WHA, how will you ensure Taiwan has the same resources to address public health issues as other partners in the region?

The United States and Taiwan conduct joint public health training exercises under the "Global Cooperation and Training Framework" (GCTF), which helps experts in the region prepare for Zika, Ebola, MERS, Dengue Fever, and other communicable diseases.

If confirmed, how will you build on the success of the GCTF to help Taiwan play its role in combating global health concerns?

Answer. I fully agree with you that global health security requires all countries to help prevent, detect, control, and fight such outbreaks of infectious diseases. I agree with you that Taiwan is a valuable ally in the global health arena and deserves to be treated as such.

If confirmed, I commit to working with the World Health Organization (WHO) leadership to affirm Taiwan's observer status at future World Health Assemblies.

COLORECTAL CANCER SCREENING

Question. Seniors on Medicare undergoing a recommended colonoscopy—which is used to screen for polyps that could become colon cancer—are not supposed to pay any out-of-pocket costs. The rationale is that when more seniors get screened for colon cancer in a timely manner, cancer diagnoses can occur earlier and will be cheaper for Medicare to treat; an advanced case of colorectal cancer can cost up to $300,000 in treatment costs per year. However, there is a technical loophole in Medicare by which seniors undergoing these "free" screening colonoscopies wake up and find they are faced with a surprise bill of $300 or more due to biopsies taken under anesthesia.

I have introduced a bill that has 40 bipartisan cosponsors that would fix this loophole. However, I want to encourage you in your capacity as HHS Secretary, if con-

firmed, to examine any opportunities to fix this problem without going through a long arduous legislative process.

Are you aware of this loophole regarding colorectal cancer for Medicare beneficiaries? If confirmed, will you examine administrative fixes to the payment policy?

Answer. I appreciate you raising this issue. If confirmed, I commit to working with CMS to make sure they thoroughly review the rules to ensure they are implemented consistently with the law and with the utmost regard for the accessibility of high quality health care for all impacted Medicare beneficiaries.

PAMA IMPLEMENTATION

Question. In 2014, Congress passed the Protecting Access to Medicare Act (PAMA), which requires the Centers for Medicare and Medicaid Services (CMS) to update the way clinical laboratories are paid under the Medicare program through the development and implementation of a new, mandatory reporting system and revised fee schedule. On January 1, 2018 the CMS-proposed new CLFS rates went into effect based on flawed data that does not represent all sectors of the clinical laboratory market and therefore are not reflective of current market rates.

I remain concerned that the proposed rule and implementation timeline impose a significant burden on clinical laboratories across the country and may threaten access to clinical laboratory services for Medicare beneficiaries. I am also concerned with the quality of the data collected by CMS—it reflects less than 1 percent of the market and does not include an accurate representation across large and small independent labs, hospital labs and physician office labs.

Will you commit to working with Congress and the laboratory community to address these concerns?

The narrow definition of "applicable" lab as defined by CMS resulted in a small group of labs deciding to report data. What would you do as HHS Secretary to ensure data collection more accurately reflects the entire clinical laboratory market?

Answer. I appreciate your concerns regarding the implementation of PAMA. The use of laboratory reported, market data to establish Clinical Laboratory Fee Schedule (CLFS) payment rates is intended to strengthen Medicare by paying more appropriately for laboratory services and is expected to save the Medicare program and taxpayers money while maintaining beneficiaries' access to high quality laboratory services. It is my understanding that the definition of applicable laboratories was established through notice and comment rulemaking. Certainly, we should strive for accuracy in this market data collection process. I understand that in the Medicare Physician Fee Schedule proposed rule for calendar year 2018 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 under the new CLFS payment system. Accordingly, I will ensure that CMS considers the comments for potential future refinements to the data collection and reporting periods and, if confirmed, I look forward to learning more about this issue.

OPIOID DATA COLLECTION

Question. As I mentioned to you during your hearing, Ohio is second only to our neighbor, West Virginia, when it comes to the rate of overdose deaths due to opioids. In 2016, more than 4,000 Ohioans lost their lives due to an opioid overdose.

Tackling the opioid epidemic requires reliable data for accurately estimating the market forces that drive drug consumption and designing appropriate interventions. It is crucial that the Federal Government provide States with data that are reproducible and understandable across a wide range of audiences.

As HHS Secretary, how would you collect this data, control for quality, and distribute it in an accurate and timely manner to the States?

Answer. One of HHS's goals under its five-point opioid strategy is to strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves. Data is critically important to monitoring and addressing this opioid epidemic, and I believe HHS, through the CDC, plays an important role in surveillance of this epidemic. If confirmed, I look forward to being briefed on the State of our current data systems and working with the States to ensure they are receiving needed data to adequately fight this epidemic.

LOW-INCOME HEATING ASSISTANCE PROGRAM (LIHEAP)

Question. As you know, the Low-Income Heating Assistance Program, or LIHEAP, plays a key role in helping the elderly and low-income families stay warm in the winter and avoid dangerous heat in the summer. With the sustained cold in Ohio this winter, we see firsthand how critical it is to the nearly 450,000 households in my State that would otherwise be forced to choose between keeping warm or going hungry. When your predecessor was before the committee, he indicated that he supported this program, then he proceeded to eliminate it in the FY18 budget request.

If confirmed, would you propose to once again eliminate the program?

Answer. If confirmed, I will prioritize programs that demonstrate results for the populations they intend to serve. If resources for LIHEAP continue to be appropriated by Congress, I will continue to implement the program in the most effective and efficient manner possible.

ACCURATE PUBLIC HEALTH TERMINOLOGY AT CDC

Question. A few weeks ago, several of my colleagues and I wrote to CDC and HHS about the importance of using accurate, scientifically sound terminology at the agency—including, but not limited to, in budget documents. The CDC's "Pledge to the American People" states that CDC will "[b]ase all public health decisions on the highest quality scientific data that is derived openly and objectively," and "[p]lace the benefits to society above the benefits to our institution." In order to carry out these promises, the agency must remain steadfast in its commitment to the best science and the best words to describe that science. It is essential that CDC rely on science-based and evidence-based decisions, and use specific and accurate language to promote its work.

You yourself have mentioned that the CDC and its career staff are the envy of the world, that they have saved countless lives, and that you will continue to advocate for CDC's funding to meet the challenges of the 21st century if confirmed.

Do you believe that science and evidence should drive policymaking decisions at CDC and HHS at large? Will you encourage your employees and other administration appointees, both at HHS and across other agencies you partner with, to use science and evidence to drive policymaking?

If confirmed, would you permit employees across the agency to use terms such as "evidence-based" or "science-based" in official HHS communications?

Answer. Science and evidence should always be the basis of our policymaking decisions, and my understanding is that there is no attempt whatsoever to remove such words from official documents. However, I want to make clear that, if I am confirmed, there would never be a policy banning any words.

MEDICAID EXPANSION

Question. As I mentioned during your hearing, Ohio's expanded Medicaid program is critical to our State's fight against addiction. Ohio's Governor John Kasich, in a letter to Senator Hatch last year, wrote "we strongly recommend that States be granted the flexibility to retain the adult Medicaid coverage expansion and Federal matching percentage." Governor Kasich's letter also said that those States that have opted to expand Medicaid are experiencing significant positive results.

In Ohio, high-cost ER utilization has gone down, overall health status has improved for 48 percent of Ohioans, and most enrollees have found it easier to keep or find work. Further, thanks to ACA's Medicaid expansion, Ohio was able to extend coverage to 700,000 previously uninsured Ohioans. The uninsured rate for low-income adults in Ohio is the lowest ever recorded.

Do you support the flexibility provided to States under the ACA to expand Medicaid? Will you continue to support this option for States?

As a cabinet-level advisor to the President, how will you advise the President on any bill that would limit a State's flexibility to expand Medicaid—like Ohio did—as provided for under the ACA?

Governor Kasich also has engaged providers, payers, community organizations and employers to work with the Medicaid population and provide a ladder out of poverty. One program in particular, CareSource's Life Services pilot program provides supports, voluntary educational and workforce training opportunities, and

mentoring to help individuals achieve physical and behavioral health and economic stability.

As Secretary of Health and Human Services, how will you work to expand support for voluntary programs like Life Services, which are designed to help address both an individual's social determinants and health needs?

Answer. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it. I also commit to working closely with States to ensure they have the flexibility they need to serve the vulnerable populations the Medicaid program is intended to assist.

MEDICARE PART D NEGOTIATIONS

Question. President Trump supports the elimination of the noninterference clause in Medicare Part D. He would like to have the Centers for Medicare and Medicaid Services (CMS) negotiate directly with drug manufacturers to get the best deals on prescription drugs for our Nation's seniors.

Your stance on this issue is less clear. While you seem to support the role of pharmaceutical benefit managers (PBMs) as excellent negotiators on behalf of the Federal Government when it comes to Medicare Part D, you have seemed to point a finger at PBMs for the high cost of prescription drugs in other circumstances.

Regardless of the role of PBMs, eliminating the noninterference clause in Medicare Part D and providing the Secretary with formulary authority would allow the Federal Government to get the best deals for our Nation's seniors.

Given your prior work with the Medicare Part D program, if Congress passes legislation supported by the President that gives the Secretary of HHS the authority to negotiate—and this legislation is signed into law—would you use this administrative authority to negotiate better prices on behalf of the more than 40 million Part D beneficiaries?

What are your ideas on effective ways to reduce out-of-pocket prescription drug costs for Medicare beneficiaries?

Answer. Drug prices are too high. The President has made this clear. Through my experience helping to implement Part D and with my extensive knowledge of how insurance, manufacturers, pharmacy, and government programs work together, I believe I bring skills and experiences to the table that can help us address these issues, while still encouraging discovery so Americans have access to high-quality care.

The President has generally spoken about the desire to ensure that Medicare is negotiating and getting the best deal possible for drugs. Part D plans are actually negotiating today with the three or four biggest pharmacy benefit managers that negotiate and actually secure the best net pricing of any players in the commercial system. If confirmed, I would like to consider further ways that we can take the lessons from Part D to improve Medicare.

ANTIBIOTIC RESISTANCE

Question. The first incidence of the bacteria E. coli containing the antibiotic resistance gene mcr-1 was discovered in 2015. This gene has the capability of promoting the bacteria to "superbug" status by conferring resistance to the last resort antibiotic colistin. Since 2015, the mcr-1 gene has been found in bacteria in over 30 countries from around the world. The emergence of this superbug is extremely serious and illustrates both how quickly infectious pathogens can spread across the world and the need for international cooperation in detecting newly emerging health threats.

Do you agree that a dedicated effort to improving surveillance, data collection and research efforts is needed to prevent such rapid spread and evolution of antibiotic resistant bacteria?

How will you ensure that the threat of antimicrobial resistance remains a high priority for the U.S. Department of Health and Human Services (HHS) and its affiliates the National Institutes of Health (NIH), Food and Drug Administration (FDA), and CDC? How should the United States work with other nations to combat these threats?

Answer. One of our largest public health threats is antibiotic drug resistance. If confirmed, I will work with all agencies involved in antibiotic drug development—including FDA, CDC, and BARDA—to ensure the department is involved and supportive of antibiotic drug development and is working with stakeholders, such as physicians and nurses, to ensure strong antibiotic stewardship programs are in place and implemented. I agree with you that improving surveillance is also important and commit to working internally on this issue but also with our global partners.

INFANT MORTALITY

Question. Ohio consistently ranks among the top 10 States in the country with the highest overall rates of infant mortality. African American babies in Ohio, in particular, suffer disparately high rates of infant mortality. I have introduced legislation to improve prevention efforts nationwide by improving Federal reporting of infant and childhood deaths, putting the power in the hands of the Secretary of HHS to generate the metrics by which these incidences are reported.

As HHS Secretary, how would you work to ensure adequate funding for the issue of infant mortality, and which metrics and protocols would you use to improve reporting of infant mortality cases across the country?

Answer. If confirmed, I commit to reviewing the current resources available and ensuring that these resources are used wisely. I look forward to being briefed on the state of current infant mortality metrics and protocols, and I commit to working on this issue.

LEAD

Question. Last year, the CDC lowered its reference level for public health intervention for elevated childhood blood lead levels from 5 to 3.5 micrograms per deciliter.

Lead is a neurotoxin, and exposure to it can have devastating lifelong consequences for children. Ohio is one of 29 States receiving funding from CDC for a State-wide lead poisoning prevention program. In 2014, almost 6,000 children under age six in Ohio, or 3.85 percent of those tested, had elevated blood lead levels.

If confirmed, will you keep the CDC's lowered lead reference level?

What actions would you have HHS take to reduce the number of American children with elevated blood lead levels?

According to a Reuters investigation in 2016, our country is failing when it comes to screening and testing at-risk children for lead. Millions of at-risk children are never screened or tested for high lead levels, despite early childhood lead screening and testing requirements.

What proposals do you have to increase the rate of lead screening in children? How will you use the authorities you have under Medicaid and CHIP to increase the number of at-risk children who are screened for high lead levels?

Answer. It is important that every child has access to high-quality health coverage and that we take all health-care threats to our children seriously, including high lead levels. Medicaid and CHIP play an important role in accomplishing this objective, but there is also a need to focus on family coverage in the private market and employer plans, as well as giving States flexibility to address the unique needs of their communities. Each State is different. HHS should work with States to ensure that their children's program provide the best possible coverage to their residents. If confirmed, I would ensure that CDC continues its science-based work with respect to lead reference levels.

LGBTQ HEALTH DISPARITIES

Question. According to the Office of Disease Prevention and Health Promotion (ODPHP,) research suggests that LGBTQ individuals face health disparities linked to societal stigma, discrimination, and denial of their civil rights. These disparities are driven in part by lower rates of health insurance in the LGBTQ community, as many employers do not offer coverage for same-sex partners or their children. The ACA made significant strides in addressing LGBTQ health disparities, by ensuring that the LGBTQ population cannot be excluded from health plans due to pre-existing conditions such as HIV, prohibiting marketplace discrimination based on sex and gender identity, and requiring that insurance plans offer the same coverage to married same-sex couples that is offered to opposite-sex couples. The ACA also required the inclusion of sexual orientation and gender identity variables in national health surveys.

As HHS Secretary, do you commit to working to eliminate health disparities across populations, including the LGBTQ community?

Will you ensure that married same-sex couples are offered equal opportunities for insurance coverage?

Will you commit to collecting data on sexual orientation and gender identity, and using this information to guide evidence-based policy to address health disparities?

Answer. If confirmed, I will work to enhance and protect the health and well-being of all Americans. Americans have equal rights under the law, without distinction, and the government cannot deny any individual access to health care for illegally arbitrary reasons. If confirmed I will ensure HHS will faithfully implement the anti-discrimination protections contained in the laws passed by Congress.

340B

Question. CMS recently finalized its 2018 Medicare Hospital Outpatient Prospective Payment Program System, which—despite a significant amount of pushback from the stakeholder community and many members of Congress—included a provision to change Medicare's reimbursement for discounted drugs under the 340B program to 340B hospitals to −22.5 percent as compared to the prior (and current rate for non-340B hospitals) of ASP +6 percent. I am concerned by these cuts, which do not save the Medicare program any money and will disproportionally affect hospitals serving Ohio's most vulnerable individuals.

During your confirmation hearing in front of the Senate Finance Committee, you said several times that one of your focus points for reducing the price of drugs will be to focus on what the patient pays in out-of-pocket costs, including copays. While the proposal CMS OPPS proposal that was finalized may reduce some out-of-pocket costs for Medicare beneficiaries who are faced with high drug costs, it redistributes that higher out-of-pocket burden across Medicare beneficiaries receiving other services. If we are to be serious about lowering the cost of prescription drugs, we should do so in a way that truly lowers the cost of the drug—not by paying some hospitals less than others and shifting out-of-pocket copay and coinsurance burden from individuals with high drug costs to those with high procedure costs.

What are your views on the 340B drug discount program?

Do you believe in supporting safety-net providers who are working to help low-income individuals access quality health services through programs such as 340B?

What are your proposals for working with all stakeholders in this space—including the provider community—to ensure the 340B program aligns with congressional intent and meets the needs of communities?

Answer. I understand that CMS recently finalized a change for 2018 to the Medicare payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. The reduced payments on 340B purchased drugs would better align with hospital acquisition costs and directly lower drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments by an estimated $3.2 billion over 10 years. Certain hospitals are exempted from this Medicare payment reduction for 340B drugs such as rural sole community hospitals, prospective payment system-exempt cancer hospitals and children's hospitals. Additionally, all critical access hospitals are not affected by this policy because they are not paid under the outpatient prospective payment system. If confirmed, I will faithfully

implement any laws related to the 340B program as passed by Congress, and I look forward to working with Congress and stakeholders to ensure that the 340B program is putting patients first.

COMMUNITY SERVICES BLOCK GRANT

Question. The administration proposed to eliminate all funding for the Community Services Block Grant (CSBG) in FY2018. If this were to take place, it could result in a complete dismantling of the Community Action network, which is uniquely required to identify and address local causes and conditions of poverty. While CSBG allotments are a relatively small component of the overall budget for many Community Action Agencies (CAA), designation as CSBG eligible entities and the flexibility of their CSBG allotments help CAA agencies bring a wide variety of public and private resources into local communities. CSBG funds are critical to helping address both chronic and short-term critical needs, and support many innovative activities that help promote self-sufficiency. In the absence of CSBG funding, many of these initiatives would lack financial backing.

Do you know if HHS has made any efforts to analyze the unintended consequences of eliminating the CSBG? For example, if the CSBG were to be eliminated, to what extent would State and local governments face pressure to compensate for services now provided through CAAs?

Will you commit to, if confirmed, protecting the CSBG and ensuring that communities do not lose these cost-effective resources?

Answer. If confirmed, I look forward to working with leadership at the Administration for Children and Families, Congress, and States to identify the most effective programs that alleviate the very real problems of families living in poverty.

QUESTION SUBMITTED BY HON. SHERROD BROWN, HON. MICHAEL F. BENNET, AND HON. ROBERT P. CASEY, JR.

PROVIDER STATUS

Question. The Pharmacy and Medically Underserved Areas Enhancement Act recognizes pharmacists as health-care providers in underserved areas in order to expand access to care. In areas with a shortage of primary-care providers, pharmacists may play a key role in helping patients manage their diseases to avoid Emergency Department visits and hospitalizations. These services are especially important for patients with multiple chronic conditions who may be taking several medications at a time.

As HHS Secretary, would you support this approach as a way to increase care in rural and underserved areas?

Answer. If confirmed, I look forward to learning more about your legislation and working with you to increase access to quality health care, especially in rural and underserved parts of the country.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN AND HON. BILL CASSIDY

DELIVERY SYSTEM REFORM AND SOCIAL DETERMINANTS OF HEALTH

Question. Last fall, we wrote to then-Secretary Price asking him to work with us to convene a diverse commission of national health care experts to develop a strategy for improving and advancing our Nation's health care delivery system so that can effectively meet the needs of all Americans. What we wrote then is still true now: in many ways, the United States is the envy of the world when it comes to health care. In other ways, our country continues to lag behind others when it comes to health-care efficiency and effectiveness. In 2016, we spent more than 18 percent of our national gross domestic product on health care, yet we spent more to treat disease than prevent it in the first place. Our system of care delivery is complicated and remains siloed, and we struggle to address health disparities that divide us by race, socioeconomic status, and geography, and our public health outcomes are stagnant.

We are ready to work together and with health-care experts across the country, including community health partners, providers, patients, payers, and clinicians, to develop a new approach to health care delivery in the United States.

If confirmed, will you help us shift the government's focus from a system that simply treats the sick, to a system that keeps Americans healthy, regardless of where they live, their race, or their socioeconomic status?

Will you commit to working with us to identify innovative thought leaders from around the country to help achieve the following goals?

- Evaluate our current health care delivery system;
- Assess the improvements our Nation must make to reduce disparities and deliver the highest quality, most affordable care to all Americans;
- Encourage innovation in clinical and community approaches;
- Improve the health and well-being of individuals and communities; and
- Build a thoughtful framework for future health-care reforms.

Answer. As I indicated in my opening statement, one of my top priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. If given the opportunity to serve I will use the appropriate tools within the Department to meet this goal and measure our progress in reaching it. If confirmed, I look forward to working with you and hearing your ideas on how we can identify reforms and ensure that all Americans have access to the highest quality care. I also look forward to coordinating with CMS, their Innovation Center, States, and others in the Department as they work toward fostering an affordable, accessible health-care system that puts patients first. I believe we need to review the work of the Department periodically to identify what's working and what is not. I also firmly believe that Department authorities must be used in ways that are open and transparent and that seek out collaboration and input as much as possible. In that spirit, I look forward to working closely with you to identify and implement needed reforms and drive improvements in our health-care system.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Press reports have highlighted that we should soon expect an executive order on welfare reform and the President has made multiple comments on the topic. Last month, Paul Ryan also stated, "we're going to have to get back next year at entitlement reform, which is how you tackle the debt and the deficit."

The President has not said what he means by "welfare" or what he is referring to when he says, "People are taking advantage of the system."

Have you had any conversations with the President or administration officials related to their ideas on "welfare reform"?

If confirmed as Secretary, how would you advise the President on his goals of reforming welfare?

Given that welfare and entitlement reform may be on the priority list for next year, can you provide a clear view of what "welfare reform" means or should mean?

Answer. I see a lot of opportunity to improve the efficiency and effectiveness of our welfare programs for our beneficiaries and taxpayers. If confirmed, I will work across the department to prioritize reforms that maintain an emphasis on national values of community engagement and personal responsibility. Responsible reforms should focus on reducing burdens and inefficiencies and should recognize that States are in a better position than the Federal Government to operate programs that best meet the needs of their citizens. I see the Federal Government's role as a catalyst for engaging all sectors of the community to develop and implement a shared vision to grow the capacity and reduce the dependency of economically and socially vulnerable populations.

Question. In the past, you have touted the success of Medicare Part D, stating that it would "[provide] high-quality, affordable drug coverage to beneficiaries" in 2006. Part D beneficiaries may have access. However, the largest barrier to accessibility is *affordability* due to high drug prices for consumers, which has also meant higher government spending. Federal payments for catastrophic coverage tripled from $10.8 billion in 2010 to over $33 billion in 2015. In 2015, only two drugs accounted for almost $8 billion of the $33 billion.

How would you improve Medicare Part D to address these price increases?

Do you see any need for the government to negotiate for extremely high cost drugs that have no competition?

Answer. Part D has worked to make prescription drugs available and affordable to millions of our seniors. Medicare Part D prescription drug program access will also remain strong in 2018 with 100 percent of people with Medicare having access to a stand-alone prescription drug plan. Earlier this year, CMS announced that the average basic premium for a Medicare prescription drug plan in 2018 is projected to decline to an estimated $33.50 per month. This represents a decrease of approximately $1.20 below the average basic premium of $34.70 in 2017. The Medicare prescription drug plan average basic premium is projected to decline for the first time since 2012. But for a senior who has to pay out of pocket during their deductible or in the donut hole, high list prices can make certain drugs unaffordable for some beneficiaries. As I stated in my testimony, I believe drug prices are too high. My experiences at HHS, helping to implement Medicare's Part D prescription drug program and in the private sector have provided me with a deep understanding of the many factors that influence and determine the prices patients are paying for their medications. If confirmed, I am committed to working with Congress to address the challenges that are contributing to higher drug prices to ensure when seniors go into the pharmacy, they can afford the medications they need to improve their health and well-being.

Question. In Colorado, we have a teen pregnancy prevention program, which promotes long-acting reversible contraception or LARCs. This initiative resulted in lowering the State's teen pregnancy by over 50 percent and saving $65 million in health-care costs over 8 years. Through this statewide program, these contraceptives are available at 75 Colorado family planning clinics.

Would you consider this program a success story?

Given the success stories of the teen pregnancy prevention program, why is the administration seemingly moving to eliminate the TPPP program, having cut short the grants from 5 to 2 years?

Answer. We all share a commitment and desire to decrease unintended teen pregnancies, but we should do so through programs that the evidence suggests actually contribute to a decline in teen pregnancy rates. With respect to the Teen Pregnancy Prevention Program, I understand that an evaluation of a number of TPP projects published in 2016 on the HHS website showed that many were ineffective or actually harmful and that few showed sustained positive results.

Question. We saw several versions of ACA repeal and replace last year. Each of these proposals would have meant massive cuts to Colorado, especially in the Medicaid program, which stood to lose up to 50 percent in funding. You had said, "I think there's a lot to commend [about] a block grant approach, because the States are the laboratory for experimentation."

While our State has sought more flexibility, our Governor said, "Greater flexibility cannot make up for the lack of funding. Should the Federal Government pull back its financial commitments, we simply cannot afford to make up the difference." While that flexibility is important, it is meaningless if States do not have adequate resources.

Do you agree with our governor's assessment?

Do you still support the block grant and per capita cap approach?

Answer. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. As I said before the committee, the details of any block grant approach are incredibly important. The details determine whether States are receiving adequate funding and whether the approach is providing States with the flexibility they need. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to

be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it.

Question. The death rate from drug overdoses, including legal and illegal opioids, has been climbing in Colorado. Heroin overdose deaths increased by 23 percent in 2016 from the previous year. Neonatal abstinence syndrome went up by 83 percent from 2010 to 2015. The Colorado Health Institute recently found that 31 out of 64 counties in the State do not have a location that provides medication-assisted treatment. They also found that large parts of the State are not within a 30-mile radius of any treatment center. Even when treatment centers are close by, there could be wait times because of the surge in patients.

Medicaid has been a vital program for Americans struggling with addiction. About one in three Americans who gained access to health care through the Medicaid expansion had a mental health or substance use disorder for which they were able to receive treatment. Republican proposals to repeal and replace the ACA included Medicaid cuts that would have dramatically reversed any progress we have made in combatting the opioid crisis.

Can you commit that you would oppose similar bills that would worsen this epidemic at a time when we need to invest in more treatments and resources?

Answer. I am committed to ensuring that HHS brings all it has to bear in fighting the opioid epidemic. If confirmed, I look forward to working with Congress to ensure that legislation supports our efforts to address this crisis.

Question. When Congress passed Medicare Part D in 2003, it had a public option as a fallback for areas with little competition in the market. The fallback would have kicked in even in areas that had one private plan for a total of at least two plans. The fallback was ultimately never triggered but there was agreement that sometimes the private sector cannot or will not, participate in certain markets, especially in rural areas that are more difficult to cover.

My colleague, Senator Kaine, and I introduced the Medicare-X Choice Act, which would create a public option run through the Medicare program. It would first start in regions where insurance companies have stopped offering services or there is only one health plan on the exchange. In our proposal, the Medicare public option would then extend to all counties and on the small business exchange.

Do you think a public option would be helpful in areas with little competition in the individual market, specifically in rural counties where there may only be one plan?

Answer. I share your commitment and concern for access to rural health care and affordable insurance options, and, if confirmed, I look forward to working with you on these issues. However, I am concerned that a Medicare-based public option could stifle innovation and exacerbate some of our current challenges. It is also important to recognize that Medicare is a heavily subsidized program, so I'm not sure an unsubsidized Medicare benefit to non-senior individuals would be an affordable option. Right now, we have a system where Washington is too often in the driver seat and defining what is health care, and that is taking away choices and the ability of individuals and families to find the care they need. We need a system that is responsive to all Americans and where both health coverage and health care are affordable and accessible. I do share your concern about access to affordable and accessible health insurance for individuals, especially in these circumstances, and look forward to working with you and others, if confirmed, to try to develop a system that actually delivers these types of solutions for those who are in the marketplace and for those who have been denied the promise of the marketplace.

Question. Consumers tend to be largely unaware of what they will be billed after having a test or procedure. Common surgeries like a knee replacement could cost anywhere between $11,000 and $70,000 depending on where you live.

What steps will you take as HHS Secretary to improve price transparency for consumers and policymakers?

