

**NOMINATION OF ALEX AZAR TO SERVE AS
SECRETARY OF HEALTH AND HUMAN
SERVICES**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE NOMINATION OF ALEX MICHAEL AZAR II, OF INDIANA,
TO BE SECRETARY OF HEALTH AND HUMAN SERVICES

NOVEMBER 29, 2017

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Wednesday, November 29, 2017

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR,
AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 9:34 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Murray, Isakson, Paul, Collins, Cassidy, Young, Roberts, Murkowski, Scott, Casey, Franken, Bennet, Whitehouse, Baldwin, Murphy, Warren, Kaine, and Hassan.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

Today's hearing is on Alex Azar, the nominee to serve as Secretary of the Department of Health and Human Services.

While the HELP Committee holds a courtesy hearing on the nomination of the Secretary, the Finance Committee receives his paperwork and will vote on the nomination.

Senator Murray and I will each have an opening statement. Then former Secretary and former Governor of Utah, Michael Leavitt—who we welcome today; Mike, good to see you and to have you back—and Senator Young, who is a Member of this Committee, will introduce Mr. Azar.

After Mr. Azar's testimony, Senators will each have 5 minutes of questions.

We have a lot going on today in the Senate, but we already have a good turnout, so I anticipate a good, vigorous questioning period.

Mr. Azar, if confirmed to lead the Department of Health and Human Services, you will be running a \$1.11 trillion organization. That almost equals the total of the 12 appropriations bills that Congress passes each year to fund everything from National Parks, to National Defense, to National Laboratories.

You will be overseeing Medicare and Medicaid, our Nation's Government-run insurance programs for the poor and elderly; mental health and substance abuse, where you will have to address the opioid crisis, among many other issues; the National Institutes of Health where, with Francis Collins' excellent leadership, the

United States is leading efforts to develop a cure for Alzheimer's, a new non-addictive pain killer to prevent opioid abuse, and new treatments for cancer; the Food and Drug Administration, where Scott Gottlieb has gotten off to an excellent start speeding up the approval of generic drugs, and working to spur innovation and access to regenerative medicines; and you will be faced with skyrocketing premiums in the individual health insurance market that are currently a nightmare for the nine million Americans who do not receive a Government subsidy to help pay for their health insurance.

You will also have an opportunity to implement what the Majority Leader of the Senate called, "The most important piece of legislation last year," the 21st Century Cures Act—which Senator Murray and I, and Members of this Committee agreed upon—and gave broad, new powers to the FDA and the National Institutes of Health. It included the first major reorganization—Senators Cassidy and Murphy especially worked on that—of mental health programs in a decade, as well as significant new funding for the opioid crisis, which virtually all of us support.

I believe you are an excellent nominee for this job. You have been confirmed by the U.S. Senate twice. You have offered to meet with every Member of this Committee, and have met, or spoken with, 15 Committee Members.

You have served in the Judicial Branch as a law clerk for Supreme Court Justice Scalia. You know the executive branch, having been HHS General Counsel for 4 years and Deputy Secretary for 2 years. You know the private sector. You spent a decade in a leadership position at one of the country's major pharmaceutical companies, so you know the system of how drugs get from the manufacturer to patients.

With all of these perspectives, you should need no on-the-job training to lead this Department, and should be able to take advantage of this exciting time in biomedical research to speed safe drugs through the system to patients more rapidly.

I see your broad experience as one of your principle assets. Experience in healthcare, to me, is an obvious asset for someone called upon to lead the Nation's most important healthcare agency.

One reason Dr. Gottlieb, the FDA Commissioner, has done so well so rapidly is he knows the agency, having been Deputy Commissioner, and he knows the private sector as well having worked in it. Similarly, Dr. Collins' knowledge of NIH, and his experience leading the Human Genome Project, has made him an especially effective leader at the National Institutes of Health.

I am glad to know that people like you, Dr. Gottlieb, and Dr. Collins have the experience on the issues that you will be dealing with every day.

Healthcare costs, and drug pricing, are issues this Committee has studied to better understand existing challenges and find solutions. We plan to hold a third hearing on how the supply chain affects what patients pay for prescription drugs on December 12 to hear from the National Academies. Given your experience, I would welcome your input as we continue to examine the price patients pay when picking up their prescriptions.

Healthcare is much broader than health insurance, and only about 6 percent of insured Americans purchase their health insurance in the individual market, but that is where we have had most of our debate and discussion. As I mentioned, nine million in the individual market do not qualify for a subsidy and are really getting hammered by skyrocketing prices.

In Tennessee, premiums have increased 176 percent in 4 years, and an additional 58 percent for this coming year. Both Congress and the Administration need to act to provide relief for these Americans.

Senator Murray and I, and Members of this Committee, worked together on an agreement, co-sponsored by 11 other Republicans and 11 other Democrats, which the Congressional Budget Office says will prevent a 25 percent price increase in premiums by 2020 by paying cost sharing subsidies, decreasing the Federal dollars spent on ACA premiums, and as a result, lower the deficit.

The agreement would also give states the authority to use the Innovation Waiver already in the law to find other ways to lower premiums.

For example, Alaska created a reinsurance program and lowered premiums by 20 percent with no new Federal spending.

Yesterday, the President said he supported the Alexander-Murray agreement becoming law by the end of the year.

Our agreement has so much in it, and it appeals to so many Democrats and Independents, that it is hard to imagine our not passing something that prevents a 25 percent increase in premiums by 2020 and offers states flexibility to further lower rates.

The Democratic Leader called it a “good compromise,” and said it has the support of, “all 48 Democrats” in the Senate. The Chairman of the Democratic National Committee, Tom Perez, tweeted last month that, “Alexander-Murray . . . has widespread bipartisan support.”

As Secretary, there are other steps you can take to lower premiums and stabilize the markets, such as approving states’ Innovation Waivers, which could increase access to lower cost plans, and incentivize younger and healthier individuals to purchase insurance.

The opioid crisis that is ravaging this country is a priority for the President and for every Member of this Committee. We are having a hearing on the state perspective on the opioid crisis tomorrow.

You will be coordinating a Department-wide effort to help combat the opioid drug abuse. Drug overdose deaths in Tennessee went up by 12 percent from 2015 to 2016. In particular, overdose deaths related to fentanyl, a synthetic opioid, have dramatically increased 74 percent from 169 in 2015 to 294 in 2016.

Congress has passed legislation to streamline programs and provide funding to states and communities on the front lines of this crisis, including the Protecting Our Infants Act, the Comprehensive Addiction and Recovery Act, and the 21st Century Cures Act. We have also included \$816 million in the fiscal year 2018 Appropriations bill to help address this growing and tragic crisis.

As you implement these laws, we want to hear from you what is or is not working. We stand ready to work with you if additional tools or authorities are needed.

Some are saying we need an opioid czar. I hope you will join me in advising the President that this is a bad idea. You need to be the czar. The Federal Government does not need a new czar. Once confirmed, you need to be the one to take charge of leading the Federal Government response and letting us know how to help.

As I mentioned at the beginning, we have an exciting opportunity to implement the 21st Century Cures Act. As we continue oversight hearings on Cures, I hope you will work with us to take advantage of all this law offers, including President Obama's Precision Medicine Initiative, the Vice President's Cancer Moon Shot, and the BRAIN Initiative.

Cures also gives you, and the FDA, new authority to hire the scientists it needs to make sure these exciting new advances are safe and effective for Americans. We all thought that was a big priority. I hope you use these authorities to make sure we take full advantage of this exciting time in science.

The Committee will also perform oversight on the Drug Quality and Security Act, the law we passed to help ensure the safety of compounded drugs. I also hope we will continue to look at how to lower healthcare costs, including the cost patients pay for prescription drugs and how to keep people healthy.

Looking at next year, the Committee will have to reauthorize the Pandemic and All-Hazards Preparedness Act, which provides the authority to ensure our Nation is prepared for, and able to respond to, public health emergencies such as hurricanes, infectious diseases like Zika, and bioterror attacks. Another important bill to fund the FDA, this one focused on animal drugs, is the Animal Drug and Generic Animal Drug User Fee Act.

There is a lot to do. I look forward to working with you on this and hearing more about your priorities today.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Chairman Alexander, and thank you to all of our colleagues for being here today.

Mr. Azar, thank you and your family, for being here and your willingness to serve.

In November 2016, people started emailing me and calling, coming up to me in the grocery store and everywhere else with tears in their eyes wondering what the future held, especially for their healthcare, and it has not stopped.

Because these worries and challenges are what this Congress and the Department—and what we are discussing today—is supposed to be focused on, I am going to start my remarks with a few examples of the stories I have been told over the last year.

My constituent Julie, from Mercer Island, is a four time cancer survivor. She has said she would not be able to afford her medical expenses, or even stay alive, without Affordable Care Act protection.

Kim from Ellensburg shared her story about her addiction to opioids and her ability to overcome it with the right comprehensive treatment.

Kristina from Marysville said that before going to Planned Parenthood, she struggled to get birth control regularly given her unpredictable schedule in the fast food industry.

Those are just a couple of examples. There are many others and so many pressing health problems this Administration could be solving. But it appears that instead of solving problems, the Department of Health and Human Services under President Trump so far has been determined to create problems.

The Department has not attempted to help people get high quality, affordable coverage. They made it harder by stopping payments for out of pocket cost reductions, by letting insurers cover fewer benefits, by cutting this year's Open Enrollment period, and slashing funding for consumer outreach, and a lot more.

Rather than allowing women to make their own healthcare choices, the Department has tried at every turn to impose right wing ideology on women and even prevent them from getting care from a provider that they trust.

President Trump went to states like New Hampshire and Ohio and said he would confront the opioid epidemic head on and called it a tremendous problem. People believed that he would make sure hard hit communities get the resources that they need.

But this Administration, and its health department, did the opposite. It proposed gutting Medicaid, which offers critical wrap-around services and substance use disorder treatment, to people who otherwise could not afford it. Experts say that would cripple response efforts.

All it took was a meeting with a few pharmaceutical executives for President Trump to "go dark" on the skyrocketing costs of prescription drugs, despite the President's promises about bringing prices down.

In fact, it is hard to find a healthcare problem the leadership at HHS has not only failed to address so far, but actively made worse.

The Department has proposed using public health funds to close near term budget gaps rather than to prevent costly illness and disease down the road. It utterly failed to see the urgency of the public health crisis that is still unfolding today in Puerto Rico and the U.S. Virgin Islands in the wake of Hurricane Maria.