Answer. I favor increased transparency within our health-care system, and I especially share your concern about transparency of pricing for the patient at the point of care delivery or sale. Of course, the goal of transparency is ultimately to create more competition and lower prices, so we do need to make sure transparency is not counter-productive. I would be very happy to study the issue more and work with you to ensure that all options are evaluated as we think about this important issue,

and to help make sure that our policies related to transparency will actually aid patients in making choices and lower costs and reduce what patients pay out of pocket.

Question. In 2014, CMS promulgated a rule in the Home and Community-Based Services waiver program that directly conflicted with Colorado's Community Centered Boards system. The CMS rule, which is now adapted in Colorado law, will lead to major changes in the way that families access the system of care that CCBs currently operate.

As CMS and States move forward with the implementation of the conflict free case management rule, how can we help ensure that families and individuals do not lose access to the case workers and providers with whom they have developed relationships?

Answer. I understand that promoting community integration for older adults and people with disabilities remains a high priority for CMS. If confirmed, I look forward to reviewing and helping to improve the work underway at the Federal and State level in implementing the regulation that finalized criteria for home and community-based settings appropriate for the provision of HCBS.

Question. In 2015, over 428,000 children were in foster care nationally. Parental substance use is cited as a reason for removing children from families in 32.2 percent of cases.

If confirmed as Secretary of HHS, what policies will you recommend to address this population of children and their families that are affected by the opioid crisis?

Answer. Addressing the opioid crisis is a top priority for the Department of Health and Human Services. It is critical that we address the unique needs of children in foster care as a result of parental substance use. If confirmed, I commit to working with all relevant agencies within HHS to address this problem.

Question. I worked with Senator Portman to introduce the Medicare PLUS Act, which would set up a pilot program to manage the sickest and the highest-cost Medicare beneficiaries by coordinating their health-care needs through an Accountable Care Organization or Medicare Advantage plan. As you may know, 15 percent of Medicare beneficiaries have six or more chronic conditions and account for 50 percent of total Medicare spending.

If confirmed as Secretary of HHS, what steps will you take to pilot this program and ensure that these patients receive the coordinated care they need?

What other plans do you have to advance the use of alternative payment models such as Accountable Care Organizations?

Answer. I look forward to learning more about the Medicare PLUS Act. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. If we start from the principle of empowering patients and putting their needs first, we can reform our health insurance system to realize efficiencies, reduce health-care spending and improve patient care. If confirmed, I will strive to work with staff across HHS to make health care more affordable, more available, and more tailored to what individuals need in their care. I look forward to working with Congress and the staff at HHS to identify and execute reforms that will put patients and beneficiaries first.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

HELP COMMITTEE QFRS

Question. Historically, nominees to be Secretary of the Department of Health and Human Services have answered questions for the record from both the HELP Committee and the Finance Committee. Former Secretary Price did not respond to HELP questions for the record and you have yet to respond to them either, despite having received them on December 1, 2017. Accordingly, I have attached the questions my Democratic colleagues and I submitted for that hearing for you to respond to here.

Answer. I have—and will continue to—faithfully comply with the rules of both the committee and the Senate to the best of my ability. As the Senate Finance Committee is the committee of jurisdiction, I provided answers to those questions for the

record first. However, I am glad to submit answers to the HELP Committee questions as promptly as possible.

MEDICAID AND CHIP

Question. This administration has pushed to repeal the Patient Protection and Affordable Care Act, an action that would end the expansion of Medicaid to millions of people and would result in significant cuts to State budgets. This action would throw millions of people into the realm of the uninsured, including hundreds of thousands with disabilities. They would no longer have access to such services and treatments as behavior health care, mental health treatment, and preventative services. The services provided by Medicaid expansion have greatly improved the quality of life for millions of citizens, particularly those with disabilities.[1] Do you propose those individuals return to being uninsured? Do you propose that their health care, including mental health treatments, be discontinued? Do you support returning hundreds of thousands of people with disabilities into the category of the uninsured?

Answer. As I noted before the committee, we need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. To address concerns that the ACA's expansion of able-bodied adults without children has impacted access to Medicaid services for Americans with disabilities, we need to customize our programs and benefits to the characteristics of our beneficiaries and allow for States to best serve their most needy citizens by providing them flexibility while also holding them accountable. I firmly believe that States are best positioned to make these decisions, and if confirmed, I will work with States to ensure they have the flexibility and authority they need to structure their Medicaid programs in ways that best meet the unique needs of their populations.

Question. If plans to create per captia allotments or block grants for Medicaid are implemented, many people with disabilities will lose Medicaid coverage. Those individuals with disabilities depend on Medicaid for services that are unavailable through private insurance such as personal care services, respite care, or intensive mental health services. These health, personal care, and preventative services allow individuals to live in the neighborhoods of their choice, be independent, work, and participate in their communities. Many of these people, capable, able people, will potentially be forced into institutions if they lose access to these crucial services. How will you ensure that this group of Americans retains the needed supports and services to remain in their own homes and active members of their communities?

Answer. As I said above and before the committee, the details around financing and flexibility are key to evaluating any block grant reform approach, including those proposed last year. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. To address concerns that the ACA's expansion of able-bodied adults without children has impacted access to Medicaid services for Americans with disabilities, we need to customize our programs and benefits to the characteristics of our beneficiaries and allow for States to best serve their most needy citizens by providing them flexibility and holding them accountable. I firmly believe that States are best positioned to make these decisions, and if confirmed, I will work with States to ensure they have the flexibility and authority they need to structure their Medicaid programs in ways that best meet the unique needs of their populations.

Question. Federal flexibility in Medicaid has allowed Pennsylvania to take extra steps to ensure that children with extensive health care needs have access to Medicaid, in what's referred to as Family of One program. This program, in addition to the Medicaid expansion for parents, has improved the economic security of families in Pennsylvania. The State's budget relies on the Federal share in order to support these Medicaid programs. However, the budget in the House last year would have cut Medicaid funding by $1 trillion dollars, about one-third over a 10-year period. Given that half of Medicaid enrollees in this country are children, how will you ensure that children and families aren't harmed by cuts in Medicaid funding through block grants?

Answer. As I said above and before the committee, the details around financing and flexibility are key to evaluating any block grant reform approach, including those proposed last year. We need reforms to give States as much freedom as pos-

sible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste, and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it.

Question. Medicaid covers a broad range of services to address the diverse needs of the populations it serves. In addition to covering the services required by Federal Medicaid law, many States elect to cover optional services such as prescription drugs, physical therapy, eyeglasses, and dental care. Coverage for Medicaid expansion adults contains the ACA's 10 "essential health benefits," which include preventive services and expanded mental health and substance use treatment services. Medicaid provides comprehensive benefits for children, known as "EPSDT," that are considered a model of developmental pediatric coverage. EPSDT is especially important for children with disabilities because private insurance, which is designed for a generally healthy population, is often inadequate to their needs.

Unlike commercial health insurance and Medicare, Medicaid also covers long-term care, including both nursing home care and many home and community-based long-term services and supports. More than half of all Medicaid spending for long-term care is now for services provided in the home or community that enable seniors and people with disabilities to live independently rather than in institutions. Given that both EPSDT for kids and long term services and supports are not generally covered in commercial health plans. How will you ensure that these essential services are retained given the policy proposals to block grant Medicaid or to place a per capita cap on recipients?

Answer. As I discussed above, we need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. I believe States must have the flexibility to create the best Medicaid program for their residents and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I would support proposals that would make the Medicaid program work better for the Americans who rely on it.

Question. Forty percent of Pennsylvanian children rely on Medicaid and CHIP, which serves our State's most vulnerable children: children living in or near poverty; infants, toddlers, and preschoolers during key developmental years; children with special health care needs; and children who have been place in foster care due to neglect or abuse. Medicaid's comprehensive, pediatrician-recommended services under EPSDT—Early and Periodic Screening, Diagnostic and Treatment services—are critical for their health and to ensure that they hit key development milestones. In recent years, there is clear evidence of the long-term return on investments in Medicaid. Children enrolled in Medicaid are healthier as adults and more likely to graduate from high school, attend college, resulting in greater economic success. Do you support the EPSDT benefit package for children which ensures that America's most vulnerable children receive the services they need to thrive? Are you willing to protect these benefits by not allowing States to waive this important benefit?

Answer. Medicaid and CHIP are a critical part of the safety net for millions of American children who are exactly the type of vulnerable beneficiaries that these programs are intended to serve. If confirmed, I will support continued coverage of EPSDT services for children in Medicaid consistent with the Department's statutory obligations.

Question. The health repeal bills from last year that the Trump administration supported would have given States an option to block grant Medicaid, leading to the elimination of many critical patient protections. With our current Medicaid struc-

ture, children have a right to the full array of services they need, from critical health screenings for cancer treatment to services for children with autism or mental health needs. For many children, this coverage can be the difference between life and death. Medicaid as currently structured also enables children with disabilities to live up to their potential, be successful in school, and have the opportunities to be full citizens. Do you support the continuation of Medicaid's requirement to cover a comprehensive array of services for children through the Early Periodic Screening Diagnosis and Treatment (EPSDT) program? Will you commit to ensuring that HHS will actively enforce the requirement to provide screenings, diagnosis, and treatment for children with disabilities or with potential disabilities?

Answer. As I said above, Medicaid and CHIP are a critical part of the safety net for millions of American children. If confirmed, I will support continued coverage of EPSDT services for children in Medicaid consistent with the Department's statutory obligations.

Question. Many people with disabilities want to work and can do so with the home and community based services only available through Medicaid, to help them work. These services include supported employment for people with mental health disabilities or personal care attendants for those with intellectual or physical disabilities. Without these services, many people with disabilities will be unable to work. How will you ensure that a person with a disability, mental health, intellectual, physical, sensory, or any other type of disability as defined by the Americans with Disabilities Act, has access to the services currently available through Medicaid?

Answer. Ensuring access to care for people with disabilities is a central promise of the Medicaid program. If confirmed, I would make sure that HHS follows the law and continues to engage stakeholders in the disability community to ensure these individuals have access to high-quality care.

Question. As economies evolve, professions change and while new types of jobs emerge, certain types of jobs are reduced or eliminated and workers must make transitions. This happens to people across the workforce, but it happens almost twice as often to workers with disabilities. Do you support taking away people's Medicaid coverage because they lose their jobs? Do you support work requirements as an eligibility for Medicaid? How will you ensure that people with disabilities who become unemployed are able to retain Medicaid benefits?

Answer. Medicaid is a single program dealing with many completely different population subgroups, including for the first time under the expansion, able-bodied adults without children. We need to customize our programs and benefits to the characteristics of our beneficiaries. While I have not been involved with CMS's efforts to allow States to implement work and community engagement requirements in their Medicaid programs, I do believe there is significant evidence that one of the best ways to improve the long-term health of low-income Americans is to empower them with skills and employment, for those who are able to work. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

Question. In 1999, in the *Olmstead* decision, the U.S. Supreme Court agreed that individuals with significant disabilities have the right, under the Americans with Disabilities Act, to access services in the community rather than only in an institutional setting. Since the *Olmstead* decision, the U.S. Department of Health and Human Services has employed its authority over Medicaid waivers to encourage States to expand home and community-based services and to shift away from over-reliance on institutional care. Will you continue this longstanding Federal policy? If no, why not? If yes, what steps will you take?

Since the *Olmstead* decision, Congress has authorized several programs to incentivize States to meet their obligations under the *Olmstead* decision by increasing Federal dollars for providing community-based services. These programs include the Money Follows the Person program, the State Balancing Incentive Program, the Community First Choice State Plan option, and the Home and Community Based Services option. These programs are implemented and managed through the Department of Health and Human Services. Is it your view these programs should continue? Why or why not?

Answer. I and the administration support the availability of home and community-based services for those for whom that is a better setting than an institutional setting. There is important work underway at the State level in implementing the home and community based services regulation that finalized criteria for home and

community-based settings appropriate for the provision of home and community based services. State partners, stakeholders representing beneficiaries and their families, providers, and other community organizations have been collaborating with the Federal Government, and with each other, to develop transition plans that would make the reforms described in the regulation a reality for over a million Medicaid beneficiaries receiving home and community based services. If confirmed, I would continue to work with States to implement these programs.

Question. The proposals from congressional Republicans over the past year have called to change Medicaid from a program that includes an open-ended Federal financial commitment to fixed block-grant payments to the States. Would this change end the Federal oversight and incentive programs that have helped State systems transform into systems that allow individuals with significant disabilities to live in the community? How would you ensure that any changes in Medicaid would not move people with disabilities back into nursing homes and other institutional settings that are linked to significantly poorer quality of life, physical and mental health outcomes, and longevity?

Answer. Ensuring access to care for people with disabilities is a central promise of the Medicaid program. If confirmed, I look forward to working with States to give them additional flexibility, while holding them accountable to ensure patient access to high quality health care.

Question. In 2011, the Department of Health and Human Services promulgated a rule to ensure that Medicaid funds designated for services in home and community-based settings were not used to fund services in segregated, institutional settings. For example, the second floor of a building used to provide inpatient hospital care could not be considered a community-based setting. That rule has been championed by the disability community as critical to afford people with disabilities the chance to live independent and fulfilling lives in their own homes and communities. Do you support the continuation of this rule? Do you commit to ensure that HHS assertively enforces it?

Answer. Ensuring access to care for people with disabilities is a central promise of the Medicaid program. If confirmed, I would make sure that HHS follows the law and continues to engage stakeholders in the disability community to ensure these individuals have access to high-quality care.

Question. A major focus in recent years has been on pursuing delivery system reforms that improve quality and reduce costs. The Federal Government over time has focused more on the needs of children in these reforms, but Medicaid for children still lags behind Medicare in supporting improvements in care. What steps will you take to promote increased emphasis on reforms targeting the unique needs of children?

Answer. We need reforms to give States as much freedom as possible to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse.

Medicaid is a safety net program that provides life-saving medical care to millions of Americans facing some of the most challenging health circumstances. The program currently faces significant challenges. If confirmed, I will work every day to implement the laws that Congress passes, and to help provide health insurance that works for Americans and meets their unique needs, particularly our most vulnerable populations that the Medicaid program is intended to serve.

Question. To ensure kids continue to receive the critical care they need under Medicaid, any potential restructuring needs to consider children's unique health care needs and the impact of limiting our investments into their future and the Nation's as a whole. Any reforms must ensure children's funding is stable, clearly defined, protects current services, and begins to remediate shortages in critical areas, such as mental and behavioral health services. How will you ensure that Medicaid continues to deliver essential services tailored to the unique needs of children?

Answer. It is a priority of mine and this administration that every child has access to high-quality health coverage. Medicaid plays a significant role in accomplishing this objective, but there is also a need to focus on family coverage in the

private market and employer plans, as well as giving States needed flexibility. If confirmed, I will 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 health-care system that is more affordable and accessible, especially for children.

MEDICARE

Question. Too often, I hear from constituents who struggle to understand when to sign up for Medicare Part B. As a result, too many older Pennsylvanians and people with disabilities are paying lifetime late enrollment penalties or going without needed health care simply because of an honest mistake.

In 2016, nearly 700,000 with Medicare were paying a Part B Late Enrollment Penalty (LEP) and the average LEP amounted to a 31 percent increase in a beneficiary's monthly premium. For a senior living on a fixed income who is paying the standard Part B premium in 2017—$134 per month or over $1,600 per year—this lifetime penalty presents a significant hardship.

Medicare Part B enrollment rules are more than 50 years old and sorely in need of updating. Importantly, we should look to align Part B enrollment rules with newer programs, like Medicare Advantage and Part D.[2] Further, the Federal Government does little to notify and educate individuals who are not auto-enrolled into Part B about what a person's responsibilities are and what consequences can result if someone delays Part B enrollment. Mr. Azar, if confirmed, will you commit to enhanced education for those approaching Medicare eligibility about the rules of the road? Will you work with Congress to modernize outdated rules and prevent Medicare Part B enrollment errors?

Answer. CMS's top priority must be to put patients first, and I understand that CMS has established an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience.

CMS should always make sure that seniors are in the driver's seat of their health care and have necessary, timely, and accurate information to make health-care decisions. If confirmed, I will work with CMS to make sure beneficiaries and individuals eligible for Medicare have the information they need to make decisions about the coverage that best fits their needs.

Question. The State Health Insurance Assistance Programs (SHIPs), known as the APPRISE program in Pennsylvania, are the only source of unbiased, one-on-one Medicare counseling for older adults and people with disabilities. In 2015, over 7 million people with Medicare received help from SHIPs. Since 1992, counseling services have been provided via telephone, one-on-one in-person sessions, interactive presentation events, health fairs, exhibits, and enrollment events. Individualized assistance provided by SHIPs almost tripled over the past 10 years.

Administered by the U.S. Department of Health and Human Services' (HHS's) Administration for Community Living (ACL), this modest program operates in every State and U.S. territory and has been significantly underfunded for years. And despite growing need, as 10,000 Baby Boomers become Medicare eligible daily, this administration recommended zeroing out funding for the program. This is not the right path forward for the Nation or for Pennsylvania. Mr. Azar, will you pledge to support funding for SHIPs?

Answer. For older adults, people with disabilities and their families, identifying what services and supports are available, understanding how to access them, and navigating the systems that provide them can be overwhelming. If confirmed, I look forward to working with all parties to ensure that older adults, people with disabilities, and their families understand the choices and services available to them and how to access them.

Question. Opioid misuse is becoming a growing concern in the aging community as many older adults are prescribed opioids for chronic pain and other conditions. HHS' Inspector General (IG) found that in 2016, approximately 500,000 Medicare Part D beneficiaries received high amounts of opioids. The IG also found that nearly 90,000 of these beneficiaries were at risk of misuse or even overdose.

Though Medicare beneficiaries should have access to medication needed to maintain their health, we must also safeguard them from inadvertently becoming a part of the opioid epidemic. Also, we must make resources available to beneficiaries who do become addicted. If confirmed, how will you ensure that Medicare beneficiaries are using opioids in a way that will not harm them in the long term?

Experts have indicated that medication-assisted treatment (MAT), which combines behavioral therapy and medication, can be effective in recovery from opioid use disorder. Methadone is one of the MAT medications used in more severe cases of addiction but is currently not covered under Medicare Part B (outpatient coverage) or Part D (prescription drug coverage) because the way in which it is dispensed does not line up with the requirements for coverage. Beneficiaries who would benefit from methadone should not miss out on its benefits because of seemingly unintended consequences of the law. Do you believe that beneficiaries should have access to methadone in these cases? If so, what will you do to ensure that they do?

Answer. As I mentioned during my hearing, addressing the opioid epidemic will be one of my top four priorities, if confirmed. Overprescribing of opioids is still a major problem, and I know that HHS is currently ramping up its efforts to address the problem from both the provider and the patient side. For instance, CDC has developed guidelines for providers, while at the same time has launched a media campaign targeting patients. SAMHSA provides educational tools to help providers identify signs of prescription drug abuse or doctor shopping. Additionally, CMS has taken numerous steps to combat opioid abuse in Medicare including the use of the Overutilization Monitoring System (OMS) to help ensure that prescription drug plan sponsors have established reasonable and appropriate drug utilization management programs. I understand CMS also released an interactive online mapping tool to assist health-care providers in assessing opioid-prescribing habits while ensuring patients have access to the most effective pain treatment and that beneficiaries' personal health care information is secure. These educational tools can aid providers who are serving Medicare beneficiaries. In addition, it is critical that we educate beneficiaries about the potential harms of opioid abuse and misuse. I believe that medication-assisted treatment is an important element of recovery for many individuals and that we should work to ensure that patients have access to the care that they need.

Question. Most seniors and people with disabilities live on low and fixed incomes, with more than half of people with Medicare living on only $26,200 per year or less. Older adults spend upwards of $5,000 per year on out of pocket health-care costs, including deductibles, premiums, and copayments. In September 2017, CMS released a Request for Information (RFI) for the Center for Medicare and Medicaid Innovation (Innovation Center) which appeared to be seeking input on models to radically restructure Medicare, including premium support (or Medicare vouchers) and private contracting.

While the RFI does not explicitly mention the terms "premium support" or "Medicare voucher," the ambiguity of the proposal allows for a variety of interpretations. I interpreted the language in the RFI to mean that CMS is considering models that would fundamentally restructure the guaranteed benefit traditional Medicare provides to older adults and people with disabilities through a premium support model. Did CMS intend to seek comment on a premium support model? If no, please clarify the type of model CMS is seeking input on in this RFI.

The RFI also seeks input on private contracting, a practice in which Medicare beneficiaries would be required to negotiate their out-of-pocket health-care costs directly with their providers. This practice undermines protections Congress put in place more than 30 years ago to ensure that Medicare providers fairly bill older adults and individuals with disabilities who have Medicare. If you become Secretary, will you commit to upholding existing balance billing protections? Further, will you refrain from allowing private contracting through CMMI models, specifically any practices that would force people with Medicare to negotiate out-of-pocket costs directly with their provider?

I am also troubled by the disregard of normal process for posting the RFI. The RFI was posted to the Innovation Center website, but not formally included in the Federal Register. This practice creates unnecessary barriers to review and comment submission. The RFI also includes a statement that "CMS may publicly post the comments received," which creates a concern that CMS is attempting to obfuscate regular process in order to withhold unfavorable comments from public view or decide against responding to certain comments. Mr. Azar, if you are Secretary, do you agree to make public the more than 1,000 comments submitted on the Innovation Center RFI?

My concern about this RFI is compounded by the fact that the proposals under consideration may not allow for Medicare beneficiaries to maintain choice and that beneficiaries may not have the ability to opt out of Innovation Center models. I am concerned about this premise, especially since providers will be allowed to opt out

of such models. Mr. Azar, if you become Secretary, can you assure that Medicare beneficiaries are notified and educated about their involvement in Innovation Center models and given the choice of participating? Similarly, how would you guarantee that beneficiary protections, including opt-out mechanisms, are incorporated into model design?

Answer. One of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. CMMI will be a critical part of these efforts. Of course, we must exercise the power of CMMI and other authorities in ways that are open and transparent, and that seek out collaboration and input as much as possible. I am not familiar with any details or deliberative process behind the most recent actions cited in this question, but if confirmed, I look forward to exploring models that reduce costs and increase quality for Medicare beneficiaries, taking full advantage of the stakeholder input CMS receives through the recent RFI.

Question. Telemedicine has helped to bring specialty care to rural and underserved areas across the country, but there are barriers within the Medicare and Medicaid programs that have hampered this progress. Do you support removing barriers to telemedicine under Medicare and Medicaid and what role do you see for telemedicine in the coming years?

Answer. Telehealth can provide innovative means of making health care more flexible and patient-centric. Innovation within the telehealth space could help to expand access to care within rural and underserved areas. With respect to Medicare, the Centers for Medicare and Medicaid Services (CMS) recently sought information regarding ways that it might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. I understand that CMS is carefully reviewing comments and considering commenters' suggestions for future rulemaking and any appropriate sub-regulatory changes. If confirmed, I look forward to continued discussions on telehealth, including on the best means to offer patients increased access, greater control and more choices that fit their medical needs.

CHILDREN'S ISSUES

Question. You have hardly any record on child welfare issues. The largest Federal investment in child welfare is made through title IV–E of the Social Security Act, which reimburses States for activities associated with foster care, and it is managed by the Department of Health and Human Services. While foster care is a critical, often life-saving intervention, we should be moving toward a system that not only supports children who can no longer remain safely with their families, but one that also helps stabilize struggling families so that they can keep their children when it is possible to do so safely. This focus on prevention is not only often in the best interest of children, but also in the best interest of State budgets, and States that have started shifting to a prevention-focused model have seen lower downstream costs associated with foster care, homelessness, health care and criminal justice. This is an especially critical issue right now, at a time when we are seeing foster care caseloads increasing as a result of the opioid epidemic. How will you, as Secretary of Health and Human Services, prioritize investments in services aimed at helping vulnerable families?

Answer. If confirmed, I will continue the collaborative work that the Children's Bureau, within the Administration for Children Youth and Families at ACF, has begun with the Department of Education (ED) providing the tools and resources necessary to connect education and child welfare agencies across the country. In addition, I look forward to working with States to help them improve outcomes for child welfare involved children and families.

Question. Will you commit that, if confirmed as Secretary of Health and Human Services, you will take action to guarantee parents coverage of and access to mental health and substance use disorder services, to prevent child abuse and neglect, and help reunify families?

Answer. I am committed to ensuring that all individuals have access to the necessary mental health care they need. Children, in particular, are an important subset of the population, and I would work to review current programs at HHS that target treatment for children.

Question. Currently, when families adopt children with special needs from foster care, those children are guaranteed Medicaid coverage through the age of 18. This

is an important support for these children and their adoptive families. If confirmed as Secretary of Health and Human Services, what assurances can you give to these children and their adoptive parents that their health care needs will continue to be met?

Answer. It is important that every child has access to high-quality health coverage. Medicaid certainly plays a role in accomplishing this objective, so it is of paramount importance to provide States flexibility to address the unique needs of their communities. If confirmed, I look forward to partnering with the States to ensure that families who adopt children benefit from access to high-quality health care.

Question. Recently, there have been reports that "welfare reform" would be a priority for the coming year. What programs within and outside of HHS do you consider to be "welfare" and what reforms and changes do you think need to be made to these programs?

Answer. There are many programs both within and outside HHS that have come to comprise the economic safety net for low-income families. The 1996 welfare reform law tackled a subset of those, with a key outcome being the replacement of the Aid for Families with Dependent Children (AFDC) cash assistance program with the Temporary Assistance for Needy Families (TANF) program. I see a lot of opportunity to continue to make improvements to the efficiency and effectiveness of welfare programs for beneficiaries and taxpayers, and, if confirmed, will continue to look for ways to improve HHS programs, whether considered welfare or not, to better meet the needs of the people they assist. If confirmed, I will work across the Department to prioritize reforms that maintain an emphasis on national values of work, community engagement, and personal responsibility. Responsible reforms should focus on reducing burdens and inefficiencies and should recognize that States are in a better position than the Federal Government to operate public benefit programs that best meet the needs of their citizens. I see the Federal Government's role as a catalyst for engaging all sectors of the community to develop and implement a shared vision to grow the capacity and reduce the dependency of economically and socially vulnerable populations.

Question. In 2015, Congress recognized the importance of high-quality early learning and care by authorizing a new Preschool Development Grants program in the bipartisan Every Student Succeeds Act (ESSA PDG). As the Secretary of HHS, you will be responsible for implementing this important program, along with the Secretary of Education. Under ESSA PDG, Congress explicitly allowed States to use funds to promote access to high-quality early learning and care during the renewal period. If confirmed, will you commit to respecting this allowance and helping States to increase the number of low- and moderate-income served in high-quality early learning and care programs?

Answer. If confirmed, I will work with the Assistant Secretary for Children and Families and the Secretary of Education to implement the PDG program as specified by the authorizing legislation, with an emphasis on State leadership and flexibility in high-quality, mixed-delivery, comprehensive early childhood State systems that provide low-income children from birth through age 5 and their families with supports to assist these children to be successful in school and beyond.

Question. Oftentimes, changes in the larger health-care landscape take place, for example in the Medicaid program, without a full examination of how these changes could potentially impact children, even inadvertently. As you look at health-care changes at the national level as Secretary, how will you ensure that children's unique health-care needs are taken into account?

Answer. Medicaid has been the safety net for many vulnerable American children. If confirmed, I will support continued coverage of services for children in Medicaid consistent with the Department's statutory obligations.

Question. Children's health-care needs are unique and electronic health records play an important role in guaranteeing the care our children receive is appropriate and safe. The 21st Century Cures Act included a provision instructing the Secretary of Health and Human Services to issue draft criteria for the voluntary certification for pediatric health information technology. Developing pediatric specific standards will help ensure our children are getting age appropriate vaccines and tests and coordinate care for children with complex medical needs. If confirmed, what steps will you take to ensure that electronic health records are meeting the needs of our children?

Answer. I am committed to the goals of the 21st Century Cures Act. It is vitally important to make sure that all Americans have access to high quality health care and we know that care would benefit from the use of EHR technology.

THE OPIOID EPIDEMIC

Question. According to the recent *Facing Addiction: Surgeon General's Report on Alcohol, Drugs, and Health,* "Substance misuse and substance use disorders are estimated to cost society $442 billion each year in health-care costs, lost productivity, and criminal-justice costs." The National Survey on Drug Use and Health (NSDUH) reported in 2015 that 21.5 million people in the United States, over 8 percent of the population, had a substance use disorder.[3] The Center for Disease Control and Prevention reported over 52,000 drug overdose deaths in 2015.[4] Of the millions of people struggling with a substance use disorder, only about 10 percent receive substance use disorder treatment in a given year.[5] If confirmed as Secretary of Health and Human Services, what actions will you take to address the needs of Americans struggling with substance use disorders, especially those who are seeking treatment?

Answer. It is extremely important that individuals with substance use disorder be able to access treatment. The improvement of access to prevention, treatment, and recovery services is one point of HHS' five-point strategy to address the opioid epidemic. If confirmed, I would continue to support efforts at the Department to advance improved access to these services.

Question. If confirmed as Secretary of Health and Human Services, will you commit to supporting, and as a Cabinet member advising the President to support, continued funding for opioid crisis grants, as administered by SAMHSA?

Answer. If confirmed, I commit to reviewing the current resources available and ensuring that these resources are used wisely. I will support continued funding to address the opioid crisis.

Question. If confirmed as Secretary of Health and Human Services, will you commit to supporting, and as a Cabinet member advising the President to support, funding for the Substance Abuse Prevention and Treatment Block grant to preserve the critical safety net for Americans who require substance abuse treatment but who are uninsured?

Answer. If confirmed, I commit to reviewing the current resources available and ensuring that these resources are used wisely. I will support continued funding to address the opioid crisis.

Question. If confirmed as Secretary of Health and Human Services, would you commit to supporting, and as a Cabinet member advising the President to support, funding requests for the National Institute of Mental Health and the National Institute on Drug Abuse to develop better treatments for substance use disorders?

Answer. If confirmed, I commit to reviewing the current resources available and ensuring that these resources are used wisely. I will support continued funding to address the opioid crisis.

Question. Integrated primary care and mental health care is one promising strategy to improving outcomes for Americans with substance use disorders. If confirmed as Secretary of Health and Human Services, will you support demonstration programs—which as Secretary you would have the ability to direct—to integrate primary and behavioral health care, through the Center for Medicare and Medicaid Innovation?

Answer. As I noted above, one of my top four priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. CMMI will be a critical part of these efforts. Of course, we must exercise the power of CMMI and other authorities in ways that are open and transparent, and that seek out collaboration and input as much as possible. I would be very interested in working with you on any proposals and ideas you have to address critical issues of public health, including integrated proposals related to the treatment of substance use disorder. It is my understanding that CMS recently issued a Request for Information seeking feedback on a new direction for CMMI, in which it notes that it is interested specifically in proposals for payment models and State and local interventions to improve care in areas of opioids and substance abuse. I look forward to learning more about proposals seeking to achieve these goals.

LIHEAP

Question. The Low-Income Home Energy Assistance Program (LIHEAP) provides short-term aid to vulnerable populations for heating or cooling assistance, crisis assistance or weatherization assistance. Without this support, many low-income participants would quickly fall behind on their bills and face shut-off of essential energy services. The program effectively utilizes a partnership between the Federal Government, State government and the private sector.

LIHEAP protects the most vulnerable in our society. According to the Campaign for Home Energy Assistance, in Pennsylvania in 2014, 35 percent of households receiving LIHEAP were elderly, 30 percent were disabled, and 18 percent had children under 5. You were a member of the Task Force on Poverty, Opportunity, and Upward Mobility that drafted the "A Better Way" plan that proposed to combine LIHEAP with 10 other social program grants to create a large block grant to States. Should such a plan come to pass, it would eliminate a dedicated fund for utility crisis assistance. In addition, your recent budget took across the board cuts from safety net programs and highlighted LIHEAP as one of several "duplicative anti-poverty programs." While the Department of Energy also oversees an energy program (the Weatherization Assistance Program), this program provides grants to States to improve the weatherization and energy efficiency of low-income homes. Thus, serving a different, though just as important, service from LIHEAP?

Can you explain why you think LIHEAP is a duplicative anti-poverty program and which other programs in particular you think are providing the same services?

According to the National Energy Assistance Directors Association, States have been forced to reduce the number of households served by LIHEAP from 8 million to the current level of 6.7 million due to Federal cuts to the program. This equates to 1.3 million eligible households nationwide that did not receive assistance.

Answer. I am not familiar with the Task Force on Poverty, Opportunity, and Upward Mobility, and I did not participate in that drafting of the "A Better Way" plan.

Question. LIHEAP is a critical safety net program to support the elderly and families as the country recovers from the economic recession. Families should not have to choose between heating their homes and putting food on the table. You have previously voted in the House of Representatives against increasing funding for LIHEAP.

Do you support increasing funding for LIHEAP? If not, why do you not support it?

Will you support maintaining the funding at the current level of $3.3 billion in the President's final recommendations for FY 2017 and proposed FY 2018 budget?

Answer. I never served in the House of Representatives.

If confirmed, I will prioritize programs that demonstrate results for the populations they intend to serve. If resources for LIHEAP continue to be appropriated by Congress, I will continue to implement the program in the most effective and efficient manner possible.

HIV/AIDS

Question. Many agencies within HHS share responsibility for implementing policies to address the public health problems of HIV and hepatitis. Fortunately, we have made significant steps in recent years to treat these diseases, reduce their transmission, and in the case of hepatitis C, even cure the disease. Despite this progress, there are still 37,600 new cases of HIV in the United States each year, and only approximately half of people living with HIV have been identified and treated so that they are virally suppressed. Additionally, nearly 20,000 people die each year from hepatitis C and its complications, which exceeds deaths from HIV and many other nationally notifiable disease combined. The opioid epidemic is also driving a surge in new hepatitis C infections. As a result, I am extremely concerned about actions that could hamper our progress in combating these communicable diseases.

What are your plans to continue the progress made in fighting HIV?

How will HHS, under your leadership, work to combat the increasing rates of hepatitis due to the opioid epidemic?

Will you appoint new members of the President's Advisory Council on HIV/AIDS?

Will you commit to implementing the National HIV/AIDS Strategy and the National Viral Hepatitis Action Plan?

Answer. If confirmed, I am committed to ensuring HHS remains a world leader in HIV/AIDS prevention and treatment strategies and research. I look forward to reviewing both the National HIV/AIDS Strategy, as well as the National Viral Hepatitis Action Plan, and working with stakeholders to reduce new infections and improve access to care and treatment outcomes. The rising rates of infectious diseases and other health consequences associated with injection drug use are of great concern. Syringe Services Programs have been highly effective in certain places, such as Scott County, Indiana. If Congress should decide to continue funding for support of SSPs, I would ensure that these programs are fully implemented, consistent with such laws. If confirmed, I would also ensure that we continue our education of individuals about the risks associated with opioid misuse and abuse. Addressing the opioid crisis would be one of my top four priorities, if confirmed, and I would be pleased to work with you on this issue. If confirmed, I look forward to appointing new members to the President's Advisory Council on HIV/AIDS and reviewing the National HIV/AIDS Strategy and the National Viral Hepatitis Action Plan.

ACA SABOTAGE AND TRANSPARENCY

Question. At your hearing in front of the HELP Committee, we had the opportunity to discuss the Trump administration's sabotage of the Affordable Care Act. Despite a host of actions the administration has taken to deliberately undermine the ACA, at least 8.7 million people have signed up for 2018 Marketplace coverage. There is clearly a high demand for these plans. One wonders how many more people would have signed-up for coverage if the administration had maintained prior education and outreach efforts.

At your HELP Committee hearing, I told you that your past hostility toward the Affordable Care Act made me concerned that the sabotage of the ACA will continue under your watch. I recently received a document from HHS that details how the administration secretly plotted behind closed doors with congressional Republicans on regulatory changes to undermine the ACA. HHS refused to share this document with me and other members of Congress for over 8 months, with no reasonable basis to withhold it.

Now, it has come to our attention that HHS has developed a list of hundreds of other regulatory actions to sabotage the ACA. On December 21, 2017, I, along with Ranking Member Wyden and others, requested HHS provide this document, but HHS has once again refused to share information with Congress by stating that it is "unable to release information pertaining to planned regulatory actions."

At the HELP hearing, you told me that if the ACA remained the law of the land, it would be your job to implement it as faithfully as possible. Not only does the ACA remain the law of the land, it is clear that the majority of the people support it and want it to succeed. As such, if you are confirmed, do you believe it is important to be transparent and accountable to Congress for programs it has established, including providing information in a timely manner when requested?

Answer. I agree that it is important for HHS to be transparent and accountable to Congress on matters involving Federal programs, which includes responding to congressional inquiries within a reasonable time.

Question. Congress has a constitutional responsibility to conduct oversight of the executive branch to ensure the faithful implementation and administration of policies enacted by Congress. Withholding information for more than 8 months and refusing to provide information to Congress about planned regulatory actions is an assault on Congress as a co-equal branch of government. Congressional oversight and administration transparency are especially important when administration actions and policies are clearly aimed at undermining legislative intent and sabotaging a program established by Congress, as seems to be the case here. If you are confirmed, do you commit to providing the document detailing the more than 200 planned regulatory actions that were developed and maintained by HHS in a timely manner and without redactions?

Answer. I am not familiar with such a document, but if confirmed as Secretary, I will review this matter immediately and assess whether disclosure of any such documents is lawful and appropriate.

COOPERATION

Question. Earlier this year, there were reports that the White House instructed agencies not to cooperate with Democratic requests for information. I saw this lack of responsiveness firsthand as HHS failed to respond to multiple letters I had sent. In July, Marc Short, the White House's Director of Legislative Affairs, stated in a letter to Senator Grassley that it was "[t]he administration's policy to respect the right of all individual members, regardless of party affiliation, to request information" and that "the executive branch should voluntarily release information to individual members where possible." After this clarification regarding the administration's policy, I started to receive responses from HHS to some of my letters, but the responses have been wholly inadequate. HHS has often failed to respond to the questions posed in the letters, HHS has declined to make certain officials available for briefings with my staff, and HHS has refused to provide documents to me even when those documents have already been shared with other members of Congress.

If you are confirmed, do you commit to providing thorough, complete, and timely responses to requests for information from all members of Congress, including requests from members in the Minority?

Answer. If confirmed, I will work with my staff to ensure that the Department's responses to requests from Congress are timely, appropriate, and reasonable.

Question. If you are confirmed, do you commit without reservation to take all reasonable steps to ensure that you and your agency complies with deadlines established for requested information?

Answer. Yes, I will take all reasonable steps to try to ensure that the Department meets all relevant deadlines.

Question. Do you believe the administration should provide documents to Congress when requested absent a legal basis for withholding them?

Answer. Yes.

LGBTQ ISSUES

Question. During the campaign, President Trump said that he would "do everything in [his] power to protect LGBTQ citizens." The administration has failed to live up to that promise. In particular, HHS has taken numerous actions that will make it more challenging for its programs to serve LGBTQ Americans. In the spring, HHS eliminated sexual orientation and gender identity questions on two data collection instruments used to evaluate the effectiveness of Older Americans Act programs and programs designed to serve people with disabilities. In October, HHS withdrew a proposed rule that would have ensured that same-sex spouses were recognized and afforded equal rights in long-term care facilities that receive Medicare and Medicaid funds. Furthermore, this administration has eliminated provisions from the HHS homeless youth Street Outreach Program designed to protect LGBTQ youth and specifically focus on the needs of LGBTQ youth. Ranking Member Murray, myself, and many members of this committee have urged HHS to reverse course on all of these actions. Will you commit to reviewing all of these actions and ensure that key HHS programs will fully consider and meet the needs of the LGBTQ population?

Answer. If confirmed, I will do everything in my power to ensure that all Americans have meaningful access to medical care. I will work to ensure that the Department continues to empower patients and consumers so that they will have increased access to medical care, health, and wellness. Our Nation's health-care system is founded on the respect for the human person, evidence-based research, and effective medical treatment. It must be a system that treats each patient with the respect that they deserve, in compliance with the law.

NINETY-FIVE PERCENT OF CHILDREN ARE INSURED

Question. In the last several years, we have made enormous progress in ensuring that every child has access to health insurance, through the Children's Health Insurance Program, Medicaid, and other programs. The Patient Protection and Affordable Care Act has reduced the number of uninsured children under age 18 from over 9 million in 2012 to 3.7 million in 2015. Another 3 million young adults between the ages of 19 and 26 have also received coverage thanks to the ACA. You have been clear that you support repealing the law. I am deeply concerned about the impact that would have on the number of uninsured children and young adults.

As HHS secretary, will you guarantee that under your leadership, the number of uninsured children will not increase and their coverage will cover all medically necessary care?

Will you commit to ensuring that we will maintain the current level of insurance among children and young adults?

Answer. It is important that every child has access to high-quality health coverage. CHIP and Medicaid play an important role in accomplishing this objective, but there is also a need to focus on family coverage in the private market and employer plans, as well as giving States needed flexibility. If confirmed, I am committed to working to provide high quality health insurance to children and young adults.

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. If confirmed, I will 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 health-care system that is more affordable and accessible.

PREGNANCY ASSISTANCE FUND

Question. As a part of the Affordable Care Act, I advocated for the Pregnancy Assistance Fund, a $250-million, 10-year program to support pregnant and parenting teens and young women. The program, which is funding projects in 20 communities around the Nation, supports efforts to keep these young parents in school so that they will be able to support their children upon completing their educations, and promotes connections to local services and supports that can help young families. The Pregnancy Assistance Fund is administered by the Administration for Children and Families (ACF). While the first two rounds of grant funding were for 3 years, the most recent round of funding, in FY 2017, was for just 1 year. I am concerned that HHS has shortened the grant periods from 3 years to 1, as of this year, and I am concerned that this could have an adverse impact on the ability of grantees to enroll participants in their programs when future funding is uncertain. Will you commit to working with me to extending this program past 2019?

Answer. I agree that it is important to encourage pregnant and parenting teens and young women to complete their educations and connect them with supports that can help young families. If confirmed, I commit to learning more about this program and working with you in the future.

DISABILITIES

Question. In 1999, in the *Olmstead* decision, the U.S. Supreme Court clearly found that individuals with significant disabilities have the right, under the Americans with Disabilities Act, to access services in the community rather than only in an institutional setting. Since the *Olmstead* decision, the U.S. Department of Health and Human Services has employed its authority to encourage States to expand home and community-based services and to shift away from over-reliance on institutional placement and care versus support and independence. The right to home and community-based supports is established law and long instituted policy. If confirmed, will you continue this commitment and protect people with disabilities from the threat of institutionalization?

Answer. Since January, my understanding is that the administration has worked with State partners and other stakeholders to implement provisions of a final regulation defining home and community-based setting. In the upcoming years, if confirmed, I will work with the Department to examine ways in which it can improve engagement with States on the implementation of the home and community based services rule, including greater State involvement in the process of assessing compliance of specific settings. I would also continue to work with States on home and community based programs that meet the needs of those who rely on them, including those with disabilities.

Question. Mr. Azar, in 2008, Congress passed, by an overwhelming bipartisan majority, the Americans with Disabilities Act Amendments Act. This law clarified the intent of Congress to include people with epilepsy, diabetes, AIDS, and other long-term health conditions, as people with disabilities and thus protected by the law. Your predecessor, Dr. Price, voted against this legislation. I'd like to know where you stand on this issue. Do you think people who get treatment for disabilities such as epilepsy and diabetes should not be protected from discrimination by the ADA?

On a similar note, do you think it should be legal to discriminate against people with chronic health conditions?

The bills offered over the past 10 months to repeal and replace the Affordable Care Act would have made it possible to discriminate against those with pre-existing conditions. This was one of the foundational principles of the ACA and one of the most important components of the ADA to the general public. In Pennsylvania, 5.5 million people have pre-existing conditions. Just a few of the conditions that counted as pre-existing before we banned insurance companies from denying coverage to people with existing conditions include: cancer, mental illnesses, diabetes, epilepsy, multiple sclerosis, pregnancy.[12] Will you commit to supporting the ACA's ban on discrimination on the basis of pre-existing conditions?

Answer. The President has made clear that any replacement system must make insurance more affordable, have more choices, and provide the insurance coverage that people need. In addition, any system must effectively address the issue of risk pooling, beyond mandates. I would look forward to working with Congress and States in examining these alternative approaches. As I said in my opening statement to the committee, we must make health care more affordable, more available, and more tailored to what individuals need in their care. If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

Question. Mr. Azar, before the ACA, people with pre-existing health care conditions, including children with cerebral palsy, Down syndrome, leukemia, hemophilia, and diabetes, would simply be cut off from health coverage when they hit their annual limits or their lifetime limit, regardless of their immediate or long-term health care needs. Do you think that someone with a congenital disability, a chronic condition, or an acquired long-term disability, who needs significant health care treatment and supports, should be excluded from coverage after a financial cap is reached? Will you commit to supporting the ACA's ban on both annual and lifetime limits?

Answer. As stated above, the President has made clear that any replacement system must make insurance more affordable, have more choices, and provide the insurance coverage that people need. In addition, any system must effectively address the issue of risk pooling, beyond mandates. I would look forward to working with Congress and States in examining these alternative approaches. If confirmed, I will commit to continuing to implement and enforce the laws within the purview of the Department of Health and Human Services.

Question. With major demographic changes occurring in the United States there is a great need for racial and ethnic minority mental health professionals as well as health professionals who, themselves, have disabilities. How will you work to promote Federal efforts to increase the numbers of individuals from diverse ethnic backgrounds and individuals with disabilities to enter into health professions as well as increase the cultural and disability competence of our health workforce?

Answer. America is facing a real workforce shortage especially in the field of mental health, and it is an issue that I look forward to addressing, if confirmed. I know that SAMHSA and HRSA, in particular, are involved with programs that aim to address the workforce shortage and encourage individuals from diverse backgrounds to pursue health professions. I look forward to learning more about these programs and ensuring that we are working to solve the problem of a mental health workforce shortage.

Question. Mr. Azar, there has been extensive focus on employer wellness programs during the past decade with many companies using the current maximum penalty of 30 percent of the cost of the group health plan (employer and employee share) if an employee does not participate. Evidence is mounting that such penalties do not significantly increase participation in workplace wellness programs. Moreover, such penalties disproportionately affect low-income workers and those with unseen disabilities that they may not wish to disclose. Such penalties force a person to either reveal their health-care status to their employer or pay a significant financial penalty, on average, $5,000 per family. Do you believe that workers who choose to keep their health information private from their bosses should be forced to pay that kind of penalty?

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[12] *http://kff.org/health-reform/issue-brief/pre-existing-conditions-and-medical-underwriting-in-the-individual-insurance-market-prior-to-the-aca/*.

Answer. Employer wellness programs have been highly successful in encouraging individuals to improve their health. Each program is unique and tailored to the employer's workforce, and must be reviewed individually to determine whether it is compliant with current regulations. I believe we should continue to study the impact financial and other incentives and behavioral economic interventions might have on employee wellness and behavioral health.

Question. Mr. Azar, the current director of the Centers for Disease Control and Prevention has publicly announced that she will be reorganizing the Centers. The National Center for Birth Defects and Developmental Disabilities has been critical in responding the increased incidence of autism and other developmental disabilities, including such congenital disabilities as Down syndrome and other trisomy syndromes. Your predecessor called for a 12-percent cut to the CDC budget through the elimination of the Public Health and Prevention Fund, a fund that supports many of the efforts of the NCBDDD and which helps to inform families, physicians, and health-care providers about autism and developmental disabilities. Do you support less information being shared with self-advocates, families, and health-care providers about autism and developmental disabilities?

Answer. I support CDC's commitment to protecting the health of Americans and helping people with developmental disabilities reach their full potential by providing a better understanding of autism and developmental disabilities.

EARLY LEARNING

Question. We know that investments in early learning offer some of the highest returns on investment of any Federal support. We also know that if children learn more now, they'll earn more later. Unfortunately, despite bipartisan support for these policies that help children learn and parents go to work, fewer children are receiving access to child care assistance than at any time in the history of the Child Care and Development Block Grant. From 2006 to 2015 alone, the average monthly number of children served fell by 373,100. Do you commit to providing funding that will allow States to turn around the precipitous drop in families receiving child care assistance so children can receive high-quality care that prepares them for bright futures and parents can go to work knowing their children are well cared for?

Answer. Current funding levels for CCDBG are the highest in the history of the program, and the President's Fiscal Year 2018 Budget Request includes funding to serve about 1.4 million children each month. HHS is committed to working with States to help leverage available resources to provide access to child care for the working families who need it.

Question. There have been policy proposals from within the Trump administration that suggest privatizing the Corporation for Public Broadcasting (CPB). The CPB plays a critical role in supporting public television across Pennsylvania and the Nation. Given the important role that public broadcasting programming plays in creating high-quality educational content for young children, do you support privatization of the CPB?

Answer. I am not aware that the Corporation for Public Broadcasting (CPB) is within HHS's jurisdiction.

Question. According to the 2013 National Survey of Early Care and Education, the median wage for center-based early childcare staff was $9.30 an hour, or about $19,000 a year. This means child care workers on average make less than parking lot attendants, manicurists, and massage therapists. One amazingly dedicated worker I met told me she had to choose between paying for food and her medicine. This problem is repeated in Head Start as well. We say that children are our most valuable resource, so we should be paying the individuals who take care of them accordingly. I believe high quality early learning opportunities for all children are critical for success later in life—if children learn more now, they'll earn more later. What will you do to help increase wages for our child care and early childhood workforce?

Answer. States have the flexibility to decide how they invest their CCDBG funds, and are allowed to use those funds to support professional development and financial assistance for child care workers. HHS is committed to providing innovative ideas, technical assistance, and research to States that choose to focus funds on these activities in order to assist them to better support the child care workforce for the benefit of the children they serve.

Question. Given the critical need for more access to more high quality early learning services, how will you work to strengthen and expand our system of early learning so more children can receive high quality supports?

Answer. If confirmed, I will work with ACF to support States through technical assistance and research as they continue to lead the way on systemic investments in quality improvement and increasing access to child care for low-income working families.

Question. Early childhood educators—including those working in publicly funded preschools—are often paid less than their equally qualified counterparts in K–12 education. Do you believe the pursuit of compensation parity is important? If yes, how would you support States to promote and implement policies that support it?

Answer. Every community has different demographic, budgetary, and policy needs that shape its approach to early childhood education programs and their workforce. I believe a one-size-fits-all approach is not feasible for a country as diverse as the United States. If I am confirmed, I will work with ACF leadership to identify ways that we can work to support early childhood care providers and educators for the benefit of the children they serve.

Question. Since its inception, Head Start has served over 32 million children and families, providing our youngest learners with vital skills they need for a healthy future and strengthening the parenting skills of parents and guardians. Will you make investments to support and strengthen Head Start to ensure that low-income students under the age of 5 are ready to succeed in school and life?

Answer. I share your support for and commitment to the Head Start program. If confirmed, I will work to ensure that HHS implements the Head Start statute in an effective and efficient manner so that the children served by the program are better prepared for success in school and life.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Question. The Agency for Healthcare Research and Quality (AHRQ) is the Department's lead agency in generating research evidence to improve patient safety. Under AHRQ's initiatives over the past 5 years, hospital-acquired conditions fell by 21 percent, saving 125,000 lives and $28 billion in health-care costs. Do you support these efforts to improve patient safety and will you continue to support the agency's funding requests?

Answer. Efforts to improve patient safety are important. I have not been privy to budget formulations and cannot speak to AHRQ's funding request.

MATERNAL AND INFANT HEALTH

Question. The Department of Health and Human Services Draft Strategic Plan for FY 2018–2022 recognizes the importance of increasing breastfeeding rates and access to breastfeeding support, supplies and counseling. For example, the Draft Strategic Plan supports increased access to breastfeeding supports and lactation accommodations; encourages the practice of breastfeeding to support the healthy development of children and youth; and encourages breastfeeding to reduce obesity. If confirmed, what actions will you take to ensure that the Department of Health and Human Services takes the appropriate steps to implement the goals set forth in the Draft Strategic Plan?

Answer. I am not familiar with the current programs at HHS related to breastfeeding, but I know the agency has an important role to play in developing information based on science and educating the public. I look forward to supporting these efforts, if confirmed.

Question. There is ample evidence that supports breastfeeding to improve the health and well-being of children, whenever feasible. If you are confirmed, you will have broad authority to significantly change or repeal the regulations that implement the Affordable Care Act. Will you work with Congress to ensure that any regulatory changes, including to the breastfeeding preventive services requirement, are implemented in such a way that mothers will continue to have uninterrupted and broad access to these important services?

Answer. I believe that all women should have access to quality, affordable health care and to services they choose that work for them and that meets their needs.

VIRAL HEPATITIS ELIMINATION

Question. Nearly 5 million Americans are now living with hepatitis B or C. Infection with hepatitis B and/or C is a leading cause of liver cancer, the rates of which have steadily increased since 2003. Since 2012, hepatitis C has accounted for more deaths than all 60 of the reportable infectious diseases combined.

Earlier this year, the Centers for Disease Control and Prevention (CDC) released an updated estimate of the costs needed to prevent, treat, and eliminate hepatitis B and C. The CDC's letter to HHS begins by stating: "Our Nation is losing ground in the battle against viral hepatitis—infections of which kill more Americans than all reportable diseases combined." According to the CDC, our government will need to spend $3.9 billion over the next 10 years to cut the incidence of hepatitis B and C in half. To achieve this, the CDC recommends investing $1.7 billion over the next 5 years. Will you, if confirmed as Secretary of Health and Human Services, commit to following the CDC's recommendations to eradicate the hepatitis B and C epidemics?

Answer. Viral hepatitis is a serious public health threat to the Nation. The sharp increases in viral hepatitis incidence can primarily be attributed to injection drug use associated with the growing opioid crisis. I know the administration and the Department are fully committed to addressing this crisis and the resulting increases in hepatitis B and C. I look forward to working with CDC, if confirmed, to address this issue.

Last year, the National Academies of Sciences, Engineering, and Medicine reported that with greater will and resources, our country can eliminate hepatitis B and C. This spring, the National Academies released a report detailing the key strategies for how to eliminate hepatitis B and C. If confirmed as Secretary of Health and Human Services, do you intend to make the elimination of hepatitis B and C a major priority, and—if so—what role will the National Academies' report play in shaping your strategy?

Answer. The rapidly rising rates of viral hepatitis are of great concern. I look forward to reviewing the National Academies' report and working with CDC to outline a clear path toward eliminating hepatitis B and C as a public health threat.

Question. Our country is in the midst of an opioid epidemic. In 2015 alone, more than 30,000 people died from opioid overdose. For the first time in decades, heroin accounted for more of these deaths than prescription pain killers. And for the first time in our Nation's history, more people died from heroin-related causes than from gun homicides. The opioid epidemic has fueled an outbreak of hepatitis B and C, and we are also seeing elevated rates of HIV infection. From 2010 to 2014, acute hepatitis C infections increased by 250 percent. From 2006 to 2013, acute hepatitis B infections increased 114 percent in three States that have been on the forefront of the opioid overdose epidemic—Kentucky, Tennessee, and West Virginia. If confirmed as Secretary of Health and Human Services, what strategies will you use to address the spike in hepatitis B, hepatitis C and HIV infections caused by the opioid epidemic?

Answer. Viral hepatitis and HIV infections are a serious public health threat to the Nation. The sharp increases in viral hepatitis incidence and new HIV infections can primarily be attributed to injection drug use associated with the growing opioid crisis. I know the administration and the Department are fully committed to addressing this crisis and the resulting increases in hepatitis B and C and new HIV infections. I look forward to working with CDC and other agencies within HHS, if confirmed, to address this issue.