The Administration is even rolling back protections that prevent discrimination against people who have historically been denied equal access to healthcare. It should not have to be said, but the absolute last thing our Nation's health department should be spending time on is encouraging more discrimination in our healthcare system. That is wrong.

Now, Mr. Azar, you and I do have some stark disagreements, but your nomination, still, could be an opportunity for HHS to reset, to put aside the extreme politics that are actively endangering people nationwide, and start focusing on the Department's mission instead of President Trump's ideological agenda.

People across the country would be far better off if you took this opportunity. But, Mr. Azar, I have to say with concern that my review of your record leaves me with serious doubts that you will.

You know as a pharmaceutical executive you raised drug prices year after year. Eli Lilly, as we know, is currently under investigation for working—under your tenure—with other drug companies

to needlessly raise the price of insulin. You have said many times you oppose Government efforts to lower drug prices.

You have also made it clear on questions of women's health. You said with ideology over science and right wing politicians over women.

Although conservative experts, and Governors, and even some Members of Congress have rejected President Trump's attempts to sabotage the healthcare system and jam Trumpcare through, you said this legislation would have spiked premiums, undermined protections for people with preexisting conditions, gutted Medicaid, cost tens of millions of people their healthcare, defunded Planned Parenthood, and more. You said it did not go far enough.

Mr. Azar, this leaves me very concerned about whether you would faithfully implement the bipartisan agreement—that Chairman Alexander just talked about with us—that we reached earlier this year should it become law.

Finally, in light of President Trump's profoundly underwhelming follow through on his campaign promises about tackling the opioid epidemic, it is deeply disappointing that yet another nominee for the role of Secretary of Health has not supported committing the new resources we need for this effort.

Mr. Azar, I worry about your professional history and statements that point to a continuation of some of the extremely damaging and politically driven approaches we have seen so far from this Administration.

Let me just return briefly to the stories I mentioned at the beginning of my remarks to make my final point.

Right now, Julie is traveling around the country raising awareness about Open Enrollment to help more people sign up and get access.

Kim is now pursuing a Master's in social work, and helping people in central Washington to get the necessary treatment and services so they can overcome their addiction.

Kristina has become a vocal advocate for helping women in Washington and, actually, nationwide to get care that works for their needs.

Julie, and Kim, and Kristina are doing more than their part to keep our communities health and well.

My question is why is our Nation's health department not doing the same?

People should have a Secretary of Health who will work for, and with, patients and families, not against them and who is committed to making policy based on science, not ideology.

Mr. Azar, I am looking forward to your thoughts on the many serious concerns that I have raised and how you would be an appropriate choice for this position.

I am concerned that President Trump has yet sent us an extreme ideological driven nominee to pick up where Secretary Price has left off and that women, and children, and seniors, and families deserve a lot better.

I am interested in your responses today. I hope I am pleasantly surprised.

I do want to say, if you are confirmed, I want to make it very clear I have not, and will not, let this Administration's approach

so far lower my expectations for any of the Department this Committee oversees. I will continue doing everything I can to hold HHS to the highest possible standards of ethics and service for people in my state and across the country.

With that, thank you very much for being here and I will turn it back over.

The CHAIRMAN. Thank you, Senator Murray.

We will now welcome the nominee, Mr. Alex Azar and we also welcome your family, and friends, and attendants. We thank them all for being here. There is a pretty good group of them and you may want to introduce them when you begin.

Mr. Azar will first be introduced by Governor Mike Leavitt. Governor Leavitt served as President George W. Bush's Secretary of the Department of Health and Human Services from 2005 to 2009. He worked closely with Mr. Azar then while Mr. Azar served as his Deputy Secretary.

Then the nominee will be introduced by his home state Senator, and a Member of this Committee, Senator Todd Young.

Governor Leavitt, please introduce Mr. Azar, and welcome.

STATEMENT OF MICHAEL LEAVITT

Mr. LEAVITT. Thank you, Chairman Alexander, and Senator Murray, and Members of the Committee.

Senator Alexander and Senator Murray have very ably described the complexity and the importance of this role. Therefore, it is my privilege to introduce, and to unequivocally recommend, Alex Azar. He is up to the task. He is supremely well qualified to carry out this important work.

As mentioned, during my service as Secretary of HHS, Mr. Azar was Deputy Secretary. In essence, he was the Chief Operating Officer of this very large and complex department.

Prior to his service, he served as the General Counsel under Secretary Thompson who, I believe, later will also introduce, and robustly recommend him, to the Finance Committee as they consider his nomination.

That, plus his experience in the private sector that has been mentioned, leads me to conclude that there may not have been a nominee to this office of Secretary better prepared to hit the ground running than Alex Azar.

It was mentioned that HHS is a large and complex place. While Deputy Secretary, Alex Azar was essentially the manager of the day to day operations of 90,000 employees and a \$1.1 trillion budget. Just a brief example that, I think, would illustrate his capability.

President Bush had a management agenda that laid out criteria of several dozen different objectives, and then had a dashboard of green, yellow, red. Alex set an objective to have every criterion green, and he was the first Deputy Secretary in the entire Federal Government to achieve that.

He was also delegated oversight of much of the regulatory process. In a very skillful and lawyerly like way, he managed to carefully and equitably adjudicate the administrative rules process, which is robust at HHS.

He is a world class policy thinker. He is a good communicator. You will see that today. I can assure you that if he is confirmed as Secretary, you can expect good communication on both sides of the aisle. He is an experienced diplomat.

Experienced, I think, is a word that will be underscored here. I have seen him under fire; 9/11, he was part of the response.

There was a point in time when [Hurricane] Katrina, pandemic influenza, and the rollout of Medicare Part D were happening at the same time. This is a person with great experience in a complex Department.

Most important, can I just say, he is an extraordinarily good human being. He has got the kind of compassionate heart that, I believe, it requires to serve, to lead the mission of this important Department, and I commend him to you, and urge the Senate's confirmation of him as the Secretary of Health and Human Services.

The CHAIRMAN. Thank you, Governor Leavitt, and thank you for joining us again as you have before to help this Committee.

Senator Young.

Senator YOUNG. Well, thank you, Chairman Alexander, and Ranking Member Murray, and fellow Members of this Committee.

I am grateful for this opportunity to introduce a fellow Hoosier, Alex Azar, to be Secretary of the U.S. Department of Health and Human Services.

President Trump made an outstanding choice in selecting Alex to lead this critical agency, which happens to be the largest civilian cabinet agency in the entire U.S. Government.

Alex is, as has been said now by a couple of individuals, an extremely qualified nominee. He is a well known expert in the healthcare industry.

His previous leadership experience, both as General Counsel and Deputy Secretary of HHS, and as President of Indiana-based Lilly Incorporated, Lilly USA—which is the largest affiliate of one of the largest healthcare companies in the world—will collectively be an effective combination as we work to solve our Nation's most significant healthcare challenges.

Former HHS Secretary, Tommy Thompson, said that, "Azar is one of the most competent people I know, an experienced leader with deep substantive healthcare knowledge."

I agree.

In addition to his impressive academic record, which includes degrees from Dartmouth and Yale, Alex also clerked for the late U.S. Supreme Court Justice Antonin Scalia.

He first began his service at HHS in 2001 when the United States Senate confirmed him to serve as the Department's General Counsel. Since then, Alex has been a leading voice in healthcare reform and healthcare innovation with a reputation as an effective leader.

He has been particularly outspoken on the need to lower the price of prescription drugs saying patients are paying too much. If anyone could help solve this problem, it is Alex Azar. He is the right person to help reform our broken healthcare system and to ensure the Department succeeds in its mission to enhance and protect the well-being of the American people.

Alex was confirmed to both of his previous positions at HHS with unanimous, bipartisan support. I will say that again.

Confirmed twice by the United State Senate for positions at HHS with unanimous, bipartisan support and I am hopeful this time will be no different.

I know Alex is a good man with a heart for service. I have gotten to know him personally over the years. I look forward to supporting his nomination and working together to ensure all Americans have access to high quality and affordable care.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Young.

Mr. Azar, we now invite you to give your opening remarks. Your full statement will be incorporated into the record.

Welcome.

STATEMENT OF ALEX AZAR

Mr. AZAR. Well, thank you very much.

If I could take just a second to introduce my family that I have here today, Mr. Chairman, at your invitation.

I am pleased to be joined today by my wife Jennifer, my daughter Claire, my son Alex, and my father, Dr. Alex Azar, as well as my sister Stacy and her family.

Unfortunately, my mother Lynda could not be here today and most tragically, my stepmother, Wilma, died of cancer just in July, and I am very sad she could not be here for this moment.

Having an opportunity such as this does not happen without the support of family and their guidance.

Thank you, Mr. Chairman. Thank you, Ranking Member Murray, and Members of the Committee for the opportunity to appear before you today as the President's nominee to be the Secretary of Health and Human Services.

Senator Young and Governor Leavitt, thank you so much for those extremely kind words, for your friendship, and your mentoring over the years.

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

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 that 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 well-being of all Americans through programs that touch every single American in some way, every single day. We are at an historic

time in terms of delivering on that mission through innovation. Through its outstanding leaders and career staff, HHS is primed to meet that challenge.

This task is humbling. Marshalling 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 think 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 future and 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 programs; and our response to threats such as SARS and monkey pox; in our efforts to continue to reform welfare programs to make them as modern, responsive, and as 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 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 of HHS, it is often 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 can 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 healthcare more affordable, more available, and more tailored to what individuals want and need in their care. 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 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. 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 results.

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

[The prepared statement of Mr. Azar follows:]

PREPARED STATEMENT FOR ALEX MICHAEL AZAR

I'm pleased to be joined today by my wife, Jennifer, my daughter, Claire, my son, Alex, and my father, Dr. Alex Azar, and my sister Stacy and her family. Unfortunately my mother, Lynda, could not be here today, and most tragically my step-mother Wilma passed away just this 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 Murray, 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.

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

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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. We are at an historic time in terms of delivering on that mission through innovation. Through its outstanding leaders and career staff, HHS is primed to meet that challenge. The task is humbling. Marshalling 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 monkey pox, 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.

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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. 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.

The CHAIRMAN. Thank you, Mr. Azar.

We will now begin a round of 5 minute questions, and I will begin.

I am just going to ask one question and I would like to reserve 2 minutes at the end, at least, so I can ask questions later.

During the nomination process for the Secretary of Agriculture, Secretary Purdue, there were concerns about his close ties to the agriculture industry. He had been a farmer.