Question. Hepatitis B impacts over 2.2 million Americans in the United States, and prevalence rates are rising. Significant research investments have been made to ensure that there is a safe and effective vaccine and clinical interventions. If confirmed as Secretary of Health and Human Services, how do you plan to continue the efforts toward eradicating hepatitis B?

Answer. CDC is taking action—and will continue to take action—to prevent and reduce the incidence, morbidity, and mortality associated with hepatitis B virus. CDC's viral hepatitis strategic plan for 2016–2020 *(Bringing Together Science and Public-Health Practice for the Elimination of Viral Hepatitis)* outlines the agency's prevention priorities. The strategies include assuring vaccination, early detection and response, and screening and linkage to care/treatment. I am supportive of these efforts and look forward to continuing the work in this space, if confirmed.

INTIMATE PARTNER VIOLENCE

Question. Injuries and violence are now the leading cause of death for Americans ages 1 to 44. Each year, injuries and violence account for 192,900 American deaths, 3 million hospital admissions, and $671 billion in medical and work loss costs. The National Academies have recommended a comprehensive Federal injury and violence prevention agenda. The Centers for Disease Control and Prevention's National Center for Injury Prevention and Control is tasked with studying violence and injuries and researching the best ways to prevent them. If confirmed as Secretary of Health and Human Services, will you continue to support Federal initiatives to prevent injuries and violence, including domestic violence and sexual assault?

Answer. Yes.

PUBLIC HEALTH PREPAREDNESS

Question. During the last reauthorization of the Pandemic and All-Hazards Preparedness Act, I worked to ensure that our public health preparedness strategy included an appropriate evaluation of, and planning for, the medical and mental health needs of children in the case of a disaster or public health emergency. Children make up 25 percent of the population in the United States and, as we frequently say in health policy, "are not little adults." Therefore, disaster planning and response must take their unique anatomic, physiologic, and developmental/behavioral characteristics into account in order to be truly prepared. In light of the recent public health emergencies that have affected children, from Ebola to Zika, the government can and must do better to meet the needs of children. The HHS National Advisory Committee on Children and Disasters has been particularly helpful in providing advice and recommendations to the Federal Government, and I hope you will act on these recommendations. How will you ensure that all communities are prepared to respond to the unique needs of children before, during and after a disaster? How will you advocate for needed resources for HHS to address the public health, medical and mental health needs of children and their parents who have been affected by disasters, such as the U.S. citizens in Puerto Rico and U.S. Virgin Islands?

Answer. Children possess unique needs leading up to, during, and after disasters that require a special focus. Recommendations made from the National Advisory Committee on Children and Disasters will receive serious consideration if I am confirmed. The impact on children from the most recent hurricanes is significant. If confirmed, I will work to ensure coordination between HHS programs and State officials is meeting the special needs of children impacted by these storms.

Question. In the last several years, we have seen the emergence of new strains of pandemic influenza, the first Ebola epidemic and the emergence of new infectious diseases such as the Zika virus and Middle Eastern Respiratory Syndrome (MERS), all of which have significantly taxed State and Federal resources and highlighted gaps in our domestic and international preparedness. The Ebola and Zika outbreaks illustrate the ability of infections to spread globally, including spreading rapidly into the United States. While we have learned that the best way to protect the United States is to engage with the global community to strengthen disease surveillance and intervention, this engagement has not been fully realized. As Secretary of HHS, are you committed to continued engagement in global health security? How will you make sure the U.S. Government is sustainably investing in research and development for new drugs, vaccines, diagnostics and other interventions so that we are ready to address both existing and emerging infectious disease threats?

Answer. During my previous time at HHS, I was deeply involved in global public health coordination activities and efforts to create sustainable research and development in biomedical countermeasures, and am committed to ensuring their continued success. The President and his administration have affirmed their commitment to global health security, including leveraging mechanisms such as the Global Health Security Agenda. If confirmed, I look forward to working to further these critical activities.

Question. If confirmed as Secretary of Health and Human Services, how will you make sure the U.S. Government is sustainably investing in research and development for new drugs, vaccines, diagnostics, and other interventions so that we are prepared to address both existing and emerging infectious disease threats?

Answer. During my previous tenure at HHS, I was deeply involved in creating mechanisms to support sustainable investment research and development for bio-

medical countermeasures. I look forward to working with Drs. Kadlec, Fauci, Fitzgerald, and Gottlieb to enhance U.S. preparedness for infectious disease threats.

Question. If you were to be confirmed as Secretary of Health and Human Services, how do you envision the Department addressing biothreats and the regulation of select agents?

Answer. The Biomedical Advanced Research Development Authority (BARDA), as well as the Project BioShield program increase our ability to respond to biothreats. Though BARDA has successfully invested in 34 products which have received FDA approval, more work is required to meet the ever-growing threats. There are still material threats where no treatment or vaccine currently exists. If confirmed, I will work with ASPR and BARDA to build on the successes of the program so Americans are protected from additional threats. I would also work with CDC, across the Department, and with the Department of Agriculture and other components of the executive branch to ensure that the HHS select agents regulations are appropriately implemented and enforced.

Question. The rise of vector-borne diseases coincides with decreased funds and support for the Centers for Disease Control and Prevention in this area. If confirmed as Secretary of Health and Human Services, what are your plans for addressing the rising risk of vector-borne diseases on the Nation's health and safety?

Answer. Addressing the threat of vector-borne diseases remains an important priority. The recent Zika epidemic demonstrates the risk posed by vector-borne diseases. It is critical that we ensure adequate capacity at the Federal, State, and local levels to detect and respond to vector-borne threats, as well as develop innovative methods for preventing vector-borne diseases.

Question. As you know, the Biomedical Advanced Development Authority (BARDA) is the lead Federal agency that develops and stockpiles treatments for chemical, biological, radiological, and nuclear threats. Though it is located within a health-care department, BARDA's mission is critical to our national security. Most recently, BARDA has been leading the Department of Health and Human Services' efforts to successfully develop vaccines for Ebola and Zika. Like all drug development, it takes years—decades in most cases—to successfully test a smallpox vaccine or an anthrax treatment. But medical countermeasure (MCM) development is unlike any other type of drug or vaccine development because of how complex the clinical testing and regulatory review processes are. And to make it even more challenging, the only purchaser of these products is the Federal Government. Given the important role it plays in protecting America's national security, what steps will you take, if confirmed as Secretary of Health and Human Services, to ensure BARDA has the resources it needs to continue advancing MCM development programs?

Answer. During my previous tenure at HHS, I was a leader in creating these very systems to enable and support sustainable research and development of biomedical countermeasures, and I am committed to ensuring their continued success. BARDA plays an integral role in our national security. Developing and stockpiling products is costly; however, the costs pale in comparison to the cost in lives and recovery if America is attacked with one of these biothreats by a terrorist or state actor. Since my previous tenure as General Counsel and Deputy Secretary, I have recognized that, for many of these products, the only market is government entities. Industry needs confidence that, if they invest in developing a product that meets one of these government needs, the government will be willing to stockpile it. If confirmed, I'm committed to building on the success BARDA and Project BioShield have seen since their inception.

Question. In 2013 Congress reauthorized $2.8 billion in funding for Project BioShield's Special Reserve Fund (SRF). For over a decade, the SRF has created a market for biodefense medical countermeasures and signaled the government's commitment to procure MCMs against national security threats. Each year, SRF funds are used to stockpile millions of doses of drugs and vaccines against threats like anthrax, smallpox, nuclear radiation. Unfortunately, to date, only $1.5 billion has been allocated to this critical fund. Without a renewed commitment to the SRF from the Secretary of Health and Human Services (HHS), we risk the delay or cancellation of critical MCM procurements. Can you please describe what actions you will take, if confirmed as Secretary, to renew HHS's commitment to fully funding the SRF, as Congress intended?

Answer. I am committed to build on the successes of BARDA and Project BioShield. If confirmed, I look forward to gaining additional information on the current

state of the SRF and will work with the programs and Congress to address the financial needs of the program.

NATIONAL INSTITUTES OF HEALTH

Question. For decades, the United States has led the world in biomedical research. In Pennsylvania alone, we have thousands of world-class researchers who rely on funding from the National Institutes of Health to lead discovery and develop new treatments. Yet Federal funding for the NIH hasn't kept pace with inflation in the last 10 to 15 years, and we're losing ground to other countries who are *increasing* their investment in scientific research. The 21st Century Cures Act made an important investment in the Cancer Moonshot, the Precision Medicine Initiative and the BRAIN Initiative, but if we truly want to lead the world in medical innovation, we need to invest more in scientific research that leads to discoveries and new cures. If confirmed, will you commit to maintaining the United States' position as a world leader by advocating for funding the NIH at a level consistent with medical inflation?

Answer. NIH is the world leader in biomedical research, and I will do everything in my power to maintain this tradition.

Question. Thirty million Americans live with rare diseases, while treatment innovation and clinical expertise have stagnated. If confirmed, what efforts would you undertake as Secretary of Health and Human Services to improve scientific discovery and clinical management of rare diseases?

Answer. Having worked at HHS previously, I know the department is committed to working both across and within agencies to accelerate efforts to improve scientific discovery and clinical management of rare diseases. Collaboration across agencies is very important to assuring that advances leading to treatments in rare diseases are managed expeditiously to benefit the American taxpayer. I am committed, if confirmed, to ensuring that staff are supported to achieve advances in scientific discovery.

FOOD AND DRUG ADMINISTRATION

Question. If confirmed as Secretary of Health and Human Services, what strategies would you advocate to collect and share data on the safety of medical devices with the American public, so that doctors and patients can make informed decisions?

Answer. The FDA under Commissioner Gottlieb has taken several steps, including the NEST system, to make this information available to consumers. If confirmed, I would support the work of Dr. Gottlieb and the career scientists at the agency.

Question. What are your opinions on current Food and Drug Administration (FDA) policies on direct-to-consumer advertising of prescription drugs? If confirmed as Secretary of Health and Human Services, what guidance will you give to the FDA to assure that patients have accurate information on the safety and efficacy of prescription drugs?

Answer. I believe it is important to protect patients from false or misleading information and protect the integrity of the drug approval process in a manner that is consistent with the First Amendment, and that furthers the interest in ensuring that payers, practitioners, and patients have access to truthful and non-misleading information that may help them to make informed decisions. I support this goal and, if confirmed, look forward to being briefed on the agency's efforts.

Question. In April 2016 the FDA proposed a rule (81 FR 24385) banning electronic devices that shock students or residents in schools or residential facilities. Thousands of comments were submitted in support of the rule but the FDA has not yet banned such devices. Do you support the use of such aversive devices for the purposes of discipline and control of children and individuals with disabilities? Will you support a ban of such devices if confirmed as Secretary?

Answer. If confirmed, I look forward to being briefed on this issue by the agency leadership and subject matter experts.

Question. Forty-eight million Americans get sick every year from foodborne illness and 3,000 die. Prevention measures, like those in the Food Safety Modernization Act (FSMA), are essential, particularly for vulnerable citizens like children and the elderly. Do you think that it is important to keep food safe and protected, particularly from intentional adulteration and terrorism? Are you committed to preserving these protections?

Answer. Yes, FDA's role in protecting our Nation's food supply is a vital part of fulfilling FDA's public health mission and, if confirmed, I will support their work, including implementation of FSMA.

Question. On October 2, 2017, the FDA issued a proposed rule to extend the compliance date for the final rules to update the Nutrition Facts Label. The proposed rule extended the compliance date from July 26, 2018 to January 1, 2020 for manufacturers with $10 million or more in annual sales, and extended the date from July 26, 2019 to January 1, 2021 for manufacturers with less than $10 million in annual food sales. Many companies have already invested to meet these requirements. Are you committed to implementing the updates to the Nutrition Facts Label without further delays?

Answer. As someone who suffers from two medical conditions requiring accurate nutrition labeling and close scrutiny of those labels, this is an issue near to my heart. I personally want to ensure that as much as is reasonably possible, individuals have the information they need to make healthy and safe choices regarding their food consumption and companies are not unduly burdened by requirements or uncertainty. If confirmed, I look forward to supporting a successful implementation of the nutrition fact labeling updates.

Question. Do you support the "added sugars" line on the revised Nutrition Facts Label so Americans can know how much added sugar is in a food product? In addition, are you committed to releasing a final guidance for added sugars to provide clarity to industry?

Answer. I recognize the importance of consumers being empowered in their food choices. I also appreciate that guidance can be an important tool for helping industry implement regulatory requirements and providing insights into FDA's regulatory decision making. If confirmed, I look forward to being briefed on "added sugars" and any regulatory considerations by the FDA.

Question. Given the proposed rule on the Nutrition Facts Panel, manufacturers will likely be required to use the new Nutrition Facts Panel by January 2020 or January 2021. In addition, the United States Department of Agriculture (USDA) is in the process of establishing a label for products that contain genetically engineered ingredients. This rulemaking is expected in July 2018, with 2 years for compliance. For products that contain genetically engineered ingredients, manufacturers must update their labels to comply with the nutrition facts panel changes, and subsequently update their labels to disclose genetically engineered ingredients. If confirmed as Secretary of Health and Human Services, how will you work collaboratively with other agencies, such as USDA, to provide support to manufacturers in order to ensure that manufacturers can comply with these deadlines?

Answer. I support the goal of better dialogue and coordination with leaders and public servants in other departments and agencies to ensure that we are working toward our shared objectives in an efficient manner that avoids placing unnecessary burdens on regulated entities. If confirmed, I look forward to engaging in a sustained dialogue with my counterparts, including the Secretary of Agriculture, in order to advance this goal.

Question. Poor nutrition is a significant public health problem in the United States. Americans are eating too many calories and too much sugar, sodium and saturated fat. This has led to significant increases in the number of Americans who are overweight or obese and at risk for cardiovascular disease, cancer, diabetes, and other chronic health conditions. This results in significant costs to the health-care system, employers, and Americans themselves. A poor diet is also the leading cause of death among modifiable risk factors, which means behaviors can be changed to decrease the risk and help people make healthier choices. The Department of Health and Human Services has a long tradition of addressing these issues with the Dietary Guidelines for Americans, and the Food and Drug Administration provides critical guidance through nutrition labeling, menu labeling, and encouraging healthful changes to the food supply. What do you see as the agency's role in improving diet quality—and the overall health of Americans—moving forward?

Answer. Providing consumers with tools to make healthy lifestyle choices, including choices about the foods they eat, can have a significant and positive impact on reducing health-care costs. If confirmed, I look forward to working with FDA leadership on policies to better promote the use of nutritional information as a way to prevent disease and death without unnecessarily burdening food producers, retailers, and restaurant owners. I would also like to add to these efforts a consideration of the latest evidence-based behavioral economics learnings regarding how people

make choices, why they make those choices, and what interventions can assist them in that decision-making, that might aid HHS in its work in this area.

Question. As import volumes continue to grow, the Food and Drug Administration (FDA) will need additional funding to keep up with this increasing volume. If confirmed as Secretary of Health and Human Services, will you commit to working to ensure that FDA has the resources it needs to create a truly level playing field on behalf of domestic food producers, and will you seek the funds necessary to advance this initiative in President Trump's Fiscal Year 2019 budget?

Answer. I recognize the importance of consumers being empowered in their food choices. I also appreciate that guidance can be an important tool for helping industry implement regulatory requirements and providing insights into FDA's regulatory decision making. If confirmed, I look forward to being briefed on this issue and on funding levels.

Question. In December, the FDA announced that it would delay the compliance deadline for regulations pertaining to certain tobacco products. If confirmed as HHS secretary, how would you approach the regulation of the different types of tobacco products covered under the deeming regulation? Would you seek to change any of these regulations before they take effect, and if so, what factors would guide your vision for tobacco regulation?

Answer. Commissioner Gottlieb has recently announced a bold and balanced approach to tobacco and nicotine regulation at FDA, including key efforts to prevent youth and adolescents from initiating tobacco use. If confirmed, I look forward to partnering with Commissioner Gottlieb in the implementation of a science- and evidence-based framework to regulating tobacco products. The direction laid out over the past 12 months by the Commissioner is one that, if fully implemented, will drastically reduce the potential for youth addiction to cigarettes, and result in millions of individuals living longer, healthier lives by beating the scourge of addiction that afflicts so many today. This proposal is vital to our mission of saving lives; with your support, we will strive to one day see the end of addictive cigarettes, something which was viewed as impossible in the not-so-distant past.

RURAL HEALTH

Question. If confirmed as Secretary of Health and Human Services, what strategies would you implement to reduce regulatory barriers to deliver telehealth services to Americans who reside in rural areas?

Answer. It is my understanding that CMS is reviewing their existing regulations and taking steps to evaluate and streamline regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience through their Patients over Paperwork initiative. If confirmed, I will work with CMS to make sure their programs achieve a balance between protecting patient safety and avoiding undue burden on providers. I also understand that CMS recently sought information regarding ways that it might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. CMS is likely carefully reviewing comments and considering commenters' suggestions for future rulemaking and any appropriate sub-regulatory changes. If confirmed, I look forward to hearing ideas from Congress and other stakeholders on how CMS can improve access to services, including telehealth services, to make sure beneficiaries in rural areas have access to high-quality care that meets their needs.

GRANDFAMILIES AND CAREGIVERS

Question. There are an estimated 2.6 million children being raised in grandfamilies, a term used to describe families where grandparents are the primary caregiver for grandchildren or other relatives are caring for relative children. Though grandfamilies are not new, experts believe that the opioid epidemic is contributing to the rise in the number of grandfamilies. When parents are unable to care for their children due to their addiction, many grandparents and other relatives step in. Relatives who keep children out of the foster care system save taxpayers over $4 billion dollars each year. This role may be sudden and unexpected, however, and can dramatically alter the caretaker's life, significantly affecting their financial stability and health, among other things.

After hearing from experts and grandfamilies about this issue, Senator Susan Collins and I introduced the Supporting Grandparents Raising Grandchildren Act. This bill will create a Federal Task Force, including Federal agencies like SAMHSA, to

serve as a "one-stop shop" of resources and information for grandparents raising grandchildren. This bipartisan legislation is supported by many outside groups, including Generations United, AARP and the American Association of Pediatrics.

How do you think improved coordination and collaboration across the government and with experts will help these grandparents and relatives?

Given the support for this bill, we are confident that it will pass and be signed into law in the near future. If confirmed, will you commit to ensuring the collaboration and coordination required in this bill is a priority?

Answer. With the opioid crisis, supporting grandparents and relatives who act as primary caretakers in their families is an emergent need and one that SAMHSA is committed to addressing in its programs and policy initiatives. With the Administration on Community Living, SAMHSA is collaborating internally to ensure complementary efforts. However, older adults raising children and youth have concerns that affect all areas of their family lives: education, history, transportation, primary health care, behavioral health care, financial stability, and for some, juvenile justice. Working together with our Federal partners, including the Department of Education, Department of Justice, and the Department of Housing and Urban Development, we can ensure that any programs and policy initiatives address the full range of needs grandparents and relatives may have. Close coordination will ensure all efforts leverage the full range of resources across the Federal Government, are nonduplicative, and financially efficient. I am committed to implementing the laws passed by Congress, and would coordinate with the appropriate agencies across the Federal Government as needed.

OLDER AMERICANS

Question. As Americans age, they are often confronted with greater health-care needs. Historically, seniors paid up to 11 times higher premiums for health insurance than non-seniors. Medicare was established to provide older adults, ages 65 and older, with more affordable health insurance coverage than routinely available by private insurers. Prior to the Affordable Care Act (ACA), only nine States limited private insurance premiums for older adults; the ACA limited premium surcharges to three times the rate of non-seniors, and the ACA has proven to be vitally important to older adults not yet eligible for Medicare; 3.3 million people ages 50 to 64 are enrolled in the ACA Marketplaces—representing the largest share of enrollees nationwide (26 percent). Do you believe that insurance companies should be able to charge older Americans seeking coverage on the individual market more for their health insurance than younger Americans? If so, how much more? And, why?

Answer. There is an emerging bipartisan consensus that the ACA's structure is fundamentally flawed in this area. The age rating structure as currently in statute does not allow for functional risk pooling. Under the ACA age rating requirements, insurance is unaffordable for younger and healthier individuals. That is why older enrollees currently represent the largest share of enrollees. As a result, premiums have risen for older Americans far beyond anything that would have occurred in a stable risk pool even with more realistic age rating structure. This is a problem we must all work together to solve, as effective and predictable risk pools are critical to the success of any health insurance system. If confirmed I pledge to work with Congress on health-care reforms that create effective risk pools.

Question. Last year, with bicameral, bipartisan support, Congress unanimously approved and the President signed into law the Older Americans Act Reauthorization Act of 2016. If confirmed as Secretary of Health and Human Services, would you continue to protect and enhance OAA programs such as Meals on Wheels, senior centers, transportation, employment and training services for the growing number of seniors in social and economic need?

Answer. If confirmed, I will work with the Administration for Community Living to advocate for and enhance OAA programs within the budgetary constraints of the current fiscal environment. Also, I believe that the use of innovation and evidence-based practices will be critical to meeting the evolving needs of older Americans and those with disabilities.

Question. Older Americans Act (OAA) Nutrition Programs are serving 23 million fewer meals[13] than in 2005 due to limited funding, while the number of seniors experiencing hunger increased by 73 percent from 2007 to 2014. In addition, a recent

[13] *https://www.acl.gov/programs/health-wellness/nutrition-services.*

GAO report [14] found that about 83 percent of food insecure seniors and 83 percent of physically impaired seniors did not receive meals through the OAA but likely needed them. If confirmed as Secretary of Health and Human Services, would you increase funding for programs that support nutritionally at risk, vulnerable seniors?

Answer. The OAA nutrition programs offered through the Administration for Community Living help meet the needs of many of the Nation's older adults. The programs not only provide health-promoting meals in a variety of group settings, such as senior centers, and faith-based settings, as well as in the homes of isolated older adults, but also provide an important link for the individuals served to other supportive community-based services. If confirmed, I will work with the Administration for Community Living to ensure their continued effective and efficient implementation through the use of innovation and evidence-based practices, including through the flexibility Congress provided to allow up to 1 percent of ACL's nutrition funding for exploring innovative ways to provide these services.

Question. The State Health Insurance Assistance Programs (SHIPS) are the only source of one-on-one Medicare counseling for seniors and people with disabilities. In 2015, over 7 million people with Medicare received help from SHIPs. Since 1992, counseling services have been provided via telephone, one-on-one in-person sessions, interactive presentation events, health fairs, exhibits, and enrollment events, and individualized assistance provided by SHIPs almost tripled over the past 10 years. This modest program is operated in every State and U.S. territory and has been significantly underfunded for years on end despite the growing need, as 10,000 Baby Boomers become Medicare eligible each day. As HHS Secretary, you would oversee the administration of this program through the Administration on Community Living. This administration has recommended eliminating the $52 million in annual funding that allows SHIP programs to support older adults and people with disabilities with Medicare decision-making. Will you protect the SHIP program and ensure its continued funding?

Answer. For older adults, people with disabilities, and their families, identifying what services and supports are available, understanding how to access them, and navigating the systems that provide them can be overwhelming. If confirmed, I look forward to working with all parties to ensure that older adults, people with disabilities, and their families understand the choices and services available to them and how to access them.

Question. As the Ranking Member of the Senate Committee on Aging, I have a significant concern about the financial security of our Nation's older adults. Not only must they decide the best way to spend during their golden years but must also make sure they are protecting their nest eggs from fraud and abuse. It has been estimated that financial abuse targeting seniors adds up to nearly $3 billion annually. Once seniors lose money in this way, we've heard they almost never receive ample payback for their loss. This can significantly affect a person's entire life, including their health. If confirmed, how would you help to ensure that older adults are aware of the prevalence of financial abuse and the effect it could have on their lives, including their health?

Answer. HHS through the Administration for Community Living has long been engaged in efforts to protect older individuals from elder abuse including financial exploitation, physical abuse, neglect, psychological abuse, and sexual abuse. Through the Elder Justice Act of 2009, the Elder Justice Coordinating Council was developed, which is led by the Secretary of Health and Human Services and the Attorney General of the United States and includes the heads of 10 other Federal agencies that administer programs related to abuse, neglect, or financial exploitation as council members. If confirmed, I will continue to support these efforts.

Question. In July 2017, the Special Committee on Aging held a hearing highlighting food insecurity, the importance of proper nutrition on senior health, and the role federally funded nutrition programs play in seniors' access to nutritious foods. At this hearing, Pat Taylor of Penn Hills, Pennsylvania testified on the importance of federally funded senior nutrition programs and stated that awareness of and ease of access to federally funded programs is critical to older adults participating in these programs. Because of Pat, and others like her, I have introduced S. 2085, the Nourishing Our Golden Years Act. This bill will set a minimum certification period for the U.S. Department of Agriculture's Senior Food Box Program and provide States with the flexibility to extend the certification period beyond the minimum.

[14] *http://www.gao.gov/products/GAO-15-601R.*

This flexibility will reduce burden on State administering agencies as well as seniors.

Answer. If confirmed, I will continue to support the value of these vital nutrition programs for older adults.

Question. The Administration on Aging also oversees two federally funded nutrition programs that are critical to the health and well-being of older Americans, the Congregate Meal Program and the Home-Delivered Meal Program. These programs are uniquely different from those administered by the USDA and I know first-hand the importance of congregate and home delivered meals for older Pennsylvanians. If confirmed, will you commit to supporting the Congregate Meal and Home-Delivered Meal programs?

Answer. If confirmed, I will continue to support the value of these vital nutrition programs for older adults.

Question. According to the Administration for Community Living, almost half of older adults in the United States are malnourished. Malnutrition occurs among people who are underweight as well as overweight and there is a growing field of research that indicates older Americans are at increased risk of hunger and malnutrition. Poverty and food insecurity significantly increase the risk of malnutrition, however, changes with age also contribute to this risk. Nearly 60 percent of hospitalized older adults and 35 percent to 50 percent of older adults in long-term care facilities are malnourished. Of hospitalized older adults, an estimated 20 percent had an average nutrient intake of less than 50 percent of their calories needed to maintain their weight. The annual cost of disease-associated malnutrition among older adults has been estimated to reach $51.3 billion. For this reason, early nutrition interventions, including screening for malnutrition and access to nutrition assistance programs, continue to be important for the growing number of older Americans. Malnutrition screening, assessment, and intervention has been shown to decrease negative health outcomes including readmission and mortality. If you are confirmed, how will HHS integrate malnutrition screening into health and nutrition programs?

Answer. If confirmed, I will work with the Administration for Community Living and the USDA to continue to support the implementation of the vital nutrition programs they administer and seek new approaches for the integration of their nutrition screening, assessment, and intervention programs and guidelines.

TEACHING HEALTH CENTER GRADUATE MEDICAL EDUCATION (THCGME)

Question. The Teaching Health Center Graduate Medical Education (THCGME) program, currently administered by the Health Resources and Services Administration (HRSA), provides funding to increase the number of primary care medical and dental residents training in community-based settings across the country. As most health care in the U.S. now takes place in the outpatient setting, the ultimate goal of the THCGME program is to increase access to well-trained providers, particularly in ambulatory settings, for people who are geographically isolated and economically or medically vulnerable. In 2014, a report of the Institute of Medicine (now National Academy of Medicine) noted that the long term prospects of the program are uncertain without some assurance of future funding. Evidence proves that family medicine resident physicians who train in Health Center (HC) settings are nearly three times as likely to practice in underserved settings after graduation when compared to residents who did not train in HCs. If confirmed as Secretary of Health and Human Services, you would play a role in helping manage health workforce programs and addressing our Nation's physician workforce shortage and distribution challenges. What is your perspective about the value of the THCGME program and its role in supporting high quality primary care physician training in rural areas and for those who are economically and medically vulnerable? If confirmed, would you work with Congress to support the program?