During Dr. Gottlieb's confirmation to be Commissioner of the Food and Drug Administration, where he would approve moving treatments and cures through that agency, there was concern because he had worked with pharmaceutical companies.

Now, you have worked with a major pharmaceutical company in a major position for 10 years. My own view is that is a big help because having some familiarity with drug pricing is such a Byzantine situation that someone who did not know anything about that or much about it, by the time they came in, they would be gone before they even figured out 5 percent of how we might lower drug prices. I think it is a plus.

But what do you say to the skeptics who criticize you for that, especially for those who question the increase in insulin prices while you were part, while you were a leader at Eli Lilly over that 10 year period?

Mr. AZAR. Mr. Chairman, thank you for that question.

As you and others have mentioned, I had the honor of serving as General Counsel and then Deputy Secretary of HHS for almost 6 years in the senior leadership there. For me, if I were confirmed, this is returning home. This is my place that I want to be.

After HHS, I did spend 10 years at Eli Lilly where I was a senior leader, eventually the President of the U.S. affiliate directly leading the sales and marketing of all non-diabetes, non-oncology drugs in the United States. As the geographic leader, I also supported operations for those other business units.

I do believe, as the Chairman mentioned, that these public and private sector experiences do prepare me very well for the role of Secretary. I think this is especially true in the case of drug prices.

The price of many drugs has risen substantially; in particular, the product that, Mr. Chairman, you mentioned, insulin.

The current system of pricing insulin, and other medicines, may meet the needs of many stakeholders, but that system is not work-

ing for the patients who have to pay out of pocket, and we have to recognize that impact.

That is why the President, so many Members of this Committee on a bipartisan basis, and I have talked about the need to fix this system.

I do think through my experience in the public sector with Part D; through my experiences at Lilly in the private sector; understanding how the channel works, how the channel sees these issues; how manufacturers, payers, Pharmacy Benefit Managers, pharmacies, distributors, all work together; how the money flows in that. I believe I can hit the ground running to work with you, and others, to identify solutions here.

The CHAIRMAN. Thank you, Mr. Azar.

I will reserve the balance of my time.

Senator Murray.

Senator MURRAY. Thank you very much.

Let me just follow-up. I think the cost of drugs, the high cost, is something I hear about more than anything else. It affects so many people in a negative way. I am assuming that you agree with the overwhelming majority of Americans that drugs costs are too high.

Do you agree that Congress and administrative actions are needed?

Mr. AZAR. I absolutely do, Senator Murray. Thank you.

Senator MURRAY. Okay. As we know, you were President of a major pharmaceutical company when it got worse, as someone mentioned. Tell us how you would approach this as Secretary.

Mr. AZAR. Thank you, Senator Murray, and also thank you. I appreciate the chance we had to sit down together and I really enjoyed that discussion.

Also, just in terms of your opening, I hope, if I am confirmed, I do hope I can earn your trust and will show you that this is the job of a lifetime for me.

I would approach this not for any industry, not for any past affiliation, but to serve all Americans, to improve their health and well-being.

Senator MURRAY. I appreciate that.

Mr. AZAR. I think there are constructive things that we can do, and I would love to just keep—

But I would also like to hear ideas from the Committee, from people at HHS, elsewhere. But let me throw a couple of things out that, I think, are worth focusing on.

We need to increase generic and branded competition. The more drugs we get into the market, as Dr. Gottlieb is working on, the more competition we will have. That actually can help bring down cost to the system.

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.

When I was General Counsel of HHS, I actually led an effort to get rid of filing multiple patents to delay, delay, delay the exclusivity.

Senator MURRAY. Correct.

Mr. AZAR. It saved \$34 billion for consumers over 10 years for the efforts that we pushed by reinterpreting.

I think we need to look at why Americans are paying more than those in Europe and Japan. Is that fair that we are bearing the cost of other industrialized Nations?

Senator MURRAY. I am running out of time and I have other questions.

Mr. AZAR. Sorry.

Senator MURRAY. But I would just say the skepticism comes from that you were in the world of pharmaceuticals and prices did not drop. How are you going to do that as Secretary?

We can talk about it later because I have other questions.

The fox guarding the henhouse is what I hear. There is a lot of skepticism that you will do it from within the agency when you stated before that you do not believe that Government should be part of the problem, although you just said something different.

I know others will ask about that. I wanted to particularly ask a question about women's health because so far, under President Trump's leadership and former Secretary Price, a number of detrimental steps were taken that undermine women's healthcare, including appointing multiple extreme anti-choice ideologues; undermining Title X teen prevention programs; and critically rolling back preventions for women to have full coverage for birth control from their insurance plans.

I wanted to ask you. If confirmed, will you commit to putting science and access to healthcare first rather than ideology and extremism?

Mr. AZAR. Senator Murray, as we discussed in your office, if I am Secretary, I am the Secretary for all Americans. I am there to enhance and protect the health and well-being of all Americans, men and women.

We have programs that this Congress has created and that HHS is there to implement. I would faithfully implement those programs.

We may differ in different elements of how those get implemented, but I firmly believe in following evidence and science where it will take us—

Senator MURRAY. Okay.

Mr. AZAR—in running these programs.

Senator MURRAY. Let me ask it this way.

Mr. AZAR. Yes.

Senator MURRAY. Do you believe that all women should have access to the healthcare their doctor recommends for them? Yes or no.

Mr. AZAR. If the issue is, for instance, the conscience exception that HHS has come out with. I do believe we have to balance, of course, a woman's choice of insurance that she would want with the conscience of employers and others. That is a balance. That is sort of an American value, trying to balance those, and it is a very small group, I think, that would be—

Senator MURRAY. The woman's doctor recommends it, but you believe the employer has the precedence over that.

Mr. AZAR. Just in terms of, not in terms of access, but in terms of insurance. To force those very few, I believe it is less than 200 have come forward. Very few employers that would be impacted by

the conscience exception to respect, frankly, their rights as well as respecting women's access through the insurance.

Senator MURRAY. Well, I disagree. I think women's access to healthcare their doctor requires for them should take precedence, but we disagree on that.

Let me go to a critical question that Senator Alexander and I both raised. You know about the legislation we have put forward.

If confirmed, will you commit to implementing it as intended and working with us to improve further accessible coverage for patients?

Mr. AZAR. Absolutely.

Senator MURRAY. Okay. I know that some people today are claiming that the bill that we designed will fix other problems that are being proposed.

Do you think the cost sharing reduction payments will be sufficient to make up for the chaos if other tax cut proposals are passed?

Mr. AZAR. I think the work of this Committee on a bipartisan basis, frankly, it is a wonderful model for addressing it. It recognizes there are problems with the Affordable Care Act. There are problems with its implementation.

There are going to be some new authorities in the package that you are talking about. Those will be useful, but I do want to caution. I do not believe it is a long term solution to problems that are just inherent in the Affordable Care Act because I think we still need to work to address in terms of getting to affordable insurance for people, choice of insurance, that insurance delivering real access to healthcare for people.

Not just a card, but actual access to physicians and then the insurance that lets the people get the insurance that they want, not what we are telling them from the center.

I do think it is an important stopgap to help along that way.

Senator MURRAY. Well, I have a lot more questions on that, but I am way over time, so I will let other Members ask at this point.

The CHAIRMAN. Thank you, Senator Murray.

Senator Paul.

Senator PAUL. I think most Americans do not disparage or dislike people who accumulate wealth. We are fine if people honestly accumulate wealth.

If you ask Americans, Sam Walton, developed this great store, and sold inexpensive things, and became very wealthy, most Americans do not think that he is a terrible person or he somehow abused the system.

I do not think Americans have the same big, warm, fuzzy feeling for Big Pharma. I think many of us perceive that they use their economic might to manipulate the system to maximize profits. It is not like they are selling a cheaper product to more people. They are using Government to maximize their profits.

Do you acknowledge that the current system, under the current system, Big Pharma uses her economic clout to manipulate the patent system to increase drug prices?

Mr. AZAR. There are clearly abuses, Senator, in the system and that is why one of the steps that I mentioned to Senator Murray

that I believe we have to go after is the gaming of that. I have always believed——

We have the Hatch-Waxman regime. It gives innovators a time period to sell the product, but then there should be a moment certain when, “Katie, bar the door!” There should be full generic competition, and that is a gift to this country, to the system, and to patients when they walk in the pharmacy.

Senator PAUL. But I will say this is a huge problem that has been going on for decades. We have had insulin since the 1920’s. It has been 50, 60 years or more with the production of insulin by pharmaceutical companies, and we have no generics.

Everybody says they are going to fix it and they are nonspecific, but I tend to be a doubter because these problems go on, and on, and on.

When you look at the drug problem, one of the things that people proposed is to allow us to buy drugs from Europe, allow us to buy drugs from Canada, allow us to buy drugs from Mexico or Australia.

In fact, this was the President’s position when he said, “Allowing consumers access to imported safe and dependable drugs over overseas will bring more options to consumers.”

We have had legislation on this. We have passed it several times and yet, it never happens. You have taken a position against re-importation.

How does that jive with the President’s position?

Mr. AZAR. I have before publicly stated a position against unsafe importation of drugs into the United States and the President has said the same, reliable and safe. That is the first thing we have to do.

Senator PAUL. Do you think the drugs in Europe are unsafe? The drugs that they use in the European Union are unsafe?

Mr. AZAR. We have had a succession of Democratic and Republican FDA Commissioners who have been unable to certify under the law that importation would be safe.

Senator PAUL. They have been wrong and beholden to the drug companies, frankly.

You would have to sit there and say that the European Union has unsafe drugs. It would be unsafe for Americans to buy drugs from the European Union, or from Canada, or Australia.

It is just frankly not true. It is a canard and it has been going on year, after year, after year.

We have this enormous problem and people say, “We are going to fix the drug problem,” and it never happens.

But what I think is important for America to know: this is not capitalism. Wal-Mart is capitalism. Bill Gates was capitalism.

Big Pharma, it is not really Big Pharma’s fault even. They are just trying to maximize their profit by using Government, but we are letting them do it. We have this terrible system.

You get an Epipen. You have it for 20 years. You manipulate one little thing in the spring and all of a sudden, they get another 5 years, and then another 5 years.

One of the things we could do that would dramatically change this is if you have a patent on the Epipen for 20 years, you get it. If you change it and make it better, you get a patent on the new

Epipen, but guess what? We can have generics on the old. Currently, you cannot have that and we have all these impediments.

Why do we not have generic insulin?

But it is going to take someone who really believes it, and I told you in my office, you have some convincing to make me believe that you are going to represent the American people and not Big Pharma.

I know that is insulting, and I do not mean it to be because I am sure you are an honest and upright person, but we all have our doubts because Big Pharma manipulates the system to keep prices high.

It is not capitalism and it is Big Government, and we have to fix it, and we cannot tepidly go at it. We have to really fix it and you need to convince those of us who are skeptical that you will be part of fixing it, and will not be beholden to Big Pharma.

Mr. AZAR. Well, Senator, as I said in the office with you yesterday, that issue of the multiple filing of patents to evergreen a product with a modification, say, on manufacturing process or delivery device, I completely agree with you.

I think that is one of the important avenues that we ought to be pursuing because, again, there should be a time certain when competition begins with generics, and you should not be able to simply make a change there and evergreen your patent. I fought against that in the Bush administration.

Senator PAUL. I appreciate that and one thing in my last few seconds. On the drug re-importation, we are going to give you a question that you can think about and write.

Everybody says it is not safe. What I want you to tell me is why the drugs are not safe in the European Union and how you would make it safe.

If there is a restriction that says, "Oh, we have to go through one Committee," I am fine with that. Vote on a Committee for the European drugs as they come through. It needs to be expedited. It needs to be happening.

Everybody just says, "It is not safe," and so we never do it. That is "BS," and the American people think it is "BS" that you cannot buy drugs from Europe, or from Canada, or Mexico, or other places.

Could we have some rules? Yes. But we just keep, we always just say, "It is unsafe."

You are going to have to convince me that you are, at least, open to the idea. The President is. That was his position in the campaign. If you are open to it and not just say, "It is unsafe." We will say, "This is how I would do it and this is how I would reimport drugs, and make it safe." That is an honest reform. If you cannot do that, I cannot support you.

I hope you will come back with an answer that says, "This is how I would make re-importation safe."

Senator PAUL. Thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman.

Just following on my colleague's comments, another option here would be to figure out how to make our prices the same as the prices in these other places. People in America did not have to go

through the ridiculous contortion of having to import drugs from overseas, but could just afford drugs here.

I want to congratulate you, Mr. Azar, in your appointment and your willingness to serve during these difficult times.

When President Clinton left the White House, he left behind a projected \$5.6 trillion surplus and that is what he gave to President Bush.

Then we fought two wars, and we did not pay for those wars. We enacted Medicare Part D, which you have mentioned a couple of times in your testimony, which was not paid for. Then we had the worst recession since the Great Depression.

When President Obama became President, we had a \$1.5 trillion deficit when he came to office.

President Trump ran for office, and this is the one thing I would say he was consistent on in his primary, and the Republican Party nominated him, and the American people elected him. His promises were these.

He would eliminate our debt, quote, "Over a period of 8 years."

He would deliver, quote, "Giant, beautiful, massive tax cuts."

He would pass, quote, "One of the largest increases in national defense spending in American history." While also saying, quote, "I am not going to touch Social Security and I am not going to touch Medicare and Medicaid."

Those are the President's solemn promises to the United States.

In the 9-years that I have been here, this Congress has disgraced itself year after year by not being able to pass a budget, by having 30 continuing resolutions, by not being able to establish a set of priorities to the American people. We sit here today collecting 18 percent of our GDP in revenue and spending 21 percent of our GDP in expenditures.

On the floor this week, disgracefully, is a tax bill that would reduce that 18 percent to an even lower number, below at least the \$1.5 trillion additional deficit in our balance sheet, and as much as \$2.5 trillion.

The concern that a lot of people have in my state is that after this incredibly unpopular tax cut is jammed through with no hearing, that the Administration is then going to break the President's promise to not touch Medicare and Medicaid. Instead, exploit the deficits that the Republican Majority has created in the time that George Bush was President, and now in the time that Donald Trump is President, to go after Medicare and Medicaid.

I wonder if you could assure this Committee that the President, through you as the head of HHS, will honor the promises that he made on the campaign trail to make sure that he is not going to cut Medicare and Medicaid, which is what he said.

I apologize for the long windup, but the history has been forgotten by my colleagues and I think it is important.

Mr. AZAR. Okay. Thank you, Senator, and it is a pleasure to see you.

Senator BENNET. A great pleasure.

Mr. AZAR. To meet with you yesterday.

Senator BENNET. Thank you.

Mr. AZAR. I do hope we will have the chance to work together.

As I mentioned in my opening remarks, the third of those four areas I really want to focus on is about strengthening our Medicare program because there is so much mistake, fraud, waste, abuse in the program, inefficiency in how we pay for healthcare procedures and sickness.

If we can tackle that, and if we can move to a more value-driven system of healthcare, we will do two things that are really important.

One of them is we will actually stretch out the resources in the Medicare program to keep its solvency longer and allow it to serve its beneficiaries, especially as we face the Baby Boom generation.

It will also serve as a catalyst for change throughout the entire healthcare system because so much of the healthcare system just really free rides off of whatever Medicare is doing on payment, et cetera. I think it is a really unique opportunity.

I think the President is fully committed around this, both the strengthening, making Medicare and Medicaid as effective, as efficient as possible for the people that we serve.

Senator BENNET. I hope we can do that in a way that is not infected by the idiotic politics around healthcare that we have had over the last 10 years in this place.

I completely agree that incentives and disincentives in the program are misaligned, and we need to align them.

On the other hand, it is also true that the reason why we are paying \$1 in for every \$3 we are consuming in Medicare is largely because of Medicare Part D, which was not paid for when it was enacted by this Congress and under President Bush, and because of the drug prices, which is a double whammy that has caused us to blow this hole.

My concern, I have a fiscal concern, obviously, which I do not think is, for some reason, shared today by my colleagues on the other side of the aisle. But I also have a concern that beneficiaries in my state are going to pay a price for the fecklessness of Washington, DC, and I do not think that is fair.

I hope we will be able to proceed on a shared understanding of the facts and work together to accomplish that.

Mr. Chairman, thank you.

The CHAIRMAN. Thank you, Senator Bennet.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Azar, I very much enjoyed our discussion in my office on drug pricing, an issue that is very important to all of us, as you can see.

I want to follow up on a couple of issues.

There was a recent NBC investigation that found that a wide variety of prescription drugs on certain insurance plans were actually less expensive when the consumer paid out of pocket than if the consumer used his or her insurance plan.

An example of that was a customer who had a co-pay of \$43 for a common cholesterol drug where, if she had not used her insurance, she would have paid less than half of that; \$19.

I then met with a group of pharmacists in the state of Maine, and I was outraged to learn that they are under gag orders that prohibit them from informing their customers that there is a dif-

ferential in price, and that they would be better off not using their insurance and paying out of pocket.

Do you support prohibiting those kinds of agreements that prevent a pharmacist from giving true transparency on the drug pricing to their customers?

Mr. AZAR. Senator, first, again, thank you for the meeting. I really enjoyed our discussion.

How can you not hear about that and have your jaw drop? Honestly, how can you not just find that just frightening that could go on?

Yes, I think that those are the types of issues across the entire channel in drug distribution and payment that I want to bring the expertise I have to the table to work with you, and others, and HHS, to try to resolve because that should not be happening. There are many other things that should not be happening in the channel in how that system works.

I think we can work together to come up with solutions here that are going to help patients when they walk in that pharmacy pay as little as possible.

Senator COLLINS. That absolutely should be our goal, and I cannot tell you how frustrated these pharmacists were that they were unable to give that information to their customers, who they knew were struggling to pay, and had high co-pay.

A second issue that I want to explore with you today has to do with the investigation that the Senate Aging Committee undertook into sudden price spikes in off-patent drugs.

We found that the Risk Evaluation and Mitigation Strategies, or the REMS system, which were intended to manage drugs with increased risk factors were, instead, being abused by certain drug companies to block potential competitors from accessing a sufficient amount of the drug once the patent had expired to do the bio-equivalency exams that the FDA requires.

I have had extensive discussions with FDA officials about this. Dr. Janet Woodcock testified that the FDA has referred 150 cases of potential anti-competitive behavior to the FTC. The FTC claims it does not really have enough authority.

The new FDA Commissioner has suggested that there could be opportunities where the FDA could partner strategically with Medicare to prevent the deliberate blocking of generic competitors.

From your perspective, how can we address this issue?

Mr. AZAR. Senator, I am aware of that issue also as one of the abuses that occur out there to prevent generic, full generic competition in the market.

I would look forward to working with you and Dr. Gottlieb to get to real solutions there, just how REMS programs could be abused to block entry.

Once we get to the end of life, we should even be looking at: do the REMS programs even continue to make sense? Are they legacies? Are they still required for safety once we achieve the potential for generic status?

There may be statutory changes needed. I do not know, but I think we need to solve that. That is one of the changes, one of the things that has to be solved.

Senator COLLINS. Thank you very much.

You referred to “the end of life,” you meant the end of the——

Mr. AZAR. The end of patent life.

Senator COLLINS. The patent.

Mr. AZAR. I am sorry. Yes, exactly. The end of patent life.

Senator COLLINS. There is no confusion.

Mr. AZAR. No, I want to be very clear.

Senator COLLINS. Yes.

Mr. AZAR. The end of patent life, sorry.

Senator COLLINS. Thank you.

Mr. AZAR. Thank you for clarifying that for me.

The CHAIRMAN. Thank you, Senator Collins.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

Mr. Azar, I will get right to the point. Your resume reads like a how-to manual for profiting from Government service.

About a decade ago, you worked in Government helping regulate the Nation’s most profitable drug companies. When you left, you went straight through the revolving door and became an executive at Eli Lilly Company. Last year, they paid you about \$3.5 million for doing that. Not bad.

You want to go back through the revolving door and once again regulate the same drug companies. At least do it until you decide to go through the revolving door again.

Now, I do not think private sector experience should disqualify anyone from serving, but I think the American people have a right to know that the person running HHS is looking out for them, and not for their own bank account or for the profitability of their former, and maybe, future employers.

I have some questions along that line.

The first is, do you agree that when a drug company lies about its products, or defrauds taxpayers, it should be held accountable by the Federal Government?

Mr. AZAR. Of course.

Senator WARREN. Good.

Because right before you went to work for Eli Lilly, you worked at HHS while they helped the Justice Department with an investigation of Eli Lilly’s drug Zyprexa. Now, Zyprexa was approved by the FDA to treat schizophrenia and bipolar disorder.

But Eli Lilly decided to boost its profits by pushing the drug on nursing homes for uses like dementia and Alzheimer’s with no proof that it would work. The word for that is fraud and it cost the Government and taxpayers billions of dollars.