Answer. The THCGME program aims to bolster the primary care workforce through support for new and expanded primary care and dental residency programs, as well as to improve the distribution of this workforce into needed areas through emphasis on underserved communities and populations. I support the goals of this program, and, if confirmed, would work with Congress on approaches to further these goals.

DRUG PRICING

Question. As innovative new drugs are coming to market, often with significant price tags, many drug companies and payers are exploring outcome- or value-based

payment models as a way to manage the costs of these drugs, which can be life-saving or life-changing. In some cases, they can improve an individual's health or quality of life so significantly that the individual could incur significantly lower costs for health care and social services for years or even decades to come—but the initial payer may not benefit from those reduced costs. How will you, if confirmed, continue encouraging the development of outcome- and value-based payment models?

Answer. You raise a very important issue in our payment and reimbursement system, one that is particularly implicated in the case of expensive curative therapies. If confirmed, I will work with Administrator Verma, CMMI, and other parts of HHS and the U.S. Government to try to find solutions to the challenge of how therapies may be paid for by one plan when the benefit accrues to another plan years down the road.

TITLE X FUNDING

Question. Typically the funding announcement for title X grants comes out well in advance of the application deadline, which is now March 2018 for all title X programs. Given the tight time frame and that there has not yet been any funding announcement made, if confirmed, will you commit to immediately releasing a funding announcement so that interested parties have sufficient time to prepare their applications?

Answer. If confirmed, I look forward to learning about the current status of the FOA and discussing its status further with you.

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[1] *The New York Times, https://www.nytimes.com/2016/12/25/opinion/the-quiet-war-on-medicaid.html.*

[2] T.E. Price, 1995, "Why Managed Care Won't Last," *The Journal of the Medical Association of Georgia,* 84, p. 165.

[3] "Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health," *https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf.*

[4] "Increase in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015," *https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.*

[5] National Survey on Drug Use and Health, *https://www.drugabuse.gov/publications/drugfacts/nationwide-trends.*

QUESTIONS SUBMITTED BY HON. MARK R. WARNER

Question. Historically, the focus in health-care cybersecurity has been on patient records and privacy. Recent events, however, have highlighted the increasing cybersecurity importance of patient safety and ensuring the availability/continuity of critical patient care delivery. How would you address these newer emerging challenges?

Answer. The safety of American citizens should always be a top priority of the Department. If confirmed, I will ensure that HHS will continue its efforts to strengthen cybersecurity within the health-care industry.

Question. We have seen a steady trickle of stories about hospitals being hit by ransomware and we know that many of types of ransomware (along with other malware strains) can impact medical devices. Do you have any plans to strengthen HHS' guidance or requirements to health delivery organizations (HDOs) on how they secure their devices?

Answer. As I mentioned above, the safety of American citizens should always be a top priority of the Department. Ensuring the security of medical devices against the threat of cyber-attacks, including ransomware and hacking, is critical to that end. If I am confirmed, the FDA and the rest of HHS will continue to improve upon its efforts to strengthen cybersecurity within the medical device industry as well as other related industries.

Question. Last summer, the Healthcare Industry Cybersecurity Task Force issued its report to Congress. Which recommendations do you feel would have the greatest impact and why? Are there any recommendations you feel would not be a good idea? If so, please provide a rationale.

Answer. As you know, the Health Care Industry Cybersecurity (HCIC) Task Force, a Federal advisory committee established pursuant to the Cybersecurity Act of 2015, was charged with making recommendations to address the challenges the health-care industry faces when securing and protecting itself against cybersecurity incidents. If confirmed, I look forward to working with Department leaders to learn more about the recommendations contained in the Task Force's report and how they recommend that HHS respond to the recommendations directed toward it. I will be committed to working across the administration, within the Department and with HHS's private sector partners and stakeholders to help combat cybersecurity threats in the health-care industry, if confirmed as HHS Secretary.

Question. There has been some discussion about whether the Department of Homeland Security's NCCIC can sufficiently address health care related cybersecurity issues, or if an HHS-specific HCCIC would complement this function with greater domain expertise and nuance. What is your perspective on this?

Answer. If confirmed, I look forward to working with Department leaders to learn more about the HCCIC and its interaction with the NCCIC. If confirmed, I will be committed to advancing the Department's efforts to strengthen and enhance the cybersecurity of the health-care industry, in coordination with DHS.

Question. How can one find out how much HHS spends on its cybersecurity? Is it possible to point to one part of the budget to know if HHS is adequately investing in its cyber hygiene?

Answer. If confirmed, I look forward to working with you and other members of the Senate Budget Committee on HHS's budget—and will work within the Department and with the Office of Management and Budget (OMB) to ensure HHS has adequate resources to address cybersecurity threats.

Question. Despite a global ransomware outbreak that impacted hospitals worldwide last year, the President's FY 2018 budget proposed to cut the Office of the National Coordinator for Health Information Technology's budget by 37 percent—despite it being the key division within the Department of Health and Human Services developing resources and risk management tools for cybersecurity in the health-care sector. The budget also proposed cutting the Office of Civil Rights at HHS—the division responsible for overseeing HIPPA privacy and security compliance—by 15 percent. Do you believe these proposals improve our Nation's cybersecurity posture?

Answer. If confirmed, I will work within the Department and with the Office of Management and Budget (OMB) to ensure HHS has adequate resources to address cybersecurity threats in the health care sector.

QUESTION SUBMITTED BY HON. CLAIRE MCCASKILL

Question. Please describe what role, if any, you believe the Department of Health and Human Services has with respect to oversight of inappropriate prescribing practices within Medicare Part D. What steps will you take to ensure that HHS has the information it needs to properly exercise oversight in this space.

Please describe your plan for addressing rising instances in workplace violence within the health-care sector. What goals will you put in place over the next year to address this issue?

Do you believe that there is currently sufficient transparency on pharmaceutical company research and development costs? Do you believe there is sufficient transparency with respect to drug cost generally? If not, what steps will you take to increase transparency?

Answer. I am generally in favor of increased transparency within our health-care system. However, the goal of transparency is ultimately to create more competition and lower drug prices, so we need to make sure transparency is not counter-productive to that goal. I would be very happy to study the issue more and work with you to ensure that all options are evaluated as we think about this important issue, and to help make sure that our policies related to transparency will actually lower costs and reduce what patients pay out of pocket.

SUBMITTED BY HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

United States Senate

WASHINGTON, DC 20510

November 2, 2017

The Honorable Eric D. Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Hargan:

We are writing to thank you for your support for the Center for Medicare and Medicaid Services' Center for Program Integrity (CPI). CPI plays a critical role in conducting oversight, combatting fraud, and determining best practices within the Medicare and Medicaid programs. As part of your ongoing commitment to the mission of CPI, we encourage you to continue to prioritize funding and administration of the Open Payments database.

The bipartisan Physician Payments Sunshine Act (Sunshine Act) created the Open Payments database for drug and device company payments to doctors, which provide transparency on billions of dollars in gifts and payments from manufacturers to prescribers and hospitals. In doing so, the database helps patients evaluate the medical advice they are being given and better understand whether there is the potential for conflicts of interest. The need for this legislation became apparent after congressional oversight and several news reports explored industry payments to doctors, some of which potentially having undue influence over physician prescribing habits.[1]

Recent reports have raised concerns about the effect payments to health professionals may have on opioid prescribing practices, which in many ways has exacerbated this ongoing public health epidemic. Pending litigation against a fentanyl manufacturer has revealed instances of regular weekly contact with high-volume prescribers, in addition to a large number of total payments.[2]

Since the Open Payments database was launched in 2014, it has reported nearly $25 billion in total payments that drug and device manufacturers make to physicians and teaching hospitals. Studies have shown that such payments can have an effect on doctors' prescribing habits—for example, whether they prescribe a name-brand drug or its generic alternative. The Sunshine Act does not penalize relationships between drug and device companies and doctors, and does not prohibit transfers of value from drug and device companies to doctors. It simply requires that those transfers be reported and made publicly available, increasing transparency and informing patients as they make health care decisions.

Many relationships between academic medicine and industry are necessary and beneficial. During program year 2016, there were 11.96 million total records attributable to 631,000 physicians and 1,146 teaching hospitals. Health care industry manufacturers reported $8.18 billion in payments and ownership and investment interests to physicians and teaching hospitals. However, some financial relationships influence prescribing and drive up costs. The Sunshine Act has substantially improved our ability to determine whether and how industry is able to influence physicians through payments—for example, whether they choose to prescribe brand drugs or less expensive generic alternatives.

The Open Payments database enjoys wide industry and public interest group support, from members of the drug and device industry as well as key non-profit stakeholders including the Pew Charitable Trusts, AARP, and Consumers Union. We thank you for your demonstrated commitment to CPI, and encourage you to con-

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[1] Ornstein, Charles, "Doctors Prescribe More Generics When Drug Reps Are Kept at Bay," NPR, May 2, 2017, *www.npr.org/sections/health-shots/2017/05/02/526558565/doctors-prescribe-more-generics-when-drug-reps-are-kept-at-bay?sc=tw.*

[2] Stephen Stirling and Erin Petenko, NJ Advance Media for *NJ.com,* "Doctors Raked in Cash to Push Fentanyl as N.J. Death Rate Exploded," July 3, 2017, *www.nj.com/healthfit/index.ssf/2017/06/doctors_raked_in_cash_to_push_powerful_fentanyl_as_nj_death_rate_soared.html.*

tinue to prioritize the timely collection and disclosure of data within the Open Payments database that has made the Sunshine Act a success.

Charles E. Grassley
U.S. Senate

Richard Blumenthal
U.S. Senate

THE UNIVERSITY OF IOWA

Injury Prevention Research Center

Prescription opioid and heroin overdoses in Iowa: A growing crisis

March 2017

The University of Iowa Injury Prevention Research Center (UI IPRC) is conducting research on prescription opioid pain reliever (OPR) and illicit opioid (heroin) overdoses and overdose deaths in Iowa using Iowa's death certificate records (2002–2014) and insurance claims data (2003–2014). IPRC is also engaging with stakeholders in Iowa to help identify priorities to address this growing crisis in the state.

Key Findings

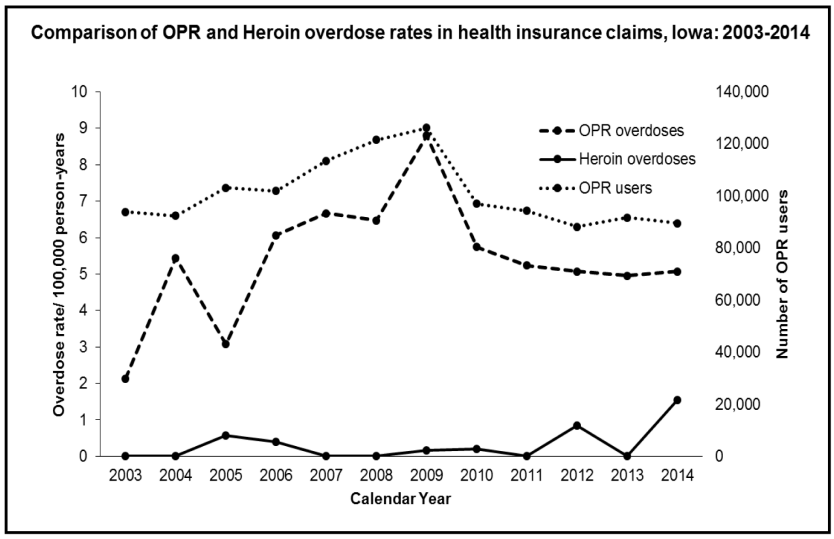
- The rate of OPR overdoses in Iowa increased from 2.1/100,000 in 2003 to 8.8/100,000 in 2009. This rate declined to 5.1/100,000 in 2014.
- In Iowa, OPR overdoses and overdose deaths are decreasing, while heroin overdoses and overdose deaths are increasing.
- Those ages 25 to 49 make up the majority of all opioid-involved overdose deaths in Iowa. Males make up the majority of deaths from both prescription opioids and heroin.

Prescription opioid use has reached unprecedented levels.
Prescription drug overdose deaths have been rising since the early 1990s, and in 2009 surpassed transportation-related events as the leading cause of injury death in the United States. OPRs are primarily driving the increase in these deaths. Since 1999, deaths due to OPRs have more than tripled in the United States. In Iowa, while OPR overdose deaths and rates of opioid prescribing are low compared to other states, rates of prescription drug deaths since 1999 have quadrupled, making it only one of four states with such a dramatic increase.

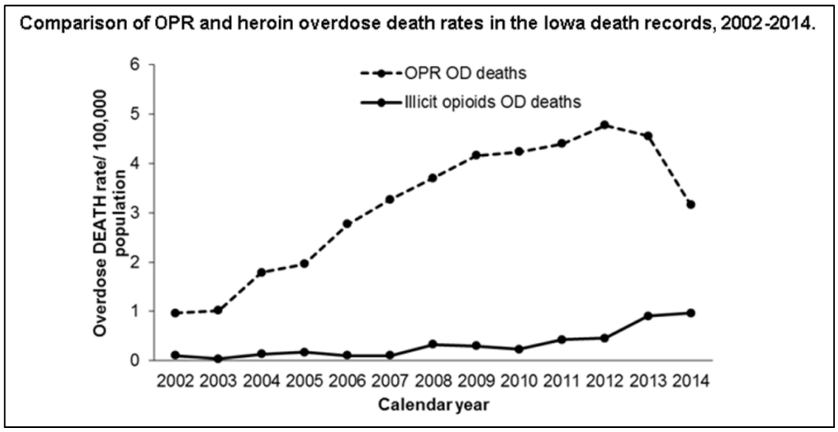
Heroin use is a rapidly growing public health problem and is associated with non-medical use of prescription opioid pain relievers.
It is suggested that while policies like the Prescription Monitoring Program (PMP) and physician education may be effective in reducing imprudent prescribing, they are not allowing patients to obtain prescriptions from multiple prescribers. As a result, patients who are OPR dependents or abusers may switch from OPRs to heroin since it is a cheaper alternative that is more easily available.

Heroin overdose death rates in Iowa have increased more than nine-fold in the past 15 years.
The rapid growth of heroin death rates in Iowa is two to three times higher than the national average. Like elsewhere in the nation, the rates in Iowa were highest in 2008–2009 when state and local agencies started acting on the prescription OPR abuse epidemic. In 2009, the state of Iowa implemented its PMP, and in 2011, the Iowa Board of Medicine implemented a mandatory continuing medical education licensure requirement for physicians who provide chronic pain management and end-of-life-care.

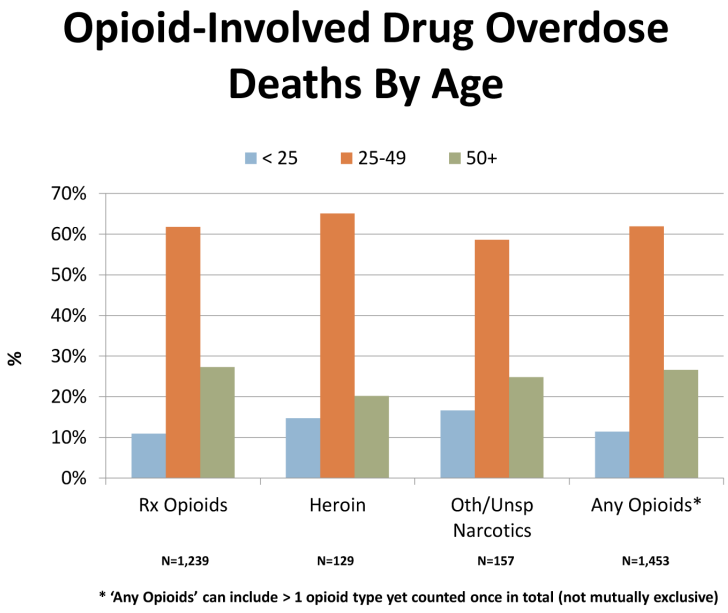
UI IPRC Research:
OPR overdoses decreasing; heroin overdoses increasing.
The rate of OPR overdoses in Iowa increased from 2.1/100,000 insured person-years in 2003 to 8.8/100,000 insured person-years in 2009. In 2009, the PMP was implemented in Iowa, after which the rate of OPR overdoses declined to 5.1/100,000 insured person-years in 2014. The data on heroin overdoses show that the rate of heroin overdoses in 2009 was 0.16/100,000 insured person-years, which increased to 1.5/100,000 insured person-years in 2014.

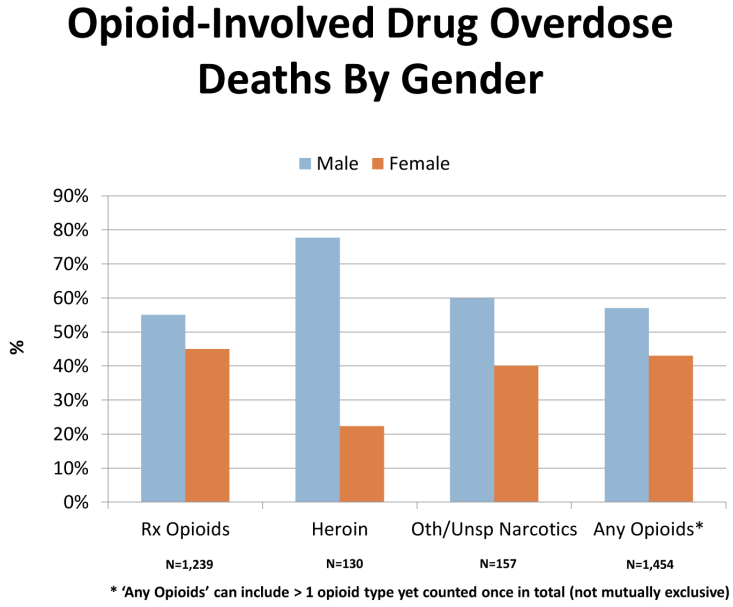


OPR overdose deaths decreasing; heroin overdose deaths increasing.
These findings suggest that Iowa is experiencing trends observed nationally, where OPR overdoses are decreasing while heroin overdoses are increasing. Using Iowa death certificate records, we see a similar trend in OPR overdose deaths and illicit opioid overdose deaths.



Those ages 25–49 make up the majority of opioid-involved overdose deaths. Those ages 25–49 make up the majority of opioid-involved deaths, followed by ages 50 and over. Males make up the majority of deaths from both prescription opioids and heroin.





Outreach: UI IPRC is engaging stakeholders in Iowa on the opioid crisis

The UI IPRC is participating in a national project funded by the Centers for Disease Control and Prevention (CDC) to make recommendations about preventing prescription opioid overdoses. It is one of four injury control centers in the United States to take part in an information sharing network to address this issue. Led by the

John Hopkins Center for Injury Research (JHCIRP), each center will promote evidence-based strategies for reducing the opioid epidemic in their state in six areas: prescription monitoring programs, prescribing guidelines, pharmacy benefit managers, overdose education/Naloxone distribution, addiction treatment and community based prevention. The UI IPRC will seek input from stakeholders in Iowa via a stakeholder meeting to create a report that reflects Iowa's priorities, and its results will be disseminated to leaders and policy makers in Iowa.

Visit our website: *www.uiiprc.org.*

For more information, contact **iprc@uiowa.edu.**

United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

January 4, 2017

The Honorable Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, SW
Washington, DC 20201

Dear Mr. Slavitt,

Recently, my staff communicated with the office of the Health and Human Services Inspector General (HHS IG) regarding a report from July 2009 entitled "Accuracy of Drug Categorizations for Medicaid Rebates." As noted in the report, manufacturers must provide the Centers for Medicare and Medicaid Services (CMS) with the average manufacturer price (AMP) by national drug code (NOC) for each of their covered outpatient drugs.[1] The report detailed a number of drugs that the Inspector General studied to determine if drugs associated with NCDs were properly categorized in the AMP file. The report noted that eight of 75 NDCs that underwent a manual review appear to be "incorrectly categorized in the AMP file."[2] The report further noted that, "these NDCs should have been categorized by their manufacturers as innovators."[3]

According to emails acquired by the Committee from the Inspector General, on March 12, 2009, CMS staff requested the HHS IG provide a list of the misclassified drugs. On March 16, 2009, the HHS IG did so. In consultation with the HHS IG, my staff was informed that the misclassified drugs included EpiPen, Dilaudid , and Prilosec. I have previously written you asking what steps the Obama Administration took to hold Mylan accountable for misclassifying the EpiPen—you have failed to respond thus far. My request was in response to CMS declaring that "on multiple occasions, [CMS] provided guidance to the industry and Mylan on the proper classification of drugs and has expressly advised Mylan that their classification of EpiPen for purposes of the Medicaid Drug Rebate Program was incorrect." Given this public pronouncement, Congress and the American public have a right to know what additional steps, if any, CMS took to hold Mylan and other companies accountable and CMS has an obligation to answer.

These misclassifications could have cost the taxpayers and states hundreds of millions of dollars. The Obama Administration's silence on these issues is unwarranted and irresponsible. Accordingly, in addition to my previous requests regarding EpiPen, please respond to the following:

1. Please provide all records relating to government communications with Purdue Pharmaceuticals and Proctor and Gamble regarding the misclassification of Dilaudid and Prilosec.
2. What steps has CMS taken to ensure that these drugs were properly classified?

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[1] Health and Human Services Inspector General, "Accuracy of Drug Categorizations for Medicaid Rebates," at i (July 2009).
[2] *Id.* at 19.
[3] *Id.* at ii.

3. Has CMS notified Purdue and Proctor and Gamble that its drugs were misclassified? If so, how was each notification communicated, when was each communication made, and what did each company do in response?
4. Has CMS determined how much the taxpayers and states have overpaid for these drugs? If so, how much? If not, why not?
5. Has the Obama Administration taken any steps to impose a civil monetary penalty, or any other penalties, upon Purdue or Proctor and Gamble for misclassifying their drugs? If so, please explain the steps. If not, why not?

Please number your responses according to their corresponding questions and respond no later than January 18, 2017. If you have questions, contact Josh Flynn-Brown of my Judiciary Committee staff at (202) 224–5225.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at the Finance Committee hearing to consider the nomination of Alex Azar to serve as the Secretary of the U.S. Department of Health and Human Services (HHS).

I'd like to welcome Mr. Azar to the Finance Committee this morning. Thank you for being here and for your willingness to serve in this important capacity.

Mr. Azar certainly has his work cut out for him. Health and Human Services is a massive, sprawling department that oversees trillions of dollars in spending and liabilities and encompasses all areas of our Nation's health care system. As a result, if confirmed, Mr. Azar's work will impact the lives of every single American.

That's a big job. It requires knowledge, experience, and, most important, strong leadership.

Fortunately, our nominee brings all of this to the table, having nearly 2 decades of experience in the health care sector, including about 6 years working at the highest levels of HHS.

During his time at HHS, Mr. Azar played key roles in implementing new policies, including Medicare Part D and the Medicare Advantage program. He was also a leader in HHS's responses to the anthrax attacks shortly after 9/11, the SARS and monkeypox crises, and Hurricane Katrina, among others.

If confirmed, Mr. Azar will be Congress's primary contact on all matters relating to our Nation's health-care system. He will be responsible for the ongoing effort to bring down costs, provide greater access to care, and give patients more choices when it comes to coverage. Whether we're talking about work to modernize Federal health programs like Medicare and Medicaid in order to preserve them for future generations, innovating the CHIP program, or reforming the private market, Mr. Azar will be the administration's primary policy driver.

He has made clear his intention to address the growing opioid epidemic that continues to ravage communities across the country, including in my home State of Utah. This crisis is robbing families of loved ones, employers of productive and able workers, and communities of the safety and security they once enjoyed.

This is an important issue to me and other members of the committee and I look forward to working with Mr. Azar to figure out how HHS and CMS can make improvements to save lives.

As many know, I co-authored the Ensuring Patient Access and Effective Drug Enforcement Act, which has recently come under scrutiny in relation to the opioid epidemic. This law requires HHS to submit a report to Congress regarding obstacles to legitimate patient access to controlled substances and issues with diversion of controlled substances.

The required report is long overdue, and so, today, I'd like to impress upon Mr. Azar the importance of getting this report to Congress so that we can have an op-

portunity to review and make any necessary changes to the law that may help turn the tide of this epidemic. I hope to get his commitment to produce and releasing this report as soon as possible, once he's confirmed.

He has expressed his commitment to succeeding in these important endeavors. And, I believe his record shows that he is more than capable of leading HHS through these next few consequential years.

Of course, there are some on the committee who have already made up their mind about Mr. Azar and are committed to opposing his nomination. This is essentially par for the course for the high-profile nominees that have come before us under this administration. And, as in previous cases, none of the attacks leveled at Mr. Azar are focused on his record, his experience, or his qualifications. Instead, we're hearing talk about supposedly revolving doors and non-existent conflicts of interest.

While I believe Mr. Azar is more than capable of responding to his critics on his own, I'd like to take just a moment to address some of the more prominent attacks we've heard thus far.

Opponents of this nomination have claimed Mr. Azar's work in the pharmaceutical industry—he's been a senior executive for the past 10 years—disqualifies him to serve in this position.

I would hope that my colleagues would want to avoid creating standards or setting new precedents where work in the private sector is somehow a knock against a nominee. That certainly wasn't a standard they applied to nominees from the previous administration, and it shouldn't apply to this one.

Mr. Azar has committed to fully adhering to all necessary ethics requirements, including the Trump administration's requirement prohibiting nominees from participating in matters involving their former employers and clients for 2 years after the end of their government service. In addition, he has committed to divesting any financial holdings that could present a conflict of interest or even the appearance such a conflict.

So, we're not talking about anything unethical. We're not talking about a nominee attempting to unduly profit off his government position.

Experience in the private sector and dealing with the policies and regulations that come from government agencies is, in my view, a mark in favor of a nominee's qualifications. Mr. Azar's work in the pharmaceutical industry will give him important insights regarding the impact of policies designed and implemented by HHS. And, when you add that knowledge and background to the years he spent as a senior official at HHS, you have an exemplary resume for an HHS Secretary.

Once again, I believe Mr. Azar is more than capable of responding to what have so far been empty criticisms. By any objective standard, Mr. Azar is well qualified to serve as Secretary of HHS. My hope is that we can have a productive hearing today and report his nomination in short order.

Thank you, once again, Mr. Azar, for being here today. Thank you for, again, for returning to the call to serve the American people. I look forward to your testimony.

Before turning to Senator Wyden, I would like to reemphasize my support for the Children's Health Insurance Program and my commitment to making sure it gets reauthorized. We have a bipartisan agreement that was reported out of committee, and I believe that it improves CHIP for the long-term. Congress has passed patches and fixes, but the time for short-term solutions is over. CHIP needs to be extended by January 19th, and I'm going to do all I can to make sure we get it done. Children, their families, and States are counting on us.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

The same Donald Trump who said almost exactly one year ago that price-hiking drug companies were "getting away with murder" has nominated a drug company executive with a documented history of raising prescription drug prices to captain the administration's health-care team. Mr. Alex Azar is here with the Finance Committee today, nominated to serve as the next Secretary of Health and Human Services.

It's my view that the issues he'll work on, if confirmed, will be defining domestic issues in 2018. That's because Americans heard a lot of promises 2 years ago about

how great their health care would be under Trump, and how the era of skyrocketing drug prices was over. Americans are going to want to know, come November, if the big guarantees they heard in 2016 ever came to fruition. To say this administration hasn't yet delivered would be a wild understatement.

Mr. Azar was the president of Eli Lilly's U.S.-based subsidiary, Lilly USA, from 2012 to 2017. He chaired its U.S. pricing, reimbursement and access steering committee, which gave him a major role over drug price increases for every product Lilly marketed in this country.

Let's look at the track record. The price of Lilly's bone-growth drug Forteo, used to treat osteoporosis, more than doubled on Mr. Azar's watch. The price of Effient, used to treat heart disease, more than doubled. The price of Strattera, used to treat ADHD, more than doubled. The price of Humalog, used to treat diabetes, more than doubled. And those are just some of the drugs that were under his purview as head of Lilly USA.