Eli Lilly was still under investigation when you left Government service and went straight to work for Eli Lilly. Then as the company’s top spokesman, you helped manage the fallout in 2009 when the company was forced to pay the largest criminal fine ever imposed in a prosecution like this, more than half a billion dollars.

At that time, Eli Lilly’s CEO said, quote, “Doing the right thing is nonnegotiable at Eli Lilly.”

Do you think that settlement represented adequate accountability for Eli Lilly’s criminal behavior?

Mr. AZAR. Senator, I want to be really clear. The conduct in that case occurred and ended long before I ever even left the Government or thought about going to Lilly.

I was not involved in that case when I was in the Government. I think I actually learned about even the investigation for the first time—although I think it had been in the media, I had not seen that—I think I learned about it, actually, when I was interviewing, and I learned about it, and I wanted to do my own inquiring because—

Senator WARREN. Right. Then you became the spokesman for Lilly.

Mr. AZAR. Well, I became the Global Head of Corporate Affairs. Senator WARREN. Right.

Mr. AZAR. I will tell you, the conduct that occurred there was unacceptable and there is not a leader at Lilly that would say differently. It was a massive learning and transformational experience for the company.

Senator WARREN. Was the settlement adequate accountability for Eli Lilly's unacceptable behavior?

Mr. AZAR. It was the largest, you said it was the largest at the time.

Senator WARREN. Yes, it was.

Mr. AZAR. I think for about a week—

Senator WARREN. It was the largest of about half a billion dollars.

Mr. AZAR. Then there was another, and then another company had one.

Senator WARREN. That is right.

But do you think it was adequate? That is my question.

Mr. AZAR. It was certainly the largest ever and what I will tell you the most—

Senator WARREN. Do you think it was adequate?

Mr. AZAR. I—

Senator WARREN. All right.

Mr. AZAR. Senator, what was important about that was that it changed behaviors.

Senator WARREN. No, I am sorry. What is important, the question I am asking, and that is whether or not there was adequate accountability.

Mr. AZAR. I do believe so. I do not have any reason to believe not.

Senator WARREN. I do not think there was adequate accountability.

Eli Lilly made billions of dollars off this scheme and they paid a half a billion dollar fine. They said, "That is a huge fine." The truth is, it is a huge fine, but they made far more money than they actually paid out. For me, that is just not adequate accountability.

Your CEO, John Lechleiter, got to keep sleeping in his own bed at night, and at the end of that year, he was paid \$1.5 million for his troubles, and another \$3.6 billion in so-called performance bonuses.

I think the message was clear to other drug companies. Within 8 months, Pfizer was caught doing the same kind of marketing and slapped with a criminal fine for more than a billion dollars. Since then, there have been four more drug company settlements in excess of a billion dollars. These settlements have become a "cost of doing business" for the drug companies.

As we speak, Eli Lilly is the subject of multiple lawsuits and investigations accusing the company of conspiring to illegally raise its prices of its insulin products.

But we are supposed to believe that this time around, you are going to be willing to hold them accountable in a way that is going to make a difference. Let me ask you.

Do you think that CEO's, like John Lechleiter, should be held personally accountable when drug companies like Eli Lilly break the law?

Mr. AZAR. Senator, there was a period of time where across the pharmaceutical industry there were various practices that then got resolved through litigation. What I am actually quite proud of is the fact that I was not there as General Counsel. I was not a general counsel. I did not negotiate the settlement of that case.

But the attitude that I saw top to bottom globally at the company around that was one of, "How do we make sure this does not happen again?" How do we ensure that this, that our, that the processes, the culture—

Senator WARREN. Mr. Azar.

Mr. AZAR—the ethics, the oversight—

Senator WARREN. Let me interrupt because I am out of time. I understand that I am out of time.

I just want to make it clear for the record. I asked the question about whether or not you think CEO's ought to be held accountable when the companies they are running break the law.

I am just trying to get a little accountability answer. If you have a yes or no answer, I will take it.

Mr. AZAR. I am satisfied with our discussion. Thank you.

Senator WARREN. Okay. I will take that as a no.

The CHAIRMAN. Thank you.

Senator WARREN. You would not hold them accountable.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Cassidy, just stepped out.

Senator Young.

Senator YOUNG. Thank you, Chairman.

Mr. Azar, you have been caricatured by some as a predatory, av-
aricious, Big Pharma executive. In response to that, I would like to give you an opportunity to actually say a few words here, as opposed to my giving an extended speech.

Can you talk about what you did in your previous tenure at the agency around the drug pricing issues?

Mr. AZAR. Well, Senator, thank you for asking about that.

Back in the Bush administration, when I was General Counsel, there was a very clear abuse that was occurring where pharmaceutical companies were taking advantage of a loophole in the drug laws to allow them to have longer, longer, longer patent periods.

What they would do is they would get to the end. They would file a new patent and then get another extension. What I said to our legal team was, "This is unacceptable. Nobody has ever thought of a way to deal with this without legislation. Let us see. Can we interpret the statute in a way that prevents that?" Drove that, drove that, drove that.

We actually got to the point where we put out a rule that allowed only a single, what is called a 30-month stay in litigation. You basically got one shot at the apple instead of these multiple four or five things that could cause a drug to last for years and years longer.

When we put that rulemaking out, the economic impact of that rule was estimated to save consumers \$34 billion over 10 years. That rule was later enshrined through the leadership of Senator McCain into statute in the Medicare Modernization Act.

Senator YOUNG. I would just like you to repeat that for a second for those who may not be paying attention and who may want to fuel a false narrative that you are not sensitive to drug pricing.

You catalyzed a process by recognizing an anomaly in the law that led to a regulatory change that saved how many billions for consumers in prescription drug prices?

Mr. AZAR. Thirty-four billion dollars over 10 years.

Senator YOUNG. Okay. My constituents will be happy to know that. Thank you.

Mr. Azar, you participated last year in a symposium at the Manhattan Institute.

Do you recall that?

Mr. AZAR. I do. Yes.

Senator YOUNG. Okay. At that symposium, you stated that, "We are on the cusp of a Golden Age of pharmaceutical breakthroughs, but the problem is our outdated system for paying for prescription drugs is threatening to squelch patient access to this recent and revolutionary burst of innovation by shifting a crushing burden directly onto individuals."

A lot of Hoosiers, a lot of Americans pay for their drugs through Health Savings Accounts.

Is there something we could do with HSA's, or other vehicles, to help with drug costs?

Mr. AZAR. I do think there is, actually.

One of the things, when you have a high deductible plan, and that is one, say, you have two, three, four, five, \$6,000 dollars that you have to pay out of pocket before the insurance starts paying.

The law says that you cannot use, that the plan cannot cover during that period of that deductible unless if something is a preventive service.

But the Government has not put out really good guidelines about what can be covered as preventive services so that patients could have first dollar coverage in that deductible period. That their Health Savings Account could cover those preventive services and also changes that would allow more money to be put away into Health Savings Accounts, more flexibility for use.

Anything that lets the patient have access to more money, or lower co-pays when they walk into the pharmacy, I think, has to be part of what we drive toward.

Senator YOUNG. I have asked you two questions, one about your past professional history with respect to drug costs. You were able to cite an example where you actually catalyzed a process to lower drug costs.

I asked you about any ideas you might have revolving around a narrow issue of Health Savings Accounts. You have put forward an idea that could help reduce the cost burden on consumers.

I am encouraged by that. I hope others are as well.

I have roughly 40 seconds left. I will note that President Trump has indicated Welfare reform will be a major priority for his moving forward. It is a priority of mine. Much of the policies that fall under the category of Welfare reform are under the jurisdiction of HHS.

I will look forward. I will submit a question for the record to you.

Senator YOUNG. But I want to see what sort of changes you anticipate HHS making through executive order as the administration is pursuing in other areas to improve our Welfare system and serve the least among us in a more effective way.

With that, thank you, Mr. Chairman.

Mr. AZAR. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Young.

Senator HASSAN.

Senator HASSAN. Thank you very much, Mr. Chairman, and Ranking Member Murray.

Good morning, Mr. Azar. Congratulations on your nomination and congratulations to your family too. This is a family affair and we are very grateful for their willingness to support you in this work.

As you know, New Hampshire has been ravaged by the fentanyl, heroin, and opioid crisis, and we are in need of real resources to help those on the front lines combat it.

HHS used a flawed funding formula to allocate resources from the 21st Century Cures Act. The hardest hit states, like New Hampshire, did not get adequate resources. Now, even though we have asked them to change the formula, HHS has declined to do that to update the formula for the second year of funding.

But another big problem is that the Trump administration has refused to request additional funding to fight the crisis, which has prompted many to question whether the President is truly serious about addressing it.

We need this administration to send a supplemental funding request to Congress for additional resources to combat the opioid addiction epidemic.

Mr. Azar, yes or no, if you are confirmed, will you commit to me today that you will encourage the Trump administration to ask Congress for at least \$45 billion in new supplemental funding to fight this crisis, a number that has had bipartisan support?

Mr. AZAR. Senator, again, thank you, and I am really glad we were able to have the discussion about this terrible opioid crisis, and the impact in New Hampshire.

I do not know the number, but what I will commit to you is if I am confirmed, I am going to work across the Government to assess, "Do we have the resources we need?"

If I do not believe we have the resources we need to address the problem, work with the President and the Congress to do that.

Senator HASSAN. I will tell you that I do not know a Governor of either political party who believes we have the resources we need. I do not know anybody on the front lines of this crisis who thinks we have the resources we need.

Will you also commit to examining all substance misuse funding sources and formulas, and directing, wherever possible under your authority, more funds for the states hardest hit by the crisis?

Mr. AZAR. I do not know the precise issues around that formula, how much is in statute and how much of it is discretionary, but absolutely.

I know your concern about the money going to New Hampshire. I certainly, if I am confirmed, will work with you to look at that, and see what flexibilities there are, and do we think it is the right approach.

Senator HASSAN. The issue here is that the money has been formulated, been distributed, basically, on population as opposed to the overdose death rate per capita, in particular states.

Let us move on to another issue.

The drug company Allergan has recently engaged in unacceptable behavior to shield the patents of its dry eye drug Restasis from review in order to prevent generic products from entering the market, and denying consumers more affordable alternatives.

In September, Allergan announced it had paid a Native American tribe to take ownership of the patents. Then Allergan licensed the patents back from the tribe continuing to sell the drug as usual, exploiting the doctrine of tribal sovereign immunity to protect its profits.

Allergan is renting the tribe's tribal sovereign immunity in order to protect its profits. The move ultimately is meant to stop generic versions of Restasis from coming to the market, which would be cheaper for patients.

This outrageous, first of its kind deal was called a ploy, recently by a Federal district court judge. I would like to know what you think about this deal.

Yes or no, should drug companies like Allergan be allowed to rent out tribal sovereign immunity in order to shield their patents from review?

Mr. AZAR. I do not know, as Secretary, if I would have any actual enforcement issue, so I do want to be careful—

Senator HASSAN. Yes, I understand that.

Mr. AZAR—about any particular situation.

Senator HASSAN. Right.

Mr. AZAR. But I would say I would share your concern about any type of abuse around extensions of patent or protecting from whatever legitimate processes there are for evaluating validity of patents.

Senator HASSAN. Well, I appreciate that. If you are confirmed, I hope you will work with me, and others, on this issue understanding that there are multiple agencies that have some jurisdiction here.

I wanted to touch on another issue. As the country recently learned of the case of Jane Doe, a 17-year-old young woman, who was forced to continue her pregnancy against her will for over a month while in the custody of a shelter that contracts with HHS overseeing unaccompanied minors.

Jane Doe was eventually able to receive the abortion that she decided was necessary for her and that a court confirmed was necessary for her. But because of this case, it has come to light that

the director of the HHS office, Scott Lloyd, used very disturbing tactics to block abortion access for the young women in these shelters.

He prevented minors seeking abortion care from meeting with attorneys. He suggested placing pregnant minors with sponsors who would override the minor's choice about her pregnancy rather than placing her with family members. He personally visited pregnant minors to pressure them to continue their pregnancies.

Political appointees in Washington, DC at HHS should not be imposing their own ideology on these young women, nor should they be coercing them or shaming them for their choices.

If confirmed as Secretary, do you agree that you have an obligation to follow the Constitution and all the laws of the United States, even those you may not personally agree with?

Mr. AZAR. I am lawyer and I take the obligation to follow the laws and the Constitution, as interpreted by the courts, as a solemn obligation. Absolutely.

Senator HASSAN. Well, I am glad to hear that.

The CHAIRMAN. Thank you.

Senator HASSAN. I know I am running over, and I will follow-up on the discussion with you.

Thank you.

Mr. AZAR. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Cassidy.

Senator CASSIDY. Mr. Azar, nice to see you. Enjoyed our conversation yesterday. Thank you.

I am a physician. I worked in the public hospital system of Louisiana taking care of the uninsured and the poorly insured, which is to say, Medicaid patients.

Now, there is a lot of data out there that patients covered through Medicaid oftentimes have worse outcomes than those who are covered through other forms of insurance, even when correcting for disease burden and socioeconomic factors.

Clearly, we should have a bipartisan interest in having outcomes data that shows who is doing a good job and who is not. If someone is doing a good job, reward it; and if they are not, figure out why, and try to improve it.

Fair statement?

Mr. AZAR. I could not agree more.

Senator CASSIDY. Any thoughts about the datasets that are currently available?

I am told that for Medicaid and CHIP, right now, there is, in theory, a structure for this outcomes data to be accumulated and compared, but in practice, it is not.

Thoughts on that?

Mr. AZAR. I do not know the dataset, Senator, but if confirmed, I will gladly look into that because I do agree.

We ought to always be evaluating our programs to see what works, what does not work. Are there certain programs that work better than others? Because our goal is that people have affordable care. They have access to care and if one approach is better than the other in delivering quality for that, we ought to be using any data we have to find that.

Senator CASSIDY. Now yesterday, you were open and meeting informally with Senators from both sides to go over certain issues.

I would just ask, at some point, because our Ranking Member and Chair have been very good about convening that, what can we do as a Federal Government to have better datasets so that patient outcomes can be monitored? Because it is an old maxim of healthcare, if you do not measure it, it does not improve.

Mr. AZAR. Yes.

Senator CASSIDY. I think we need to measure that.

Mr. AZAR. Yes. Senator, I appreciate your invitation, in the event that I am confirmed, to any kind of convened, bipartisan process to work through these difficult issues.

If I am confirmed, I hope what you will find is that my style is one where I do not believe I have the answer to every problem. These are complex and vexing issues, and I want to have an open dialog, back and forth.

I am a problem solver. My brand is that if there is a program that is not working, if it can be made better, I want to work on solving that problem. I want to get the best input and the best ideas from the directors, everyone here.

Senator CASSIDY. Well, from our perspective, if there is something you can do administratively, we do not have to mess with it. But if there is something that you need legislatively, then we should devote our attention and that would be the purpose of this.

Mr. AZAR. But I would also appreciate the ideas. If there are ideas about what can be done administratively, I want those. I would want those ideas also, if confirmed.

Senator CASSIDY. Then let me have some ideas from you right now.

Public health, there has been a problem. I was working with Senator Schatz and some others as regards how to have a public health fund so if we get another Zika, it does not take special appropriation, just to give you my thoughts on that.

I compare it to under Katrina, Congress had to come in and appropriate money for FEMA to go and respond to Katrina. Now, we have figured out no, or before I came in, they figured out, "No. Let us just put the money up front so that it can get immediately drawn down."

From my perspective, we should be doing that for public health as well.

But what thoughts do you have as regards how we can help you better respond to public health emergencies?

Mr. AZAR. Well, I was actually, back in the Bush administration, one of the architects around Project Bioshield.

I really see, in preparing for public health emergency and response, the benefit of having predictable funding and the ability for the Government to be a reliable partner in that development process.

I would be very happy to work with you. Obviously, I cannot speak for the administration, but I personally.

Senator CASSIDY. How do you safeguard from the money being frittered away on things which are not public health emergencies or being used as a slush fund to cover shortages elsewhere?

Mr. AZAR. One would have to draw the lines very clear.

I would share that concern. You would need to make sure it is really built-in to a development or response program for public health. Public health emergencies like a Zika, like an Ebola, or frankly as we have with the countermeasures development programs.

Senator CASSIDY. Now, let me also say, and this may just be something that I encourage that you monitor.

Sheldon Whitehouse and I always have to say “Sheldon.” If I say “Whitehouse,” they think 1300 Pennsylvania Avenue—so Sheldon Whitehouse and I in the 21st Century Cures Bill put forward something for Health IT.

My physician colleagues just are retiring at age 55 because they are just sick of electronic medical records and the dampening that has been upon their ability to interact, as well as their productivity.

In the 21st Century Cures, the Health IT act was included that gave some directives. Supposedly, it is progressing well. But nonetheless trust, but verify.

Any thoughts about that and how we can ensure that Health IT actually becomes an enabler of patient-physician relationships, as opposed to an impediment?

Mr. AZAR. I need to be careful here because my father, Dr. Alex Azar, may jump to the table here and start telling you about all the problems, exactly the problems you are talking about.

Senator CASSIDY. I am with you, brother.

Mr. AZAR. I think that when Secretary Leavitt was Secretary and we went down. He started the journey on health IT. He was adamant. Electrification of health records without interoperability is not useful. That is just moving files to a different place.

I am afraid we have done a bit of that where we have electrified our record systems, but we have not gotten interoperability. We have made it too complex at the point of entry with the doctor.

I would love to work with this Committee and I certainly, if I am confirmed, will work within HHS to drive toward interoperability in reducing physician burden because it should be an enabler, not something that detracts. The doctor’s eyes should be on the patient, not on the computer screen.

Senator CASSIDY. Fantastic. Amen, brother.

I yield back.

The CHAIRMAN. During our 21st Century Cures, we veered off to the side and held six hearings on Electronic Medical Records. All of us are interested in it. We made some progress with the last Administration.

We might set up, I will talk to Senator Murray about a roundtable, a less formal way that is bipartisan to try to continue that focus over the next couple of years.

Senator Baldwin.

Senator BALDWIN. Thank you.

Thank you, Mr. Azar. There has been a lot of discussion about experience, insights, as well as potential for conflicts already in this hearing today.

Obviously, experience and insights can be extraordinarily helpful, but we have heard from the President that he wanted to drain

the swamp. We have heard phrases like “foxes guarding the henhouse,” and the “revolving door.”

Noting that, the perspective that you would bring, having served in a large pharmaceutical corporation in a leadership post, brings a very specific perspective, especially as we tackle one of the critical problems of our day, the high cost of prescription drugs, oftentimes lifesaving and life extending medicines for our constituents.

We had a hearing recently in this Committee on drug prices, and I felt that there was a lot of finger pointing from the folks who were at it, talking about whether they were from the perspective of Big Pharma, or Pharmaceutical Benefit Managers, or all of the other players in this system and citing complexities. Citing, “It is their fault, not ours.”

But because of your background in the pharmaceutical industry, I would like to not hear finger pointing, but what can be done.

I have many constituents who share their very personal stories about their challenges with the increasing and skyrocketing costs of, again, lifesaving or life extending medications.

Greg from Stoddard, Wisconsin has two adult sons, both with Type 1 diabetes, and they are now expending over \$1,000 a month just to maintain insulin and test strips.

When you were President of Eli Lilly, you were there during a time that there were really radical increases in insulin prices. It increased more than 1,000 percent since 1996 and over 200 percent during your tenure.

Can you tell us—and more specifically Greg and his two sons with Type 1 diabetes—why Eli Lilly and other companies are systematically increasing the list prices of drugs that are already on the market?

Mr. AZAR. Senator Baldwin, thank you for that question and also thank you. I really enjoyed our discussion the other day on this and other issues.

First on the finger pointing, I have actually been really clear even when I was at Lilly on this issue of drug pricing. Finger pointing is not a constructive enterprise.

Everybody owns a piece of this. Everybody in the system owns a piece of this, and I think the Government owns a piece of this. That is why I want to serve because I think that the skill, the experience that I bring can help me with the Government on drug changes. One company cannot actually necessarily impact.

Senator BALDWIN. Right. I appreciate that.

Mr. AZAR. Yes.

Senator BALDWIN. But my question specifically is what would you tell Greg and other constituents about Eli Lilly’s role?

Mr. AZAR. Yes. The insulin prices have been significant, as increases have been significant for all drug prices pretty much. The problem is that system. This system makes it so that Greg and his kids—

Senator BALDWIN. The system. I should just tell them it is the system?

Mr. AZAR. The system has to get fixed. That is the problem. That is the problem.

Senator BALDWIN. What about the drug manufacturers—

Mr. AZAR. Yes.

Senator BALDWIN—are the starting point.

Mr. AZAR. The prices.

Senator BALDWIN. They set the list price.