Mr. Azar told committee staff that while he chaired the company's pricing committee he never—not even once—signed off on a decrease in the price of a drug.

This morning the committee will likely hear that this is just the way things work—it's the system that's to be blamed. My view is, there's a lot of validity in that. The system is broken. Mr. Azar was a part of that system.

Given ample opportunity to provide concrete examples as a nominee of how he'd fix it, Mr. Azar has come up empty.

And if Mr. Azar is confirmed, it won't be the first time the President and his health-care team broke their promises.

A virtual parade of Trump health care officials have come before this committee and the Health Committee and promised they'd uphold the law with respect to the Affordable Care Act. Right out of the gate, it was Tom Price telling us it would be his job to "administer the law" at HHS, not to be a legislator.

The track record there looks miserable, too, because the sabotage agenda went into effect on day one. Along with their allies in Congress, the Trump team wasted no time undermining the private health insurance markets. They cut the open enrollment period in half. They slashed advertising budgets. They made it harder for people having difficulty signing up for coverage to get in-person assistance. They attacked a rule that says women have to have guaranteed, no-cost access to contraception, but fortunately that move has been held up in the courts.

They made it easier to sell junk insurance that fails people when they have a health emergency. All in all, the Trump administration has made millions of people's health care worse, and they've got no serious plan to undo the damage.

Mr. Azar is going to have to explain today whether he'll continue the sabotage agenda as HHS Secretary. And he should, because it stands in stark contrast to what he did as a member of the Bush administration to help launch Medicare Part D. He participated in a bus roadshow, public events, and local media appearances. So when it came to promoting the Medicare prescription drug benefit, he toured like he was in the Grateful Dead. Now he's set to join an administration that's tweeted less about open enrollment than Thanksgiving safety.

There's also been a lot of talk about "welfare reform" in 2018. Mr. Azar told me he believes Medicaid counts as welfare. But everybody you ask seems to have a different answer for what exactly "welfare reform" means. The common thread to all the Republican talk is this: deep, draconian cuts to programs like Medicare and Medicaid, Social Security, anti-hunger programs, support for struggling families.

With respect to Medicaid, this program is at the heart of health care in America, and it spans generations, from newborn infants to two out of three seniors in nursing homes. Today, Medicaid is built on a guarantee. The Trump team wants to end it. They've set in motion plans that would make it harder for a lot of people to get the care they need. In some cases it's older Americans and people with disabilities who need long-term care. In other cases it's adults of limited means—people who struggle to climb the economic ladder. As the one-time director of the Oregon Gray Panthers, I came up as an advocate for seniors, and any policy that risks nursing home care they need is a non-starter. And furthermore, my view is, you can't get ahead in life if you don't have your health, so endangering the health care of low-income Americans is the absolute wrong way to go.

Some of the other issues that might fall under this "welfare reform" umbrella are on the human services side of HHS' jurisdiction—issues Mr. Azar has no experience managing. Those are all areas that the committee will need to discuss further today.

One final point—the leaders of both sides of this committee previously had regular meetings and calls with sitting HHS Secretaries, Republicans and Democrats. The last HHS Secretary broke with that tradition to the detriment of bipartisanship, so I was glad to hear Mr. Azar commit to me that he'd revive it. Thank you for being here today, Mr. Azar. I appreciate your willingness to serve, and I look forward to questions.

The PEW Charitable Trusts

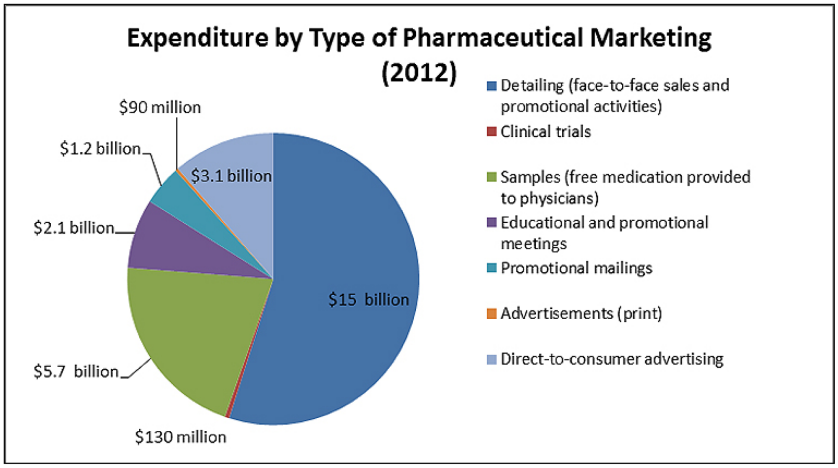
FACT SHEET

Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients

November 11, 2013 Prescription Project

In 2012, the pharmaceutical industry spent more than $27 billion on drug promotion [1]—more than $24 billion on marketing to physicians and over $3 billion on advertising to consumers (mainly through television commercials).[2] This approach is designed to promote drug companies' products by influencing doctors' prescribing practices.[3]

How Does the Pharmaceutical Industry Market its Drugs and How Much Does it Spend?



Source: Cegedim Strategic Data, 2012 U.S. Pharmaceutical Company Promotion Spending (2013).

Direct Marketing

Detailing: This marketing approach refers to face-to-face promotional activities directed toward physicians and pharmacy directors. Pharmaceutical representatives

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[1] Cegedim Strategic Data, 2012 U.S. Pharmaceutical Company Promotion Spending (2013), *http://www.skainfo.com/health_care_market_reports/2012_promotional_spending.pdf.*

[2] *Ibid.*

[3] Ashley Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?", *Journal of the American Medical Association* 283 (2000): 373–80.

typically visit doctors to pitch their drugs. Detailing also includes taking doctors out for meals and giving them gifts in the form of medical textbooks. As of 2012, approximately 72,000 pharmaceutical sales representatives were employed in the United States.[4]

Samples: Providing free medication samples to physicians has been shown to cause significant increases in new prescriptions for the promoted drug.[5] Although companies assert that samples benefit indigent patients, research indicates that most are given to insured patients whose medications are covered.[6] Indeed, patients who are given samples ultimately have higher prescription costs than those who do not receive them because they are then prescribed the sampled drug rather than its less-expensive generic alternative.[7]

Educational and Promotional Meetings: Sales representatives invite doctors to meetings during which industry-paid physicians discuss the use of particular drugs. These speakers are often leaders in their fields, which increases the draw. According to an analysis by ProPublica, an independent investigative news organization, eight pharmaceutical companies provided more than $220 million in speaker payments to physicians in 2010.[8] The companies often host these events at restaurants and provide meals to physicians who attend.[9]

Promotional Mailings: Pharmaceutical companies send unsolicited promotional materials to most doctors' offices. Typically, these brochures tout a drug's benefits and positively describe the results of recent clinical trials, which are often funded by the same company. One study found that these materials were highly biased in favor of the company's products, mainly because they selectively reported trials in which the sponsored drug outperformed that of competitors.[10]

Journal and Web Advertisements: These advertisements are standard promotional techniques that provide an important source of revenue for medical journals. The accuracy of statements in such ads is regulated by the U.S. Food and Drug Administration, or FDA. According to one study, journal advertising generated the highest return on investment of all promotional strategies employed by pharmaceutical companies, with returns ranging from $2.22 to $6.86 per advertising dollar spent between 1995 and 1999.[11] In April 2009, FDA warned 14 major drugmakers for running search ads for many of their products that highlighted the products' effectiveness without noting any of their risks.[12]

Direct-to-Consumer Advertising: In 1997, FDA issued guidance that enabled pharmaceutical companies to more easily advertise to the public. Since then, spend-

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[4] Jonathan D. Rockoff, "Drug Reps Soften Their Sales Pitches," *Wall Street Journal* (January 10, 2012), *https://www.wsj.com/articles/SB10001424052970204331304577142763014776148.*

[5] M.Y. Peay and E.R. Peay, "The Role of Commercial Sources in the Adoption of a New Drug," *Social Science and Medicine* 26 (1998): 1183–9.

[6] *Ibid.*

[7] C.G. Alexander, J. Zhang, and A. Basu, "Characteristics of Patients Receiving Pharmaceutical Samples and Association Between Sample Receipt and Out-of-Pocket Prescription Costs," *Medical Care* 46 (2008): 394–402.

[8] Charles Ornstein, Tracy Weber, and Dan Nguyen, "Piercing the Veil, More Drug Companies Reveal Payments to Doctors," *ProPublica,* September 7, 2011, accessed May 21, 2012, *http://www.propublica.org/article/piercing-the-veil-more-drug-companies-reveal-payments-to-doctors.* The eight companies were the only ones to have provided a full year's worth of data that could be analyzed.

[9] Charles Ornstein, "Doctors Dine on Drug Companies' Dime," *ProPublica* (September 7, 2011), *http://www.propublica.org/article/doctors-dine-on-drug-companies-dime.*

[10] C. Wick et al., "The Characteristics of Unsolicited Clinical Oncology Literature Provided by Pharmaceutical Industry," *Annals of Oncology* 18 (2007): 1580–82, *http://annonc.oxfordjournals.org/content/18/9/1580.short?rss=1.*

[11] Scott Neslin, "ROI Analysis of Pharmaceutical Promotion (RAPP): An Independent Study" (2011), *http://www.pharmxpert.net/web/board/b_ne01upload/RAPP%EC%A1%B0%EC%82%AC.pdf.*

[12] Food and Drug Administration Division of Drug Marketing, Advertising, and Communications, letters to Biogen Idec, Sanofi Aventis U.S., Bayer HealthCare Pharmaceuticals, GlaxoSmithKline, Forest Laboratories Inc., Cephalon Inc., Johnson and Johnson Pharmaceutical Services, Pfizer Inc., Novartis Pharmaceuticals Corp., Genentech Inc., Boehringer Ingelheim Pharmaceuticals Inc., Merck and Co., Hoffmann-La Roche Inc., and Eli Lilly and Co. (April 2009), *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773.*

ing on these direct-to-consumer ads has nearly quadrupled.[13] One study showed that 43 percent of respondents thought that only "completely safe" drugs were allowed to be advertised. Direct-to-consumer advertising has proved effective in motivating patients to ask for the branded product, even when generic equivalents exist.[14] Furthermore, these ads have encouraged one-third of respondents to speak to their doctors about the promoted drug and one-fifth to request the prescription.[15] In one study, doctors were more likely to prescribe a branded antidepressant when asked for it by name than when patients didn't specify which treatment they wanted.[16]

The United States and New Zealand are the only member countries of the Organization for Economic Cooperation and Development in which drug companies can advertise prescription drugs directly to consumers. (The organization includes 34 of the world's most advanced and emerging nations in North and South America, Europe, and Asia.)

Indirect Marketing

Continuing Medical Education (CME): In 2011, the pharmaceutical and medical device industries provided 32 percent of all funding for continuing medical education courses in the United States—$752 million out of $2.35 billion.[17] To prevent these courses from functioning as veiled marketing, they are regulated by the Accreditation Council for Continuing Medical Education. However, a 2007 Senate Finance Committee report found that "drug companies have used educational grants as a way to increase the market for their products in recent years."[18]

Grants to Health Advocacy Organizations (HAO): Patient advocates can mobilize large numbers of people on behalf of a specific issue, often to the benefit of drug companies that manufacture treatments for their diseases. One study found that organizations that had received grants from pharmaceutical manufacturers often endorsed the companies' positions, while groups that had received minimal financing focused their advocacy on drugs' potential side effects.[19]

U.S. Department of Health and Human Services

FY 2018 Budget in Brief

PUTTING AMERICA'S HEALTH FIRST

FY 2018 President's Budget for HHS

(Dollars in millions)

	2016	2017[1]	2018
Budget Authority	$1,119,166	$1,126,789	$1,112,883
Total Outlays	**1,103,145**	**1,130,835**	**1,131,256**
Full-Time Equivalents (FTE)	77,499	79,505	80,027

[1] A full-time 2017 appropriation was not enacted at the time the budget was prepared; therefore, the budget assumes operations under the Further Continuing Appropriations Act, 2017 (Pub. L. 114–254). The amounts included for 2017 reflect the annualized level provided by the Continuing Resolution.

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[13] Julie M. Donohue, Marisa Cevasco, and Meredith B. Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine* 357 (2007): 673–81, *http://www.nejm.org/doi/full/10.1056/NEJMsa070502#t=articleTop.*

[14] M. Peyrot, N.M. Alperstein, D. Van Doren, and L.G. Poli, "Direct-to-Consumer Ads Can Influence Behavior; Advertising Increases Consumer Knowledge and Prescription Drug Requests," *Marketing Health Services* 18 (1998): 26–32.

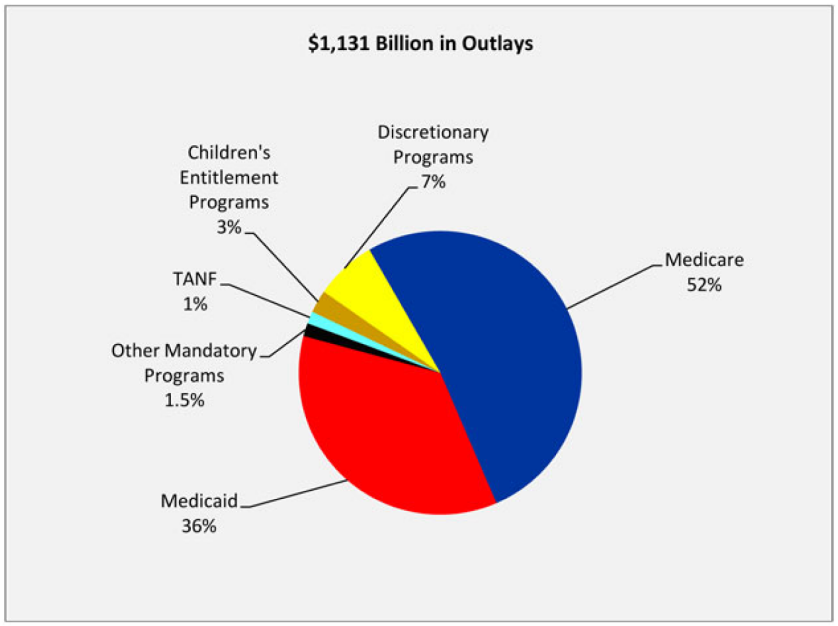
[15] Robert A. Bell, Richard L. Kravitz, and Michael S. Wilkes, "Direct-to-Consumer Prescription Drug Advertising and the Public," *Journal of General Internal Medicine* 14 (1999): 651–57.

[16] Richard L. Kravitz et al., "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial," *Journal of the American Medical Association* 293 (2005): 1995–2002.

[17] Accreditation Council for Continuing Medical Education, ACCME 2010 Annual Report Data (2011), *http://www.accme.org/news-publications/publications/annual-report-data/accme-annual-report-data-2010.*

[18] Noelle C. Sitthikul, "Senate Finance Committee Releases Report on Drug Industry CME Grants," FDA Law Blog, May 8, 2007, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2007/05/senate_finance_.html.*

[19] Jessica Marshall and Peter Aldhous, "Patient Groups Special: Swallowing the Best Advice?", *New Scientist* (October 27, 2006), 18–22.



Putting America's Health First

The Department of Health and Human Services (HHS) is enhancing the health and well-being of the American people by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

The President's Fiscal Year (FY) 2018 Budget supports the Department's mission by making strategic investments to protect the health and well-being of Americans; delivering hope and healing to the American people; promoting patient-centered care; strengthen services to tribes; investing in the health of America's future; and ensuring responsible stewardship of taxpayer dollars for long-term sustainability. Achieving these goals will require HHS to make strategic investments and carry out our mission in the most effective manner possible.

The President's Budget request for HHS proposes $69 billion in discretionary budget authority and $1,046 billion in mandatory funding to help HHS deliver on the promises the Administration has made to the American people. The Budget focuses resources on direct services and proven investments while streamlining or eliminating programs that are duplicative or have limited impact. The Department's approach to budgeting this fiscal year puts the American people first by supporting fiscal discipline within the Federal Government and saving taxpayers a net estimated $665 billion over 10 years.

A Commitment to Fiscal Responsibility—Restoring Trust to Generations of Americans

The FY 2018 President's budget brings Federal spending under control and returns the Federal budget to balance within 10 years. Of its total net estimated 10-year savings over this period, the HHS Budget contributes $665 billion in mandatory savings primarily from giving States new flexibilities to operate their Medicaid programs under per capita caps or block grants beginning in Fiscal Year 2020. The President has embraced these bold reforms that save, strengthen, and secure the promises of the Federal Government's major benefits programs. The Budget ensures that Medicaid and other programs focus on the most vulnerable Americans that they were intended to serve—the elderly, people with disabilities, children, and pregnant women.

Failing to tackle unsustainable deficit spending means passing growing debt on to our children and grandchildren and creating serious economic damage. The Federal Government's deficit spending has created a growing debt that cannot be sustained, because it is consuming an increasing portion of national income and limiting resources for private investment and public programs. Over the next 10 years, interest payments on our national debt are projected to consume trillions of dollars and surpass annual spending on national defense, Medicaid, or science.

Without action, future generations of Americans will be burdened with unsustainable debt. To restore the people's trust, we must take a fiscally sustainable approach. The Budget begins the process of expanding choices for individuals and families; enabling market forces and competition to encourage innovation and restrain costs; encouraging self-sufficiency; and promoting federalism, allowing States and localities the flexibility they need to serve their populations.

With responsibility for the major drivers of mandatory spending in the Budget, HHS is in a unique position to help lead the Administration's efforts to rebuild fiscal solvency and to secure the trust of current and future generations of Americans.

Reforming the American Health Care System

Providing Relief From Obamacare

The Budget includes $250 billion in net deficit savings over 10 years associated with health care reform as part of the Administration's commitment to expand choices, increase access, and lower premiums. The Administration continues to support a repeal and replace approach that improves Medicaid's sustainability and targets resources to those most in need, eliminates Obamacare's onerous taxes and mandates, provides funding for States to stabilize markets and ensure a smooth transition away from Obamacare, and helps Americans purchase the coverage they want through the use of tax credits and expanded Health Savings Accounts. The Administration urges the Congress to continue its work to repeal and replace Obamacare. The $250 billion in combined savings accrue to both Treasury and HHS.

The Administration will continue to work with Congress to provide for a stable transition from the burdensome requirements of Obamacare to a health care system that provides Americans with access to care that meets their needs and increases options for patients and providers. The Administration also supports State flexibility to create a free and open health care market and will empower States to make decisions that work best for their markets. In light of these goals, the Budget promotes efficient operations and funds critical activities to continue to operate the law's health insurance Exchanges.

Reforming Medicaid

The Budget fulfills the President's pledge to give States the resources and flexibility they need to care for the most vulnerable in their communities through Medicaid. To this end, the Budget reforms Medicaid funding to States starting in FY 2020 through either a per capita cap or a block grant. The Budget also provides other flexibilities to States and encourages them to innovate and test new ideas that will improve access to care and health outcomes. These proposals will save $610 billion through FY 2027 and will allow States to prioritize Federal resources for the most vulnerable populations.

The Budget extends the Children's Health Insurance Program for 2 years (through FY 2019) and makes modest reforms that taken together save a net $5.8 billion over the Budget window. The reforms to the Children's Health Insurance Program ensure the program's focus on serving the most vulnerable low-income families.

Modernizing the Medical Liability System

The current medical liability system disproportionately benefits a relatively small group of plaintiffs and trial lawyers at the expense of adding significantly to the cost of health care for every American and imposing a significant burden on health care providers. The current medical liability system does not work for patients or providers, nor does it promote high-quality, evidence-based care. The Budget proposes medical liability reforms that will save HHS programs $31.8 billion over 10 years and $55 billion to the Federal Government overall. A significant portion of these savings are attributable to the estimated reduction in unnecessary services and curbing the practice of defensive medicine. These medical liability reforms will benefit all Americans by cutting unnecessary health care spending.

In addition to reducing health care costs, these reforms will help physicians focus on patients and on evidence-based medicine rather than on frivolous lawsuits. By providing a safe harbor based on clinical guidelines, physicians can focus on deliv-

ering effective care, and—if an inherently risky medical procedure does not work out as intended—physicians will be able to express sympathy to a grieving family without fear of giving rise to a lawsuit.

Specifically, the Budget proposes the following medical liability reforms:

- Capping awards for noneconomic damages at $250,000 indexed to inflation;
- Providing safe harbors for providers based on clinical standards;
- Authorizing the Secretary to provide guidance to States to create expert panels and administrative health care tribunals;
- Allowing evidence of a claimants' income from other sources such as workers compensation and auto insurance to be introduced at trial;
- Providing for a 3-year statute of limitations;
- Allowing courts to modify attorney's fee arrangements;
- Establishing a fair-share rule to replace the current rule of joint and several liability;
- Excluding provider expressions of regret or apology from evidence; and
- Requiring courts to honor a request by either party to pay damages in periodic payments for any award equaling or exceeding $50,000.

Enhancing Direct-to-Patient Relationships

HHS is committed to reducing regulatory burdens facing medical professionals, especially those serving in rural areas. To achieve this goal, HHS continues to look for ways to improve or eliminate regulations that impede the ability of medical professionals to provide the best possible care to their patients. HHS also believes that health care providers are a valuable resource whose input and ideas are essential to a positive health care reform effort. HHS also is committed to an open and transparent process for developing new voluntary payment models that providers can participate in. Finally, HHS has established various avenues of technical assistance to help clinicians be successful in providing efficient, high-quality care to their patients.

Achieving the President's goals to reform Medicaid will require providing States with more flexibility to improve health care delivery to meet the needs of their unique populations. Direct Primary Care practices, in which physicians offer primary care services to patients at a set price, generally without payer or insurer involvement, are a mechanism to improve physician-patient relationships. Some State Medicaid programs are already testing this innovative care delivery model. HHS will explore opportunities for States and providers to further expand Direct Primary Care, which will support improved health outcomes for Medicaid populations.

Protecting the Health and Well-Being of Americans

Supporting Life-Saving Preparedness and Response Activities

The Department fills a unique Federal role in emergency preparedness and response. HHS is the Federal Government's lead agency in responding to public health emergencies. The Department coordinates the prevention of, preparation for, and response to public health emergencies and disasters. It supports numerous critical activities to enhance the Federal, State, and local capacity to respond to public health disasters—from outbreaks of infectious disease to chemical, biological, radiological, nuclear, and cyber threats.

The Budget provides $2.9 billion to ensure that the Department is equipped to support life-saving preparedness and response activities aimed at addressing public health disasters and threats. This includes maintaining key investments in biodefense capabilities.

Emergency preparedness initiatives to address pandemic influenza, as well as the research and development of medical countermeasures, are described in greater detail below.

Pandemic Influenza

The Budget supports activities within the Public Health and Social Services Emergency fund to respond to and protect the American people from pandemic influenza threats, such as the H7N9 virus circulating in China. These activities include maintenance of the current stockpiles of vaccines as well as sustaining domestic vaccine manufacturing infrastructure.

Human infections with a new avian influenza (H7N9) virus were first reported internationally in China in March 2013. The World Health Organization has reported 566 human infections with the H7N9 virus during the fifth epidemic, making it the largest to date. This count brings the cumulative number of H7N9 cases reported by the World Health Organization to 1,364.

The FY 2018 Budget includes a $207 million investment to respond to the needs of the American people in the event of an influenza pandemic.

Research and Development of Medical Countermeasures

The Budget invests $1.02 billion into the research and development of medical countermeasures needed during disasters. Using these funds, the Department partners with industry leaders to develop an effective response capability to protect Americans from radiological, nuclear, chemical, and biological threats. The Department supports a broad portfolio of countermeasures to bridge the gap from early discovery to advanced development and procurement. These investments meet a unique Federal role to partner with industry in developing drugs and other countermeasures for which a sufficient market is lacking.

Preparedness Grants

The Budget restructures HHS preparedness grants to direct resources to States with the greatest need and innovative approaches. The Budget will introduce competition, risk, and link awards to performance across ASPR's Hospital Preparedness Program and CDC's Public Health and Emergency Preparedness Program. The grants will support entities that are most innovative in their approach to health care delivery system readiness and public health preparedness.

Delivering Hope and Healing to America

The opioid epidemic is the deadliest drug epidemic in American history. Deaths from opioid overdose have risen steadily over the past 2 decades and have become the leading cause of death from injury in the United States, claiming 91 lives every day. We are losing more Americans to overdoses every year than we did during the entire Vietnam War.

The Administration has made combating opioid abuse and fighting addiction an Administration-wide effort and priority, and the Budget reflects this commitment. It continues to invest in activities to fight opioid abuse, maintains funding for substance abuse treatment, and seeks to improve prescribing practices and the use of medication-assisted treatment.

The Budget also invests in high-priority mental health initiatives by targeting resources for serious mental illness, suicide prevention, homelessness prevention, and children's mental health.

Improving Prescribing Practices and Expanding Use of Medication-Assisted Treatment

To fight against opioid abuse, medication must be correctly prescribed and utilized. HHS is focused on providing support for cutting-edge research on pain addiction and strengthening our understanding of the epidemic through health surveillance. In addition, the Budget makes investments to improve access to treatment and recovery services, target the availability and distribution of overdose-reversing drugs, and advance better practices for pain management.

Improving Access to Treatment and Recovery Services

Medication-assisted treatment is a proven effective intervention for individuals suffering from addiction. The Budget includes $500 million for the Substance Abuse and Mental Health Administration's State Targeted Response to the Opioid Crisis Grants authorized in the 21st Century Cures Act to expand access to life-saving, transformative treatments, including Medication-Assisted Treatment. The Budget also continues the $1.9 billion Substance Abuse Block Grant, which States can use to provide life-saving treatments, and $25 million in SAMHSA for other targeted efforts focused specifically on expanding access to critical interventions.

Targeting Availability and Distribution of Overdose-Reversing Drugs

First responders to an overdose in progress have precious little time to save a life by reversing the effects of an overdose. The FY 2018 Budget for SAMHSA includes $24 million to equip first responders with overdose reversing drugs and to train them on their use, supporting the implementation of key provisions of the Comprehensive Addiction and Recovery Act.

Advancing Better Practices for Pain Management

While actions to address prescription opioid abuse must focus on both prescribers and high-risk patients, prescribers are the first line of defense for preventing inappropriate access. The FY 2018 CDC Budget includes $75.4 million to improve the way opioids are prescribed through clinical practice guidelines and support State programs, which help health care providers offer safer, more effective treatments while reducing opioid-related abuse and overdose. CDC aims to save lives and prevent prescription opioid overdoses by equipping providers with the knowledge, tools, and guidance they need.

In addition, the Centers for Medicare and Medicaid Services' Budget continues to support the agency's work to implement more effective, patient-centered strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.

Improving Access to Mental Health Treatment

In 2015, an estimated 10 million American adults battled serious mental illness, such as a psychotic or serious mood or anxiety disorder. The Budget includes high-priority mental health funding that addresses suicide prevention, homelessness prevention, and children's mental health. It also includes funding to address the needs of adults with serious mental illness and children experiencing a mental health crisis. The Budget provides $119 million for the Children's Mental Health Services program, which helps States, Tribes, and communities deliver evidence-based services and support for children and youth with serious mental health concerns. These funds facilitate effective collaboration between child and youth-serving systems such as juvenile justice, child welfare, and education. The Budget also proposes that up to 10 percent of the funds will be available for a new demonstration project focused on earlier interventions. This new set-aside reflects recent research by the National Institute on Mental Health indicating that earlier psychosocial interventions with those who are high-risk may prevent the further development of serious emotional disturbances and ultimately serious mental illness.

The Budget maintains $60 million in critical funding for grants to States, colleges, and the suicide prevention resource center to raise suicide awareness and disseminate best practices for prevention. The Budget also continues to provide funding for the National Suicide Prevention Lifeline, which coordinates a national network of crisis centers by providing suicide prevention and crisis intervention services. Those seeking help can reach the Lifeline at 1–800–273–TALK at any time, day or night.

Providing Patient-Centered Care

HHS is committed to addressing the challenges many Americans continue to confront under a health care system that is failing to meet their needs. The Department is supporting a patient-centered health care reform effort that is aimed at empowering patients, families, and doctors when it comes to making health care decisions. HHS is making progress toward this priority by taking administrative and regulatory actions that will provide the American people relief from the current law, build a partnership with states to improve health care choices for patients, reform the medical liability system, and enhance the doctor-patient relationship. In FY 2018, the Department will invest nearly $400 million in services, training for medical professionals, and approaches that respond to the diverse health care needs across America.

Strengthening Services to Tribes

HHS is committed to providing quality health care to over 2.2 million American Indian and Alaska Native people by effectively leveraging resources and implementing new and innovative ways to improve access to and the delivery of quality health care. As part of the unique government-to-government relationship between the Federal Government and Tribal Governments, the Indian Health Service provides health care to members of more than 567 Federally-recognized tribes. The FY 2018 IHS Budget prioritizes funding for direct health care services, including behavioral health services.

Prioritizing Direct Health Services in Indian Country

The Budget reflects HHS's high-priority commitment to Indian Country and protects direct health care investments. In FY 2018, the Budget maintains funding for clinical services at $3.3 billion, which includes inpatient and outpatient care in hospitals and clinics, behavioral health services, and dental health services. In FY 2018, IHS estimates that they will serve 2.2 million American Indians and Alaska Natives.

Investing in the Health of America's Future

The percentage of children with obesity in the United States has more than tripled since the 1970s. Today, nearly 20 percent of school-aged children are obese. Children with obesity are at higher risk for having other chronic health conditions and diseases that impact physical health, such as asthma, sleep apnea, bone and joint problems, type 2 diabetes, and risk factors for heart disease.

The Budget represents a commitment to uplifting the health of the next generation by investing in services that promote healthy eating and physical activity. To accomplish this priority, the Budget invests in a new CDC block grant to address childhood obesity and other state priorities, and enhances Children's Health Insurance Program flexibility.

CDC Childhood Obesity and America's Health Block Grant

The FY 2018 Budget will support investments in the most effective childhood obesity prevention and intervention strategies within CDC and promote better nutrition, increased physical activity, and prevention of future chronic illness. CDC will continue to provide funding to States to implement programs intended to reduce the risk factors associated with childhood obesity, manage chronic conditions in schools, and promote the well-being and healthy development of all children and youth.

The Budget includes a new CDC $500 million America's Health Block Grant to increase State flexibility and focus on leading public health challenges. The newly established block grant will provide flexibility in FY 2018 for each State to implement specific interventions that address its population's unique public health issues, including interventions to spur improvements in physical activity and the nutrition of children and adolescents.

Responsible Stewardship of Taxpayer Dollars and Redefining the Federal Role

The Budget allows HHS to continue to support priority activities at an overall lower level while restoring fiscal discipline and promoting long-term fiscal stability across the Federal Government. In order to make targeted, strategic investments and carry out the Department's mission in the most efficient manner possible, the Budget proposes reorganizations and specific HHS efficiencies, proposals to revisit key partnerships within the private sector, and proposals to strengthen the integrity of the Medicare and Medicaid programs.

Reorganizations and HHS-Specific Efficiencies

While large-scale reorganization, workforce restructuring, and efficiency proposals are under development within the Department, the Budget offers select HHS restructuring and efficiency proposals.

Medicare Appeals

HHS remains committed to working with Congress on comprehensive and common sense reforms to the Medicare appeals process. The Budget includes investing $1.3 billion over 10 years to address the pending backlog and HHS is pursuing reforms to revamp the process to address appeals as early as possible and prevent escalation to subsequent levels. These changes will make the appeals system easier to navigate, increase adjudicatory capacity to address incoming annual receipts, and reduce backlogged appeals pending at the Office of Medicare Hearings and Appeals and the Departmental Appeals Board. The Department is committed to work with Congress to address the Medicare appeals backlog.

National Institutes of Health (NIH) Structural Changes

NIH will continue to support core mission-critical activities in the Budget, while implementing policies to reduce burden on its grantees. On average, from FY 1994 to FY 2014, NIH spent approximately 30 percent of its research resources on indirect costs, leaving only 70 percent for direct research and other supporting research activities. Other entities, including private foundations and payers, spend a much higher portion of their grants on direct science. The current indirect rate setting process requires each grantee to provide hundreds of pages of documentation to negotiate their indirect rate with the Government.

NIH will implement reforms to release grantees from the costly and time-consuming indirect rate setting process and reporting requirements. Applying a uniform indirect cost rate to all grants mitigates the risk for fraud and abuse because it can be simply and uniformly applied to grantees.

The Budget includes this critical reform to reduce indirect costs and preserve more funding for direct science.

The Budget also proposes the elimination of the Fogarty International Center, but retains all Federal staff and maintains key activities in other NIH Institutes and Centers. This change will enable NIH to focus on higher priority activities.

The Budget consolidates the Agency for Healthcare Research and Quality into NIH and maintains $272 million in discretionary funding for these activities. As part of this consolidation, NIH will conduct a review of health services research across NIH and develop a strategy to ensure that the highest priority health services research is conducted and made available across the Federal Government. The consolidation proposal preserves key activities, such as patient safety research, that improve the quality and safety of American health care. The Budget reduces or eliminates lower-priority programs that overlap with activities administered by other components of HHS.

Revisiting Key Partnerships With the Private Sector

The Budget envisions a recalibration of how to pay for the Food and Drug Administration's (FDA) premarket review activities. Industry fees are increased to fund 100 percent of costs for premarket review and approval activities in the animal drug, animal generic, prescription and generic drug, biosimilar, and medical device programs. In a constrained budget environment, industries that directly benefit from FDA's administrative actions can and should pay to support FDA's capacity. The fee-funded approach is consistent with the overarching goals of the Administration's Budget, which are to reprioritize Federal spending to advance the safety and security of the American people. The Budget also includes reforms that balance the demand for scientific rigor and access to reliable, life-saving cures. In addition, the Budget will include regulatory relief to the industry and speed the development of safe and effective medical products.

The Budget allows FDA to remain an acknowledged leader among the world's regulatory agencies in both the number of new drugs approved each year and in the timeliness of review. These proposals will allow FDA to continue carrying out its statutory responsibilities of protecting public health by promoting innovative, safe treatments that are responsive to the needs of the American people.

Strengthening the Integrity of Medicare and Medicaid

The Budget strengthens the integrity and sustainability of Medicare and Medicaid by investing an additional $70 million in new Health Care Fraud and Abuse Control Program funding in FY 2018, targeting activities that prevent fraud, waste, and abuse and promote quality, patient-centered health care.

The increase in funding reflects the Administration's commitment to fighting fraud and the belief that this investment will pay off in significant returns to the Medicare Trust Fund and the Treasury. For example, recent reports to Congress show Medicare program integrity efforts yielding approximately a $12 to $1 return and law enforcement and litigation efforts yielding a $5 to $1 return.

FROM THE PRESIDENT'S BUDGET FOR FISCAL YEAR 2018

New Policies for Jobs and Growth

The President's Budget proposes the following bold steps to spark faster economic growth, balance the budget within 10 years, and finance important new priorities.

Control Federal Spending. The first step is to bring Federal spending under control and return the Federal budget to balance within 10 years. Deficit spending has become an ingrained part of the culture in the Nation's capital. It must end to avoid passing unsustainable levels of debt on to our children and grandchildren and causing serious economic damage. When debt levels keep increasing, more and more of the Nation's resources are required to service that debt and are diverted away from Government services that citizens depend on. To help correct this and reach our budget goal in 10 years, the Budget includes $3.6 trillion in spending reductions over 10 years, the most ever proposed by any President in a Budget. By including the anticipated economic gains that will result from the President's fiscal, economic, and regulatory policies, the deficit will be reduced by $5.6 trillion compared to the current fiscal path.

As a result, by the end of the 10-year budget window, when the budget reaches balance, publicly held debt will be reduced to 60 percent of GDP, the lowest level since 2010, when the economic policies of the last administration took effect. Under this plan, the debt will continue to fall both in nominal dollars and as a share of

GDP beyond that point, putting us on a path to repay the debt in full within a few decades. Bringing the budget into surplus and reducing the level of debt sets up a virtuous cycle in which fewer tax dollars are needed to service the debt. This increases budget flexibility, in which the Government can pursue other needed priorities. Reduced Federal borrowing on the capital markets also frees up capital to flow to productivity-enhancing investments, leading to higher economic growth.

The following are a few of the ways we will bring spending under control:

Repeal and Replace Obamacare. The Budget includes $250 billion in deficit savings associated with health care reform as part of the President's commitment to rescue Americans from the failures of Obamacare, and to expand choice, increase access, and lower premiums. The President supports a repeal and replace approach that improves Medicaid's sustainability and targets resources to those most in need, eliminates Obamacare's onerous taxes and mandates, provides funding for States to stabilize markets and ensure a smooth transition away from Obamacare, and helps Americans purchase the coverage they want through the use of tax credits and expanded Health Savings Accounts. Repealing Obamacare and its regulations on businesses will also increase employment, thereby increasing GDP and creating much needed economic growth. The Administration applauds the House's passage of the American Health Care Act and is committed to working with the Congress to repeal and replace Obamacare.

The Administration is committed to providing needed flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improve the risk pool and bring stability and certainty to the individual and small group markets, while increasing the options for patients and providers. The Administration also supports State flexibility and control to create a free and open health care market and will continue to empower States to make decisions that work best for their markets. In light of these goals, the Budget promotes efficient operations and only funds critical activities for the Health Insurance Exchanges. The Administration will continue to work with the Congress to provide for a stable transition from the burdensome requirements of Obamacare and transition to a health care system focused on these core values.

Reform Medicaid. To realign financial incentives and provide stability to both Federal and State budgets, the Budget proposes to reform Medicaid by giving States the choice between a per capita cap and a block grant and empowering States to innovate and prioritize Medicaid dollars to the most vulnerable populations. States will have more flexibility to control costs and design individual, State-based solutions to provide better care to Medicaid beneficiaries. These reforms are projected to save $610 billion over 10 years.

Support the Highest Priority Biomedical Research and Development. The Budget institutes policies to ensure that Federal resources maximally support the highest priority biomedical science by reducing reimbursement of indirect costs (and thus focusing a higher percentage of spending on direct research costs) and implementing changes to the National Institutes of Health's (NIH) structure to improve efficiencies in the research enterprise. In 2018, the Department of Health and Human Services (HHS) and NIH will develop policies to reduce the burden of regulation on recipients of NIH funding consistent with the Administration's initiatives on regulatory reform and the goals articulated for the new Research Policy Board established in the 21st Century Cures Act.

Provide a Path Toward Welfare Reform. The Budget provides a path toward welfare reform, particularly to encourage those individuals dependent on the Government to return to the workforce. In doing so, this Budget includes Supplemental Nutrition Assistance Program (SNAP) reforms that tighten eligibility and encourage work, and proposals that strengthen child support and limit the Earned Income Tax Credit (EITC) and the Child Tax Credit (CTC) to those who are authorized to work in the United States.

As a primary component of the social safety net, SNAP—formerly Food Stamps—has grown significantly in the past decade. As expected, SNAP participation grew to historic levels during the recession. However, despite improvements in unemployment since the recession ended, SNAP participation remains persistently high.

The Budget proposes a series of reforms to SNAP that close eligibility loopholes, target benefits to the neediest households, and require able-bodied adults to work. Combined, these reforms will reduce SNAP expenditures while maintaining the basic assistance low-income families need to weather hard times. The Budget also proposes SNAP reforms that will re-balance the State-Federal partnership in pro-

viding benefits by establishing a State match for benefit costs. The Budget assumes a gradual phase-in of the match, beginning with a national average of 10 percent in 2020 and increasing to an average of 25 percent by 2023. To help States manage their costs, in addition to the currently available operational choices States make that can impact participation rates and benefit calculations, new flexibilities to allow States to establish locally appropriate benefit levels will be considered.

The Budget also includes a number of proposals that strengthen the Child Support Enforcement Program, providing State agencies additional tools to create stronger, more efficient child support programs that facilitate family self-sufficiency and promote responsible parenthood. Specifically, a suite of Establishment and Enforcement proposals serves to increase child support collections that in turn result in savings to Federal benefits programs, and a Child Support Technology Fund will allow States to replace aging information technology systems to increase security, efficiency, and program integrity.

The Budget also proposes to require a Social Security Number (SSN) that is valid for work in order to claim the CTC and EITC. Under current law, individuals who do not have SSNs valid for work can claim the CTC, including the refundable portion of the credit. This proposal would ensure only people who are authorized to work in the United States are eligible for the CTC. In addition, this proposal fixes gaps in current administrative practice for EITC filers that allowed some people with SSNs that are not valid for work to still claim the EITC.

Table S–3. Baseline by Category [1]

(In billions of dollars)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals	
													2018–2022	2018–2027
Outlays:														
Discretionary programs:														
Defense	$585	$592	$600	$623	$640	$653	$665	$676	$695	$713	$732	$750	$3,181	$6,747
Non-defense	600	624	618	629	637	650	659	672	688	705	722	739	3,193	6,718
Subtotal, discretionary programs	1,185	1,215	1,219	1,251	1,277	1,303	1,323	1,348	1,384	1,418	1,453	1,488	6,373	13,464
Mandatory programs:														
Social Security	910	946	1,005	1,070	1,138	1,207	1,281	1,362	1,448	1,537	1,630	1,728	5,702	13,406
Medicare	588	593	582	646	701	757	854	885	913	1,012	1,106	1,195	3,541	8,650
Medicaid	368	378	408	432	454	480	507	537	570	604	648	688	2,280	5,328
Other mandatory programs	560	656	589	626	643	670	717	719	726	759	821	846	3,244	7,115
Subtotal, mandatory programs	2,427	2,573	2,583	2,774	2,936	3,114	3,359	3,503	3,656	3,912	4,205	4,457	14,767	34,500
Net interest	240	276	316	372	431	487	542	592	634	670	706	741	2,147	5,489
Total outlays	3,853	4,065	4,118	4,398	4,643	4,905	5,224	5,443	5,673	6,000	6,364	6,687	23,287	53,453
Receipts:														
Individual income taxes	1,546	1,660	1,836	1,934	2,042	2,165	2,291	2,425	2,568	2,719	2,880	3,058	10,268	23,918
Corporation income taxes	300	324	355	375	401	400	414	425	439	455	475	497	1,945	4,235
Social insurance and retirement receipts:														
Social Security payroll taxes	810	857	892	931	972	1,027	1,081	1,133	1,191	1,251	1,316	1,379	4,903	11,173
Medicare payroll taxes	247	258	270	283	297	315	332	348	367	386	407	427	1,497	3,432
Unemployment insurance	49	49	50	49	49	50	51	52	53	54	56	57	248	519
Other retirement	9	10	10	11	11	12	12	13	13	14	15	16	56	127
Excise taxes	95	87	106	107	110	114	116	119	123	127	131	136	553	1,189
Estate and gift taxes	21	23	24	26	28	29	31	33	36	38	40	43	139	328
Customs duties	35	34	40	42	43	44	46	50	53	56	60	65	214	499
Deposits of earnings, Federal Reserve System	116	97	70	56	49	51	60	70	78	86	91	98	286	709
Other miscellaneous receipts	40	60	54	56	57	58	60	61	64	65	67	69	284	610
Total receipts	3,268	3,460	3,707	3,869	4,059	4,264	4,495	4,730	4,984	5,251	5,538	5,844	20,394	46,741
Deficit	**585**	**605**	**411**	**529**	**584**	**641**	**728**	**713**	**689**	**749**	**826**	**842**	**2,894**	**6,712**

Net interest	240	276	316	372	431	487	542	592	634	670	706	741	2,147	5,489
Primary deficit	345	329	95	157	153	154	187	121	55	79	120	101	746	1,224
On-budget deficit	620	647	436	533	564	612	682	640	593	627	681	668	2,826	6,035
Off-budget deficit/surplus (−)	−36	−42	−25	−4	20	29	47	72	97	122	145	174	68	678
Memorandum, budget authority for discretionary programs:														
Defense	607	616	616	630	645	661	677	694	711	729	747	765	3,229	6,875
Non-defense	560	551	548	562	575	589	604	619	634	650	667	683	2,879	6,133
Total, discretionary budget authority	1,167	1,167	1,164	1,192	1,221	1,250	1,281	1,313	1,346	1,379	1,414	1,449	6,108	13,008
Memorandum, totals with pre-policy economic assumptions:														
Receipts	3,268	3,467	3,707	3,838	3,991	4,151	4,330	4,505	4,703	4,902	5,116	5,339	20,017	44,581
Outlays	3,853	4,072	4,120	4,392	4,638	4,894	5,211	5,431	5,659	5,984	6,350	6,678	23,255	53,356
Deficit	585	605	413	553	647	743	881	925	956	1,082	1,234	1,338	3,238	8,775

[1] Baseline estimates are on the basis of the economic assumptions shown in Table S–9, which incorporate the effects of the Administration's fiscal policies. Baseline totals reflecting current-law economic assumptions are shown in a memorandum bank.

Table S–4. Proposed Budget by Category

(In billions of dollars)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals	
													2018–2022	2018–2027
Outlays:														
Discretionary programs:														
Defense	$585	$594	$643	$665	$670	$667	$662	$665	$679	$693	$708	$722	$3,307	$6,774
Non-defense	600	619	601	567	537	506	485	464	455	446	437	429	2,696	4,927
Subtotal, discretionary programs	1,185	1,213	1,244	1,232	1,207	1,173	1,148	1,129	1,134	1,139	1,145	1,151	6,003	11,701
Mandatory programs:														
Social Security	910	946	1,005	1,070	1,137	1,205	1,279	1,360	1,446	1,535	1,628	1,725	5,696	13,392
Medicare	588	593	582	646	700	756	851	882	910	1,017	1,085	1,166	3,535	8,594
Medicaid	368	378	404	423	439	460	467	477	490	499	518	524	2,193	4,701
Other mandatory programs	560	656	570	603	609	622	658	653	649	667	687	678	3,062	6,396

Table S–4. Proposed Budget by Category—Continued

(In billions of dollars)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals	
													2018–2022	2018–2027
Allowance for Obamacare repeal and replacement	.....	.....	−30	−30	−90	−130	−140	−155	−160	−170	−170	−175	−420	−1,250
Allowance for infrastructure initiative	.....	.....	5	25	40	50	40	20	10	5	5	.....	160	200
Subtotal, mandatory programs	2,427	2,573	2,535	2,736	2,835	2,963	3,156	3,237	3,345	3,553	3,754	3,919	14,226	32,033
Net interest	240	276	315	371	428	481	528	567	595	613	629	639	2,123	5,166
Total outlays	3,853	4,062	4,094	4,340	4,470	4,617	4,832	4,933	5,073	5,306	5,527	5,708	22,353	48,901
Receipts:														
Individual income taxes	1,546	1,660	1,836	1,935	2,044	2,167	2,293	2,428	2,572	2,723	2,884	3,062	10,275	23,945
Corporation income taxes	300	324	355	375	401	400	414	425	439	455	475	497	1,946	4,236
Social insurance and retirement receipts:														
Social Security payroll taxes	810	857	892	931	972	1,027	1,081	1,133	1,191	1,251	1,316	1,379	4,903	11,173
Medicare payroll taxes	247	258	270	283	297	315	332	348	367	386	407	427	1,497	3,432
Unemployment insurance	49	49	50	49	50	53	55	54	56	56	59	62	257	543
Other retirement	9	10	12	14	16	18	20	22	23	24	25	26	80	199
Excise taxes	95	87	106	107	110	99	101	104	106	109	113	117	524	1,072
Estate and gift taxes	21	23	24	26	28	29	31	33	36	38	40	43	139	328
Customs duties	35	34	40	42	43	44	46	50	53	56	60	65	214	499
Deposits of earnings, Federal Reserve System	116	97	70	56	50	52	61	71	78	87	92	99	290	717
Other miscellaneous receipts	40	60	54	55	57	57	59	61	63	64	66	69	282	606
Allowance for Obamacare repeal and replacement	.....	.....	−55	−60	−85	−100	−105	−115	−120	−120	−120	−120	−405	−1,000
Total receipts	3,268	3,460	3,654	3,814	3,982	4,161	4,390	4,615	4,864	5,130	5,417	5,724	20,001	45,751
Deficit/surplus (−)	**585**	**603**	**440**	**526**	**488**	**456**	**442**	**319**	**209**	**176**	**110**	**−16**	**2,351**	**3,150**
Net interest	240	276	315	371	428	481	528	567	595	613	629	639	2,123	5,166
Primary deficit/surplus (−)	345	326	125	155	60	−25	−87	−249	−386	−438	−518	−654	228	−2,017
On-budget deficit/surplus (−)	620	644	466	534	472	431	399	251	117	59	−30	−185	2,301	2,514
Off-budget deficit/surplus (−)	−36	−42	−25	−8	16	25	42	68	92	117	140	169	50	636

Memorandum, budget authority for discretionary programs:														
Defense	607	646	668	668	668	666	665	679	693	707	722	737	3,335	6,873
Non-defense	560	536	479	464	450	428	419	410	402	394	386	378	2,239	4,209
Total, discretionary funding	1,167	1,182	1,147	1,132	1,118	1,094	1,084	1,089	1,095	1,101	1,108	1,115	5,574	11,081

Table S–5. Proposed Budget by Category as a Percent of GDP

(As a percent of GDP)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals 2018–2022	Totals 2018–2027
Outlays:														
Discretionary programs:														
Defense	3.2%	3.1%	3.2%	3.2%	3.0%	2.9%	2.7%	2.6%	2.5%	2.5%	2.4%	2.3%	3.0%	2.7%
Non-defense	3.3	3.2	3.0	2.7	2.4	2.2	2.0	1.8	1.7	1.6	1.5	1.4	2.5	2.0
Subtotal, discretionary programs	6.4	6.3	6.2	5.9	5.5	5.1	4.7	4.4	4.2	4.0	3.9	3.7	5.5	4.8
Mandatory programs:														
Social Security	4.9	4.9	5.0	5.1	5.2	5.2	5.3	5.3	5.4	5.5	5.5	5.6	5.2	5.3
Medicare	3.2	3.1	2.9	3.1	3.2	3.3	3.5	3.5	3.4	3.6	3.7	3.8	3.2	3.4
Medicaid	2.0	2.0	2.0	2.0	2.0	2.0	1.9	1.9	1.8	1.8	1.8	1.7	2.0	1.9
Other mandatory programs	3.0	3.4	2.8	2.9	2.8	2.7	2.7	2.6	2.4	2.4	2.3	2.2	2.8	2.6
Allowance for Obamacare repeal and replacement	.....	.....	−0.1	−0.1	−0.4	−0.6	−0.6	−0.6	−0.6	−0.6	−0.6	−0.6	−0.4	−0.5
Allowance for infrastructure initiative	.....	.....	*	0.1	0.2	0.2	0.2	0.1	*	*	*	.....	0.1	0.1
Subtotal, mandatory programs	13.2	13.4	12.7	13.1	12.9	12.8	13.0	12.7	12.5	12.6	12.7	12.6	12.9	12.8
Net interest	1.3	1.4	1.6	1.8	1.9	2.1	2.2	2.2	2.2	2.2	2.1	2.1	1.9	2.0
Total outlays	20.9	21.2	20.5	20.7	20.3	20.0	19.9	19.4	18.9	18.9	18.7	18.4	20.3	19.6
Receipts:														
Individual income taxes	8.4	8.7	9.2	9.2	9.3	9.4	9.5	9.5	9.6	9.7	9.8	9.9	9.3	9.5
Corporation income taxes	1.6	1.7	1.8	1.8	1.8	1.7	1.7	1.7	1.6	1.6	1.6	1.6	1.8	1.7
Social insurance and retirement receipts:														
Social Security payroll taxes	4.4	4.5	4.5	4.4	4.4	4.4	4.5	4.4	4.4	4.4	4.5	4.4	4.4	4.4
Medicare payroll taxes	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4

Table S–5. Proposed Budget by Category as a Percent of GDP—Continued

(As a percent of GDP)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals 2018–2022	Totals 2018–2027
Unemployment insurance	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Other retirement	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Excise taxes	0.5	0.5	0.5	0.5	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.4
Estate and gift taxes	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Customs duties	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Deposits of earnings, Federal Reserve System	0.6	0.5	0.4	0.3	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Other miscellaneous receipts	0.2	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.2
Allowance for Obamacare repeal and replacement	.....	.....	−0.3	−0.3	−0.4	−0.4	−0.4	−0.5	−0.4	−0.4	−0.4	−0.4	−0.4	−0.4
Total receipts	17.8	18.1	18.3	18.2	18.1	18.0	18.1	18.1	18.2	18.2	18.3	18.4	18.1	18.2
Deficit/surplus (−)	**3.2**	**3.1**	**2.2**	**2.5**	**2.2**	**2.0**	**1.8**	**1.3**	**0.8**	**0.6**	**0.4**	**−0.1**	**2.1**	**1.4**
Net interest	1.3	1.4	1.6	1.8	1.9	2.1	2.2	2.2	2.2	2.2	2.1	2.1	1.9	2.0
Primary deficit/surplus (−)	1.9	1.7	0.6	0.7	0.3	−0.1	−0.4	−1.0	−1.4	−1.6	−1.8	−2.1	0.2	−0.7
On-budget deficit/surplus (−)	3.4	3.4	2.3	2.5	2.1	1.9	1.6	1.0	0.4	0.2	−0.1	−0.6	2.1	1.1
Off-budget deficit/surplus (−)	−0.2	−0.2	−0.1	−*	0.1	0.1	0.2	0.3	0.3	0.4	0.5	0.5	*	0.2
Memorandum, budget authority for discretionary programs:														
Defense	3.3	3.4	3.3	3.2	3.0	2.9	2.7	2.7	2.6	2.5	2.4	2.4	3.0	2.8
Non-defense	3.0	2.8	2.4	2.2	2.0	1.9	1.7	1.6	1.5	1.4	1.3	1.2	2.0	1.7
Total, discretionary funding	6.3	6.2	5.7	5.4	5.1	4.7	4.5	4.3	4.1	3.9	3.7	3.6	5.1	4.5

*0.05 percent of GDP or less.