Mr. AZAR. Yes.

Senator BALDWIN. What should I tell Greg about the 200 percent increase during the time you were there in the price of insulin?

Mr. AZAR. Is that what we need to do is work to fix. That Greg and his kids have insurance that covers that insulin. They have low out of pockets. So that the drug companies—

So that we have got to get the list prices down also. We need to come up with, they have gone up.

Senator BALDWIN. That starts with the drug manufacturers.

Mr. AZAR. It does. You are correct.

Senator BALDWIN. This feels reminiscent of the hearing we just had. It is a complicated system and it is this and that.

It starts with the manufacturers setting the list price.

Now, we talked, and I see I am already hitting my time, and I had lots of questions. Maybe we will have a second round.

But you have talked about generic and branded competition. You have talked about citing the gaming of the patent system and exclusivity. There was a bit of Q and A about re-importation.

The two things I wanted to talk about, should we get a second round—or I may submit written questions—is the role of transparency and getting the pharmaceutical companies to justify their increases in price. I have a bill, along with Senator McCain, to require that for companies planning on increasing their prices.

Second, the role of negotiation, somebody in your role, directly with the pharmaceutical manufacturers.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Isakson.

Senator ISAKSON. Thank you, Chairman Alexander.

Welcome. Glad to have you. I look forward to our meeting tomorrow. I am glad we did not have our meeting before this and ask you questions. I might have been talked out of asking you had you met with me before.

But having listened to your testimony, having heard Ms. Warren over the years, having been part of the re-importation debate over the years, being a Senator and advised a lot of pharmaceuticals myself, the cost of pharmaceuticals, the pricing of pharmaceuticals, the gaming of the system, as you referred to it in your remarks, is a huge issue.

I would like to give you, at the risk of being presumptuous, give you a homework assignment that I hope Chairman Alexander and Senator Murray will back me up on.

Will you come back to us in 6 months with your recommendations on what you are going to do to help end the gaming of the system in terms of pharmaceuticals?

Mr. AZAR. Absolutely.

Senator ISAKSON. I think you are uniquely qualified having been a CEO of a major pharmaceutical company, knowing what you know, and taking on the responsibility you are about to take on, to forthrightly come to us and say, “These are the things that are being abused,” by either the pharmaceutical companies, or manu-

facturers, or physicians, or whoever it is. I am not interested in blame.

Mr. AZAR. Yes.

Senator ISAKSON. I am interested in solutions.

Let us try and end the gaming of the system because oftentimes these debates and responses to the questions we ask end up obfuscating solutions that otherwise might be talked up because we do not do that. I would appreciate it.

Would you be willing to do that?

Mr. AZAR. I would look forward to the opportunity.

Senator ISAKSON. Second, to return the favor. I live in Atlanta, Georgia. I represent the State of Georgia in the U.S. Senate and I have been a representative for 20 years in the Congress of the United States.

It is the home of CDC, which is the world's health center, which got very little notoriety but, in fact, solved the Ebola problem when it contained an outbreak and ended its spread; the same thing with Zika. They did it in partnership with four institutions around the country that had built isolation chambers; Emory University in Atlanta being one of them.

We were able to get the people under care, isolate them, treat them. They, by the way, all four of them went to Emory, survived an Ebola infection.

That type of partnership is what we are going to have to do for the avian flu at some time in the future and many other things.

I want your commitment that you will continue to advocate for CDC, and its funding, and its ability to meet the challenges of the 21st century that we do not yet know what they are. But we know the solution will lie in our ability to be prepared when they come.

Mr. AZAR. Senator, the CDC, and its leadership, and its career staff are the envy of the world, and I share that view.

Senator ISAKSON. They have saved a lot of lives.

Mr. AZAR. Amen.

Senator ISAKSON. Prevented so many tragedies from happening that it is just unbelievable—

Mr. AZAR. They have indeed.

Senator ISAKSON—what they have done.

Last, this may seem to be a silly question. I was a salesman all my life. I was on commission income all my life.

The Medical Loss Ratio in the Affordable Care Act includes the cost of a sales commission as a part of the Medical Loss Ratio formula. Which, in effect, put most people who sold health insurance to individuals who bought in the spot market out of business because the commission they would be paid, although very modest, would throw it over the 85 percent cost ratio. Therefore, they did not do it.

Most Americans today, who would buy in the spot market or go look to try and find a way to get insurance, there is no financial insurance for anybody and no financial security for anybody to offer it to them because they are priced out because of the Medical Loss Ratios, the formula.

Senator Coons from Delaware, a Democrat and I, have introduced legislation 3 years in a row to end that by taking it out of

the calculation for Medical Loss Ratio which, I think, will expand the access and exposure to citizens who need healthcare can get it.

Would you help us with that to see if we can get that through?

Mr. AZAR. Senator, I would be very happy to work with you in looking at that.

It is an issue I had not really focused on so I am glad you have educated me today on that. I had not known of that concern before.

Senator ISAKSON. We will use some of our time tomorrow to do that.

Mr. AZAR. Thank you.

Senator ISAKSON. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Franken.

Senator FRANKEN. Thank you, Mr. Chairman.

Congratulations on your nomination, Mr. Azar.

I would like to ask you a few short yes or no questions, if that is Okay.

Mr. Azar, are you aware that the ACA required health plans to cover evidence-based preventive health services free of charge? Right?

Mr. AZAR. Yes, there is a provision in there that requires. I think HRSA determines preventive services and then those are part of the Essential Health Benefits in the ACA, if I understand the framework correctly.

Senator FRANKEN. Are you aware that HHS commissioned the Institute of Medicine—an independent, nonpartisan organization of highly respected experts on health and medicine—to review what preventative services are necessary for women’s health and well-being? Then on that basis, the Institute of Medicine recommended coverage for all FDA approved birth control methods free of charge?

Mr. AZAR. I believe that is the case. Yes.

Senator FRANKEN. Do you agree with the Institute of Medicine’s conclusion that access to free birth control is vital to women’s health and well-being?

Mr. AZAR. Senator, separate from the issue of any birth control, or which ones should be covered, one of the principles that we have around thinking about the access to insurance is that all of the insurance that the individual wants to acquire and the level of coverage that they want.

If I have concerns, my concerns are actually at a much more precedent level. Not about this coverage for this drug, that product, this one or the other, but rather should there be flexibility for the individual to choose the type of insurance package they want.

No animus toward any particular type of preventative service. It is more that there ought to be, our system ought to enable flexibility in there that does not exist with the current framework.

Senator FRANKEN. But you agree the Institute of Medicine’s conclusion to that free birth control is vital to women’s health and well-being.

Mr. AZAR. I could not speak. I have not studied the IOM report. Obviously, we at HHS have very important programs through Title X and otherwise to provide family planning assistance and services.

Senator FRANKEN. But do you agree with the Institute of Medicine's conclusion that access to contraception free of charge reduces unintended pregnancy, which in turn reduces frequency of abortions?

Mr. AZAR. I have not studied it. It seems to make some sense as you state it.

Senator FRANKEN. Okay. Do you agree with the Institute of Medicine's conclusion, and this is their conclusion, that reducing unintended pregnancy also reduces the health risks associated with such pregnancies? That contraception helps women to increase the length of time between births, which reduces maternal mortality and pregnancy related complications?

Mr. AZAR. I think we all share the goal that unintended pregnancies, especially by teens, is something we want to work to prevent, and we want to work to educate, and we want to use our programs to support that.

Senator FRANKEN. In light of this, do you agree with the Trump administration's actions to undermine the access to birth control?

Mr. AZAR. On that issue, that is a balance between the Essential Health Benefit and the conscience of the organizations involved.

As I mentioned earlier, I think it was close to only 200 organizations. Whereas the actual Obamacare, the Affordable Care Act implementation there around the contraception mandate actually even excluded tens of millions of people who were in grandfathered plans. This conscience exception has a much smaller impact, I believe.

Senator FRANKEN. I just want to focus here on the science. The law requires the preventive services be evidence-based and this is evidence-based.

Will you take steps as HHS Secretary to make sure that women have free access to contraception?

Mr. AZAR. I will follow the law there, if the law requires the coverage, and if the evidence, and the science, and the facts support that.

Senator FRANKEN. You will?

Mr. AZAR. Then we will follow the law there. But I also will, as the President has done, and try to balance the conscience objections of organizations and individuals there.

Senator FRANKEN. A number of my colleagues have expressed concerns regarding your track record and Eli Lilly's track record on drug pricing. I just want to tell you, I share their concerns especially in regard to Eli Lilly's actions to spike insulin prices.

But I wanted to move. I am running out of time, so I am not going to be able to, but I wanted to get into Medicare drug price negotiation. The President has said he is for Medicare being able to negotiate in Part D with the pharmaceutical companies on the price of drugs.

Do you agree with the President that Medicare should negotiate to lower drug prices?

Mr. AZAR. The President has generally spoken about the desire to ensure that Medicare is negotiating and getting the best deal possible for drugs.

Part D actually has negotiations through the three or four biggest Pharmacy Benefit Managers that negotiate and actually se-

cures the best net pricing of any players in the commercial system. I sat on the other side of that. I can assure you of this.

What I would like to do is think about, how can we take the learnings from Part D, maybe into Part B? Part B does not have negotiation. Part B is the program where when a physician administers a drug, like an oncolytic, an M.S. drug, some of them are quite expensive. The Government simply pays the sales price plus 6 percent.

How could we think about ways to take the learnings from Part D and actually bring lower cost to the system, but also lower cost to the patient because they pay a share of whatever Medicare reimburses in Part B. That is a double win. It could lower for the system and lower for the patient on their out of pocket.

That is the kind of thing I would have energy to see where we could actually really save money and improve things for our patients.

Senator FRANKEN. I am out of time, but I would just note that the V.A. is able to negotiate for prices for their drugs and I think that in Medicare Part D, we should be able to do the same thing they do in the V.A.

The CHAIRMAN. Thank you, Senator Franken.

Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman.

Mr. Azar, Alex, thank you for coming. Congratulations on your nomination, and thank you for being here today. It has already been stressed by Governor Leavitt and my colleague and fellow Marine, Captain Young, Senator Young, about your prior work at the Department of Health and Human Services, as well as the confidence in you shown by the Senate.

[Cell phone.]

Senator ROBERTS. Sometimes we have to multitask here. I apologize for that.

But at any rate, the confidence in you shown by the Senate to unanimously confirm you to positions at the agency twice already and highlight the strength of your qualifications.