Table S–6. Mandatory and Receipt Proposals

(Deficit increases (+) or decreases (−) in millions of dollars)

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals	
												2018–2022	2018–2027
Other Independent Agencies:													
Federal Communications Commission: Enact Spectrum License User Fee		−$50	−$150	−$300	−$450	−$500	−$500	−$500	−$500	−$500	−$500	−$1,450	−$3,950
Reform the Postal Service		−2,807	−4,685	−4,871	−4,791	−4,923	−4,904	−4,913	−4,795	−4,676	−4,655	−22,077	−46,020
Restructure the Consumer Financial Protection Bureau		−145	−650	−683	−706	−726	−745	−764	−784	−804	−826	−2,910	−6,833
Eliminate the Securities and Exchange Commission Reserve Fund			−50	−50	−50	−50	−50	−50	−50	−50	−50	−200	−450
Mandatory effects of agency eliminations		1				−1							
Total, Other Independent Agencies		−3,001	−5,535	−5,904	−5,997	−6,200	−6,199	−6,227	−6,129	−6,030	−6,031	−26,639	−57,255
Cross-cutting reforms:													
Repeal and replace Obamacare		25,000	30,000	−5,000	−30,000	−35,000	−40,000	−40,000	−50,000	−50,000	−55,000	−15,000	−250,000
Implement an infrastructure initiative		5,000	25,000	40,000	50,000	40,000	20,000	10,000	5,000	5,000		160,000	200,000
Reform welfare programs:													
Reform Supplemental Nutrition Assistance Program (SNAP)		−4,637	−7,627	−13,990	−16,928	−21,130	−24,871	−24,634	−25,714	−26,135	−25,266	−64,312	−190,932
Establish a SNAP authorized retailer application fee		−252	−246	−241	−236	−230	−230	−230	−230	−230	−230	−1,205	−2,355
Eliminate SSBG		−1,411	−1,683	−1,700	−1,700	−1,700	−1,700	−1,700	−1,700	−1,700	−1,700	−8,194	−16,694
Reduce Temporary Assistance for Needy Families (TANF) block grant		−1,218	−1,491	−1,550	−1,582	−1,615	−1,632	−1,632	−1,632	−1,632	−1,632	−7,456	−15,616
Provide funding for welfare research and Census Bureau Survey of Income and Program Participation, transferred from TANF													

Table S–6. Mandatory and Receipt Proposals—Continued

(Deficit increases (+) or decreases (−) in millions of dollars)

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Totals	
												2018–2022	2018–2027
Eliminate TANF Contingency Fund		−567	−608	−608	−608	−608	−608	−608	−608	−608	−608	−2,999	−6,039
Require Social Security Number (SSN) for Child Tax Credit and Earned Income Tax Credit		−449	−4,512	−4,447	−4,358	−4,309	−4,296	−4,373	−4,460	−4,555	−4,652	−18,075	−40,411
Total, reform welfare programs		−8,534	−16,167	−22,536	−25,412	−29,592	−33,337	−33,177	−34,344	−34,860	−34,088	−102,241	−272,047
Reform disability programs and test new approaches:													
Test new approaches to increase labor force participation		100	100	100	100	100	−2,494	−5,069	−9,332	−13,809	−18,627	500	−48,831
Reinstate the reconsideration review stage in 10 States			71	−10	−59	−526	−246	−263	−305	−354	−376	−524	−2,068
Reduce 12 month retroactive Disability Insurance benefits to 6 months		−113	−643	−797	−951	−1,043	−1,112	−1,191	−1,272	−1,349	−1,430	−3,547	−9,901
Create sliding scale for multi-recipient Supplemental Security Income families		−743	−827	−861	−882	−956	−906	−862	−955	−979	−1,002	−4,269	−8,973
Create a probationary period for Administrative Law Judges (ALJs)													
Eliminate Workers Compensation Reverse Offsets			−3	−8	−12	−16	−19	−22	−25	−28	−31	−39	−164
Offset overlapping unemployment and disability payments			−58	−249	−329	−324	−319	−323	−323	−296	−317	−960	−2,538
Total, reform disability programs and test new approaches		−756	−1,360	−1,825	−2,133	−2,765	−5,096	−7,730	−12,212	−16,815	−21,783	−8,839	−72,475

BBC News

PHARMACEUTICAL INDUSTRY GETS HIGH ON FAT PROFITS

By Richard Anderson, business reporter

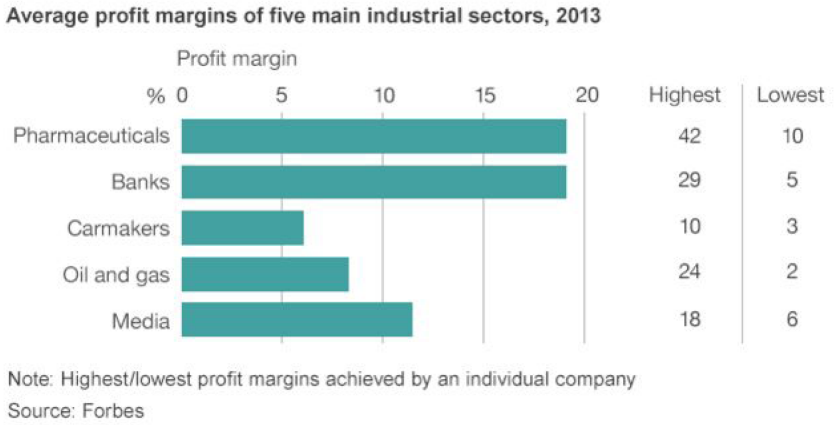
November 6, 2014

Imagine an industry that generates higher profit margins than any other and is no stranger to multi-billion dollar fines for malpractice.

Throw in widespread accusations of collusion and over-charging, and banking no doubt springs to mind.

In fact, the industry described above is responsible for the development of medicines to save lives and alleviate suffering, not the generation of profit for its own sake.

Pharmaceutical companies have developed the vast majority of medicines known to humankind, but they have profited handsomely from doing so, and not always by legitimate means.



Last year, U.S. giant Pfizer, the world's largest drug company by pharmaceutical revenue, made an eye-watering 42% profit margin. As one industry veteran understandably says: "I wouldn't be able to justify [those kinds of margins]."

Stripping out the one-off $10bn (£6.2bn) the company made from spinning off its animal health business leaves a margin of 24%, still pretty spectacular by any standard.

In the UK, for example, there was widespread anger when the industry regulator predicted energy companies' profit margins would **grow from 4% to 8% this year.**

Last year, five pharmaceutical companies made a profit margin of 20% or more—Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline (GSK) and Eli Lilly.

"Profiteering"

With some drugs costing upwards of $100,000 for a full course, and with the cost of manufacturing just a tiny fraction of this, it's not hard to see why.

Last year, 100 leading oncologists from around the world wrote an open letter in the journal Blood **calling for a reduction in the price of cancer drugs.**

Dr. Brian Druker, director of the Knight Cancer Institute and one of the signatories, has asked: "If you are making $3bn a year on [cancer drug] Gleevec, could you get by with $2bn? When do you cross the line from essential profits to profiteering?"

And it's not just cancer drugs—between April and June this year, drug company Gilead clocked sales of $3.5bn for its latest blockbuster hepatitis C drug Sovaldi.

Drug companies justify the high prices they charge by arguing that their research and development (R&D) costs are huge. On average, only three in 10 drugs launched are profitable, with one of those going on to be a blockbuster with $1bn-plus revenues a year. Many more do not even make it to market.

But as the table below shows, drug companies spend far more on marketing drugs—in some cases twice as much—than on developing them. And besides, profit margins take into account R&D costs.

World's Largest Pharmaceutical Firms

Company	Total revenue ($bn)	R&D spend ($bn)	Sales and marketing spend ($bn)	Profit ($bn)	Profit margin (%)
Johnson and Johnson (U.S.)	$71.3	$8.2	$17.5	$13.8	19%
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (U.S.)	51.6	6.6	11.4	22.0	43
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0	24
Sanofi (France)	44.4	6.3	9.1	8.5	11
Merck (U.S.)	44.0	7.5	9.5	4.4	10
GSK (UK)	41.4	5.3	9.9	8.5	21
AstraZeneca (UK)	25.7	4.3	7.3	2.6	10
Eli Lilly (U.S.)	23.1	5.5	5.7	4.7	20
AbbVie (U.S.)	18.8	2.9	4.3	4.1	22

Source: GlobalData.

The industry also argues that the wider value of the drug needs to be considered.

"Drugs do save money over the longer term," says Stephen Whitehead, chief executive of the Association of the British Pharmaceuticals Industry (ABPI).

"Take hepatitis C, a shocking virus that kills people and used to require a liver transplant. At £35,000 [to £70,000] for a 12-week course, 90% of people are now cured, will never need surgery or looking after, and can continue to support their families.

"The amount of money saved is huge."

True, but just because you can charge a high price for something does not necessarily mean you should, especially when it comes to health, critics such as Dr. Druker might say. Shareholders, who big pharma companies ultimately have to answer to, would have little time for such an argument.

No loyalty

Big pharma companies also say they only have a limited time in which to make profits. Patents are generally awarded for 20 years, but 10–12 of those are typically spent developing the drug at a cost of about $1.5bn–$2.5bn.

This leaves 8 to 10 years to make money before the formula can be taken up by generic drug companies, which sell the medicines for a fraction of the price.

Once this happens, sales fall by 90%-plus. As Joshua Owide, director of healthcare industry dynamics at research company GlobalData, explains, "Unlike other sectors, brand loyalty goes out the window when patents expire."

This is why pharma companies go to such extraordinary lengths to extend their patent—a process known as evergreening—employing "floors full of lawyers" for this express purpose, one industry insider says.

For a drug raking in $3bn a quarter, even a one-month extension can be worth huge sums of money.

New formulations, combining two existing drugs to give a wider use, and enantiomers—a mirror image of the same compound—are some of the legal ways to eke out patents. But some drug companies, including the UK's GSK, have been accused of more underhand tactics, such as paying generics to delay the release of their cheaper alternatives.

As the loss of sales at the big pharma companies far outweighs the revenue made by the generics, this can be an attractive arrangement for both parties.

Courting doctors

But drug companies have been accused of, and admitted to, far worse.

Until recently, paying bribes to doctors to prescribe their drugs was commonplace at big pharmas, although the practice is now generally frowned upon and illegal in many places. **GSK was fined $490m in China** in September for bribery and has been accused of similar practices in Poland and the Middle East.

The rules on gifts, educational grants and sponsoring lectures, for example, are less clear cut, and these practices remain commonplace in the United States.

Indeed a recent study found that doctors in the United States receiving payments from pharma companies were twice as likely to prescribe their drugs.

This may well exacerbate the problem of overspending on drugs by governments. A recent study by Prescribing Analytics suggested that the UK's National Health Service could save up to £1bn a year by doctors switching from branded to equally effective generic versions of the drugs.

Big pharmaceutical fines

$3bn—Glaxo SmithKline, 2012, over promoting Paxil for depression to under-18s

$2.3bn—Pfizer, 2009, over misbranding painkiller Bextra

$2.2bn—Johnson and Johnson, 2013, for promoting drugs not approved as safe

$1.5bn—Abbott, 2012, over illegal promotion of antipsychotic drug Depakote

$1.42bn—Eli Lilley, 2009, for wrongly promoting antipsychotic drug Zyprexa

$950m—Merck, 2011, for illegally promoting painkiller Vioxx

Source: ProPublica

This all may change when new rules in the United States and UK will force doctors to disclose all gifts and payments made by the industry.

Drug companies have also been accused of **colluding with chemists** to overcharge for their medicines and of publishing trial data that **highlight the positive at the expense of the negative.**

They have also been found guilty of mis-branding and wrongly promoting various drugs, and have been fined billions as a result.

The rewards are so great, it would seem, that pharma companies have continually been prepared to push the boundaries of legality.

Undue influence

No wonder, then, that the World Health Organisation (WHO) has talked of the "inherent conflict" between the legitimate business goals of the drug companies and the medical and social needs of the wider public.

Indeed the Council of Europe is launching an investigation into "protecting patients and public health against the undue influence of the pharmaceutical industry."

It will look at "particular practices such as sponsoring health professionals by the industry . . . or recourse by public health institutions to the knowledge of highly specialised researchers on the pay-rolls of industry."

No matter what the outcome of such investigations, however, the pharmaceutical industry is facing fundamental change, as the traditional model of developing drugs breaks down due to rising costs and scientific advances.

The cosy world of big pharmaceuticals is under threat like never before.

This is the first in a two-part series on pharmaceutical companies. The second **looks at how and why fundamental change will take place in the industry.**

COMMUNICATIONS

THE AIDS INSTITUTE
1705 DeSales Street, NW, Suite 700
Washington, DC 20036

Dear Chairman Hatch and Committee Members:

We write to submit a written statement for the record for the January 9, 2018 hearing to consider the nomination of Alex Azar to serve as Secretary of Health and Human Services.

As both a former HHS Deputy Secretary and General Counsel, together with his private sector experience, Alex Azar has the knowledge, expertise, and leadership to oversee our Nation's health response. While we may not share some of the Trump administration's objectives relative to such issues as the Affordable Care Act and Medicaid, we believe a practical problem-solver like Mr. Azar is the right person for the job for this administration. He has been a dedicated public servant with additional leadership in the health industry who understands the importance of meeting the health needs of patients. He also values the role of the patient voice in decision making.

The AIDS Institute looks forward to Senate consideration of the nomination and hearing more details from Mr. Azar on how HHS, under his stewardship, will lead our Nation's efforts to eliminate HIV and hepatitis and address other health issues. We hope the confirmation process will occur without delay in order to quickly fill the current leadership gap at HHS.

Sincerely,
Carl Schmid
Deputy Executive Director

AIDS UNITED
1101 14 Street, NW, Suite 300
Washington, DC 20005
(202) 408–4848
www.aidsunited.org

Questions for Mr. Alex Azar, Secretary,
Department of Health and Human Services

Do you believe that religious organizations should be able to receive funding from HHS to provide health care and discriminate on the basis of sexual orientation and gender identity in providing that service or in hiring staff to provide that service?

What is your vision for Medicare and Medicaid? We have long heard of this Administration's and Congress's interest in entitlement reform, including block-granting Medicaid, adding work requirements and other parameters that will necessarily impede Medicaid eligibility, and altering Medicare eligibility, all with the goal of not just reducing spending on Medicaid and Medicare, but reducing access to high-quality health care through the programs. Why not, for example, instead continue to focus on value-based service delivery and financing options as a way to ensure high quality outcomes and incentivize efficient and effective providers of services?

Will you continue to promote "state flexibility" in administration of Medicaid programs? This is code for allowing states to tinker with Medicaid's entitlement status at the state level and only serves to reduce Medicaid rolls. We know that the Medicaid benefit package is robust, state Medicaid programs' administrative overhead

percentage is much lower than commercial plans, and beneficiaries receive care in lower acuity settings that oftentimes avoids higher cost settings. Why would you allow states to change this model?

Mr. Azar, what is your perspective on the high cost of pharmaceuticals in the U.S. in comparison to other countries in North America and the rest of the developing world? President Trump has expressed interest in lowering consumer drug prices and I'd like to hear what you plan to do as HHS Secretary and as the former Eli Lilly CEO to address these concerns.

Mr. Azar, the Presidential Advisory Council on HIV and AIDS has played an important role in advising the President through the Secretary of HHS on sound HIV health policy since the early 1990s. The Council membership was recently removed, and we await a new set of council members. How will you ensure a diverse and representative membership?

HHS has an essential role in the stabilization of the health insurance marketplaces, the affordability of health insurance, and the accessibility of high quality health care services for Americans. How will you address these priorities?

The Center for Medicaid and Medicare Services plays an essential role in ensuring health-care access and long term care for the disabled, the elderly and low-income individuals through Medicaid and Medicare. Medicaid remains the essential provider of HIV related health-care services in the U.S. HIV advocates are concerned that the commitment to this essential role and the many associated responsibilities have been called into question by recent rules that threaten to diminish state's responsibilities to provide these services to all who are currently eligible. What will you do to ensure that these safety net services remain available to low income and underserved populations?

If any further information is needed regarding these questions, please contact AIDS United's Director of Government Affairs, Mr. Carl Baloney, Jr., at cbaloney@aids united.org or (202) 876–2818.

BASSUK CENTER ON HOMELESS AND VULNERABLE CHILDREN AND YOUTH, ET AL.

January 5, 2018

The Honorable Orrin Hatch
Chairman
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Bldg.
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Bldg.
Washington, DC 20510

RE: Hearing to consider the anticipated nomination of Alex Azar to serve as the Department of Health and Human Services (HHS) Secretary

Dear Chairman Hatch and Ranking Member Wyden:

The undersigned organizations appreciate the opportunity to submit questions for the hearing of Alex Azar as Secretary of the U.S. Health and Human Services (HHS). The scope of our organizations vary, but we share the common goal of ending homelessness and recognize the importance of access to health care in order to accomplish this goal. HHS is the principle agency responsible for providing essential human services to those who are least able to help themselves. Given the strong connection between homelessness and health we request the following questions be posed to Alex Azar during his hearings for HHS Secretary.

1. **Medicaid and the uninsured:** Even with large expansions under the Affordable Care Act (ACA), 29 million Americans still are uninsured. Predictably, those without insurance experience disproportionate amounts of homelessness, chronic health conditions, and incur high medical costs due to ER visits and poor health. At the same time, the Administration has supported numerous attempts to repeal the ACA, with a specific goal of undermining the expansion of Medicaid to single adults without dependent children. This provision was particularly important for those experiencing homelessness and the health-care providers who serve them, and has facilitated wider access to life-saving care. *As HHS Secretary, how will new policies ensure coverage will not be lost to those who already gained it under the ACA's Medicaid expansion, and how will you broaden access to health coverage to reach those who remain uninsured?*

2. **Housing:** Stable housing is a key social determinant of health. Poor health causes and prolongs homelessness, the experience of homelessness exacerbates existing health conditions, and lack of housing makes it more difficult to engage in health-care services. Research shows that once an individual gains stable housing they are better able to address health-care problems and attain better outcomes, producing cost savings in the process. *As HHS Secretary, how do you plan to incorporate social determinants of health, like unstable housing, into the health-care system? How do you see your budget as directly impacted by other Administration budgets like that of Housing and Urban Development (HUD), Education, and/or Labor?*
3. **Homelessness:** The most recent Annual Homeless Assessment Report estimated nearly 1.5 million people experienced homelessness in the United States in 2015. Many of these individuals have significant health-care issues, such as chronic illness and mental health and addiction disorders. *As Secretary, what role do you believe HHS has to help prevent and end homelessness?*
4. **Costs of Prescription Drugs:** As head of the U.S. division of pharmaceutical giant Eli Lilly and Co., Mr. Azar knows a great deal about the cost of prescription drugs, which are a significant portion of Medicaid budgets as well as a barrier to accessing health care for many people who are poor and uninsured and unable to afford medication. *As Secretary, how will you commit to lowering the cost of prescription drugs so there is less burden on states and local communities, as well as for low-income individuals?*
5. **Rural Areas:** Low-income Americans living in rural areas often live too far away from health providers to receive regular and comprehensive care. This is especially true of mental health and addiction treatment where too few providers exist, and far too few accept Medicaid. Rural hospitals and other safety net providers are especially struggling. Low reimbursements, high rates of poverty, and remote working conditions are significant disincentives to recruit and retain a trained health-care workforce. *How do you envision solving this problem?*
6. **Employment:** Health insurance coverage helps pay for the health care needed to maintain health. Good health is the basis for a healthy and able workforce. For individuals experiencing homelessness, policies that make access to health care dependent on working only serve as a barrier to both work *and* health care. *As HHS Secretary, what is your position on work requirements, and how do you anticipate navigating proposed barriers to care like work requirements, time limits on Medicaid benefits, drug testing, and other provisions that will deny coverage to vulnerable people?*

Thank you for considering any or all of these questions related to homelessness and health care during hearings for Alex Azar. If you would like to talk further about how health care is critical for the needs of people who are homeless, please contact Regina Reed, Policy Organizer at the National Health Care for the Homeless Council, at 443–703–1337.

Sincerely,

Bassuk Center on Homeless and Vulnerable Children and Youth
Community Solutions
Family Promise
National Alliance to End Homelessness
National Coalition for the Homeless
National Health Care for the Homeless Council
National Law Center on Homelessness and Poverty
National Low Income Housing Coalition
National Network to End Domestic Violence
Technical Assistance Collaborative
Western Regional Advocacy Project
Association for Utah Community Health (UT)
Care for the Homeless (NY)
Central City Concern (OR)
Circle the City (AZ)
Colorado Coalition for the Homeless (CO)
Health Care for the Homeless (MD)
Mercy Care (GA)
Unity Health Care, Inc. (DC)
Urban Pathways (NY)

LETTER SUBMITTED BY ALISON MICHELLE ERNST

January 5, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510–6200

While one can argue Mr. Azar is well qualified to be the Secretary of Health and Human Services Department, I will argue his background tethers him to the status quo and to dangerous paradigms which will not allow the Department of Health and Human Services to function as efficiently as we need it to, and to its fullest capabilities which all our lives depend upon.

Mr. Azar's career path informs us being a dedicated advocate for the health and welfare of the public has not been his priority. He served as the United States Deputy Secretary of Health and Human Services between 2005 and 2007 when the opioid epidemic was hitting hard and spiking fast. Yet he resigned from a key position from which to have an impact to become a pharmaceutical company lobbyist and then an executive. In 2009, "under Azar, Eli Lilly and Company paid $1.415 billion to settle criminal charges regarding its promotion of antipsychotic drug Zyprexa for off-label uses."

We are at a critical fork in the road; pharmaceutical giants are covertly interfering in ways most of you cannot begin to imagine or comprehend. Confirming Azar will undoubtedly take us down an unfortunate path.

An excerpt from a letter I sent to Attorney General Hembree:

> As you battle the opioid epidemic, I want to alert you to a seemingly small piece of the puzzle, that big pharmaceutical companies have a stake in the health care and drug treatment industries overlooking or being "willfully" blind to.
>
> Opiate consumption and addiction is fueled by of an unnatural overabundance of endocrine disrupting compounds in the form of dangerous heavy metal toxins. The EPA tracks some Superfund Sites while many go undesignated. Just mild exposure to dangerous heavy metal toxins decreases our production of the most basic hormones which enable us to have stable moods, and a natural tolerance for pain. People are craving opioids "per se" often because exposure to dangerous heavy metals makes it difficult for us to simply feel "happy," pain-free, and "strong."
>
> Basic physicals or even more extensive health exams rarely if ever screen for exposure to dangerous heavy metals. A preventative measure to decrease one's susceptibility to opioid addiction is for individuals to, as a precaution, treat the body and brain for exposure to dangerous heavy metals. The beauty is the treatment offers basic health benefits to the immune system even if one has not been exposed to dangerous heavy metals. The treatment includes small daily doses of selenium, magnesium and zinc to dislodge dangerous heavy metals, and Alpha Lipoic Acid to clear them from the body and brain. The treatment costs almost nothing.

I challenge you to consider posing the following questions to Azar.

Are you aware that United States Superfund Sites are the number one enemy of the health and welfare of United States citizens?

Are you aware that pharmaceutical companies greatly profit from Superfund Sites not being cleaned up?

Can we trust you to head the Department of Health and Human Services as an individual who has benefited from the profits of pharmaceutical companies at a cost to the public health and welfare?

As we face questions and dilemmas about Obamacare, Medicare, and Medicaid, I, as the Secretary of the Health and Human Services Department will make it my priority to improve the overall health of the public, therefore safety nets as they are intended to be, can serve their purpose efficiently and not be overburdened.

One of the paradigm shifts entails admitting profits are being made from people not being well. It is a hard one to swallow, I know.

Further, I have also compiled a large body of work which explores the subconscious coding of extreme events of violence which alerts us to larger truths. My latest at-

tempt to prove my theory includes an analysis of what the neuropathologist Dr. Hannes Vogel may discover is affecting the brain of Stephen Paddock. We still await Dr. Vogel's results to be made public. I learned early in my career as a social worker for the City of Phoenix Human Services Department that we cannot solve problems by being so quick to deem individuals deficient. To find solutions, we must look further, explore many possibilities, variables and factors. Too many men today pride themselves on being experts and having the answers because somehow even misinformation has become a commodity.

The entire United States health-care system is a failing structure rigged on the faulty foundation of profiteering. I have the energy to guide the Department of Health and Human Services to be an engine that drives this Nation in the direction it needs to go. Right now, the state of the health and wellness of the people of the United States, is a threat to global security. In addition to an overabundance of dangerous heavy metals affecting our ability to have stable moods, be generally happy and pain free, these endocrine disrupting compounds, are hindering our basic human capacity to be kind, nurturing and loving.

I am asking you to vote no on Alex Azar's nomination. I am asking you to sway President Trump to nominate me, Alison Michelle Ernst.

And with this document I declare my covert operations which entailed a broad investigation of many divisions and programs across the Department of Health and Human Services officially over.

Azar technically was involved in attempting to increase profits for a pharmaceutical giant by victimizing those that the Department of Health and Human Services has a primary duty to protect, "those who are least able to protect themselves." I on the other hand, risked everything to witness and understand the unbelievable horrors which our most vulnerable our experiencing.

I ask whole heartedly for your consideration,

Alison Michelle Ernst

HANSA CENTER FOR OPTIMUM HEALTH
12219 E. Central Avenue
Wichita, KS 67206

Statement of Dr. David Jernigan, Founder

U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510–6200

Chairman Hatch, Senator Wyden, and members of the committee:

Thank you for the opportunity to submit a statement on the nomination of Alex Azar to the position of Secretary of Health and Human Services.

America's addiction to pain pills was entirely predictable. The nation has long been over-medicated, blithely popping 3.2 billion medications annually, according to the CDC.

Watch any nightly network newscast and we're bombarded with drug ads, playing on our myriad health concerns and promising blissful remedies. Harvard tells us that the drug industry spends more than $5 billion a year on consumer advertising, supporting, according to the U.S. Government, more than $300 billion in pharmaceutical sales. Add to that the astronomical popularity of non-prescription or OTC drug products, and you can see that we're a nation consumed by our aches and pills.

Given this environment, it is somewhat concerning that the nominee for Secretary of Health and Human Services, whose job is to protect Americans' health, is the former president of the U.S. division of global pharmaceutical marketer Eli Lilly and Company. His disposition towards expanding our synthetic drug culture versus furthering the development and application of natural medicine should be carefully explored during Congress's consideration of his nomination.

While many pharmaceuticals clearly can save, extend and improve the quality of life, the reality is that their long-term use conveys merely the illusion of health. Remission is promoted as success, even though it is but a temporary abatement of

symptoms. While Americans consume the most prescription medications, the World Health Organization ranks the U.S. as having the worst health among developed countries. With drugs to control the symptoms of every named illness, Americans are oblivious to the reality that despite their pills, they're getting sicker.

A vital key to a healthier and more productive population is the development and promotion of a new medical corps, trained in the pure treatment philosophy of biological medicine, focused on identifying and treating the root causes of illness, rather than just the symptoms.

True healing cannot occur by simply masking symptoms. In those instances where pharmaceuticals are required as first-line treatment, the aim should be to get off medication as quickly as possible, and identify and correct the cause at its source.

The biological medicine treatment option is particularly effective for those with chronic pain and illness—cases that have been considered untreatable in conventional drug therapy—without the risk of addiction or worse. It applies advanced science in diagnostics and treatment technologies to treat the patient, not the disease, by restoring the body's own healing potential.

Lifetime reliance on pharmaceutical drugs only benefits the drug industry. While prescription drugs are convenient, requiring little time and effort to prescribe, symptom-suppression is not a real solution to health problems, and it often entails side effects that reduce productivity and ultimately lower quality of life.

Americans should demand that our health-care providers, elected officials and industry regulators acknowledge the drug industry's grip on our health-care system, and work to recognize and promote natural treatments and disciplines that seek to restore health, versus continuing promotion of the drug-induced illusion of health. The confirmation process for HHS Secretary-designate Azar is a prime opportunity to start this process.

David A. Jernigan, D.C.

Dr. Jernigan is a nationally recognized leader, author and lecturer in Biological Medicine and the treatment of chronic illness. Graduating from Park University with a bachelor of science in Nutrition with honors, he received his doctorate in Chiropractic Medicine at Cleveland University, Kansas City. His postgraduate work has included the study of natural and anthroposophical medicine in Germany and of Biological Medicine with Thomas Rau, M.D. of Switzerland's Paracelsus Clinic. Dr. Jernigan received his certification in Botanical Medicine from the University of Colorado School of Pharmacy. He is the developer of the diagnostic and treatment techniques Bio-Resonance Scanning™, NeuroCardial Synchronization™, and NeuroPhotonic Therapy™. Dr. Jernigan has developed over 30 novel natural medicines to date, and authored four books on the natural treatment of People diagnosed with Lyme disease; his latest is Beating Lyme Disease; Living the Good Life in Spite of Lyme, 2nd edition. The founder of the Hansa Center, Dr. Jernigan is one of the most experienced doctors in the United States in the FDA-cleared adjunctive diagnostic tests, Alfa and Computerized Regulation Thermodiagnostics.

drjernigan@hansacenter.com (316) 686–5900

www.HansaCenter.com

The preceding statement was originally published in the National Pain Report on December 23, 2017.