I appreciate the chance we had to chat. I think it was Monday on some particular areas of interest for me, improving our rural healthcare delivery system, as well as continuing to ensure a safe food supply, and basing nutrition policy on sound science.

You are a Hoosier, but you did find a Kansas girl to marry. As the folks in Overland Park, Kansas know, there is nothing greater than a Shawnee Mission South Raider. I wanted to make sure that you understood that. Thank you for bringing your family.

As both a Member of the HELP Committee and Chairman of the Agriculture Committee, I am also a Member on the Finance Committee, so we will get another opportunity to talk, I am particularly interested in HHS, and more importantly, the FDA's work on food and nutrition policy. We talked about that. A common message I hear is the need for regulatory certainty.

Just a moment. I beg your pardon. Will you turn that off? Thank you.

[Laughter.]

Senator ROBERTS. More importantly, FDA's work on food and nutrition policy. A common message I hear is the need for regulatory

certainty in particular on the biotech front, which is a critical tool for agriculture today.

Back in January, both FDA and the USDA proposed rules and guidance on biotechnology. Recently, at a recent stakeholder comments, the USDA's Animal, Plant and Health Inspections Service, that is APHIS, has decided to withdraw the proposed rule, re-engage stakeholders, and solicit comments to create a new rule.

If confirmed, what steps would you take to engage and coordinate with other agencies involved with the regulatory review of biotech products to harmonize future rulemaking efforts?

Mr. AZAR. Senator, I am not familiar on that particular rule-making with the pullback from APHIS, but I can assure you that I would share both goals that, I think, you have articulated.

The first is, it is the job of the Government when regulating to give clarity. So many enterprises, they want to comply. They want to know the rules of the road. Can we give clarity?

The second is, especially in the area of food safety, the level of coordination between HHS and the Agriculture Department is absolutely essential. It has to be a great partnership. They have to work together in this space because of the shared jurisdictions there.

I would commit to you to be an excellent partner along with, I am sure, Dr. Gottlieb in working with that.

Senator ROBERTS. I appreciate that very much. I would just want to make, I want to make one other observation, Mr. Chairman.

I have been watching your children, and I have been watching these youngsters over here, and I have been watching your dad. Your dad is very proud of you and your wife is, obviously, very proud of you.

I want to tell you young folks, welcome to "Poli Sci 101." It is a little tough. Politics is not beanbags. We are not playing politics here. We are asking questions that many members here have on their minds and they are very important questions.

I want you to be proud of your dad. He has done a good job in the past. He will do a good job in the future. He will be confirmed, in my view, and not only by this Committee, and not only by the Finance Committee, but also on the floor of the U.S. Senate, and then also by the President.

That is a long process and sometimes it gets a little tough. We ought to be handing out selective earmuffs for young people. They could put on earmuffs if it gets a little tough for you and then take them off.

Be proud of your father. He is a good man.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Roberts.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman.

Welcome, Mr. Azar.

I do not think there is much that you and I are going to accomplish today on the question of drug pricing.

But I hope, very much, that in office you will take the side of the American people and not just the pharmaceutical industry. Or worse yet, the investors who have raided the pharmaceutical industry, with no pharmaceutical background, with the sole mission to

jack up prices on necessary pharmaceuticals, and extract money with monopoly authority. We know how to deal with that ordinarily and I hope you will help us deal with that.

I want to talk about a different situation which, I think, is an opportunity for considerable bipartisan progress, and I want to start with two Rhode Island stories.

You know what a Medicare ACO is, I assume.

Mr. AZAR. I do.

Senator WHITEHOUSE. We have two Medicare ACO's in Rhode Island.

One is a very early one, Coastal Medical, which over 4 years has saved Medicare \$28 million relative to its benchmark, while maintaining a 99 percent quality score. That makes it one of the very best in the country. Its average per member per year expenditure is going down, while the satisfaction and health of its members are going up.

Similarly, Integra Community Care Network, it has been in less long, but over 2 years Integra has saved Medicare \$12 million relative to its benchmark while achieving a 95 percent quality score.

I say this, not just to brag on Rhode Island providers, but because I think it is the answer to a much larger question that we face, which is.

[Charts are shown.]

Senator WHITEHOUSE. Here is the graph of health expenditures, more or less, in my lifetime for the country; \$27 billion to \$3.2 trillion. It is a curve that is breaking the bank. We have got to figure out how to fix it.

One of the ways that we can look at fixing it is to look at this OECD

[Organization for Economic Cooperation] chart that I use all the time, which shows a lot of our competitor nations right here, and there is the U.S.A. It is a big outlier.

This maps life expectancy and this maps cost per capita. That puts us at the highest cost per capita for health insurance, for healthcare in the world, and gives us life expectancy comparable to the Czech Republic and Chile, well below other developed nations that compete with us.

We are actually beginning to see a little bit of—going to my third and final graph—we are actually beginning to see a little progress here. Let me explain what this is.

This top line, the red line, is what the CBO predicted for Federal healthcare expenditures back here when it made the prediction in 2010. Then events move forward, post-Affordable Care Act, and we got here. Sure enough, we were coming below.

Here in 2017, the baseline was rewritten by the CBO, re-predicted and the difference in this 10 year budget period, between what CBO predicted in 2010 and what it predicted in 2017 amounts to \$3.3 trillion in savings.

The case that I would make to you is that if we want to take on the healthcare cost problem, we have to take it on through entities like these ACO's because there is a sweet spot where we can bring that cost back from our outlier position in the United States, while improving the quality of care. I have seen it happen in Rhode Island.

The reason that the cost is going down for Coastal Medical patients is because they get home visits when they are sick.

Because there is telemedicine that gets their testing results in. Because a nurse will call them, when they do not hear from them.

Because somebody does a house check to make sure that there are not slippery rugs in the hallways that might cause a fall.

Over and over again, it is better, humane engagement that reaches the patient where they are, that has this wonderful twin benefit of improving health and the patient experience, while also bringing costs down.

We are not seeing less increase in the cost curve from Integra and from Coastal Medical. We are seeing cost per member going down.

Promise me that you will work with us on that. Promise me that you will not get ideological when it comes to solving this problem and that you will work to solve it in a sensible, bipartisan, thoughtful way.

Mr. AZAR. Senator, I would just say amen. Just hearing those stories is exciting to me.

It is, I think, one of the great legacies of Secretary Burwell's tenure was launching off so many of the alternative payment models that we have out there, and I would like to keep driving that forward. That was that third leg of my priorities, if I am confirmed as Secretary.

I think for those of us who care so deeply about improving quality, reducing costs in our healthcare system, improving integration, coordination. Just thinking about ways we can deliver better for our patients and our beneficiaries. There is just so much opportunity for bipartisanship here because we share so much of the same goals on this. Medicare plays such a role.

It is the only payer that sits there with enough concentration of lives to change the system.

Senator WHITEHOUSE. Correct.

Mr. AZAR. I think United Healthcare, as big as it is, I do not think there is a market, maybe, that has more than a couple of percent of patients and has to follow what Medicare does.

I would be so excited to work with you.

Senator WHITEHOUSE. Well, I am going to invite you to come to Rhode Island and see these.

Mr. AZAR. I would love to.

Senator WHITEHOUSE. They are really doing great.

Mr. AZAR. I would love to do so.

Senator WHITEHOUSE. I look forward to that visit.

Mr. AZAR. Thank you.

Senator WHITEHOUSE. Thank you, Chairman.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Casey.

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

The CHAIRMAN. Excuse me, I made a mistake.

Senator Murkowski is here and I failed to go to that side. If you will excuse me.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. I apologize.

Senator MURKOWSKI. I know I am at the end of the dais and came in later, but there is added benefit to being one of the later ones and having the full opportunity to, not only hear most of your opening comments, sir, but to hear the questions, and the inquiries, and your responses back.

Again, congratulations on your nomination.

I will also be curious to hear your response to Senator Paul's inquiry regarding importation of drugs. I think, certainly for those of us in Alaska, where our neighboring country, our neighboring state, if you will, is Canada. Many in my state wonder why we are not able to do more when it comes to safely importing.

I, too, am curious to know what you might propose in that area.

Senator Baldwin mentioned the hearing that we had some weeks ago about drug pricing and, I think, a general level of just confusion and bemusement that many of us had. Those who were here to provide testimony were engaged in a fair amount of finger pointing.

When you try to drill down to how we can do more when it comes from a transparency perspective, I think this is something that we all recognize that we can do a better job with. Again, I look forward to a more detailed response from you.

We are going to have an opportunity to meet tomorrow. I will probably hold more of my Alaska-specific questions for that time.

But one of the other discussions that we have had in this Committee recently, as we have been discussing the ACA and some of the requirements within it, we had recommendations from some who have suggested that the Navigator Program that is currently in place, no longer needs to be funded. The President really axed it not too many months ago.

It was pointed out that not all parts of America are equally situated. We do not have a drugstore on every corner in Alaska. In most of my communities, we do not have a drugstore. The role that the Navigators have played in helping to walk many Alaskans through the intricacies of insurance, and what is available, has been important to us.

Nobody has really asked that question here today, so I would ask for your views, your plans.

What do you see the role of Navigators moving forward? How can you provide assurances that, again, in areas where we simply do not have the professionals that could assist individuals, that they know what their options are?

Mr. AZAR. Senator, thank you.

It is good to see you again. I think the last time was in Anchorage that I got to see you when I was serving as Deputy Secretary, and I look forward to discussing Alaska issues with you when we meet. I doubt there will be a secretarial nominee who has spent as much time in Alaska as I have.

Senator MURKOWSKI. Which we look forward to that because, I think, you recognize that there are some unique aspects.

Mr. AZAR. There is, indeed.

Senator MURKOWSKI. Your focus on behavioral health with Native peoples—

Mr. AZAR. Yes.

Senator MURKOWSKI—is something that I am interested in exploring some more.

Mr. AZAR. Absolutely.

In terms of the Navigator Program and just outreach, my views, as it is with so much of programs, is what works, do what works. I am not at the Department, so I do not have the data. I have not seen everything.

My understanding about the changes in the Navigator Program were focused on Navigator Program elements that were not working in renewing and funding Navigators that were able to demonstrate results in doing the work. I do not know the specifics about the Alaska situation.

I can only tell you that I do genuinely “get it” in the sense of understanding the uniqueness of the very frontier nature of so much of Alaska, and would be very happy to work with you on that, if I am confirmed, to see what are the ways that we deal with it.

But for me, it is really just what works. What is effective? What works? What delivers for the program?

Senator MURKOWSKI. I think I said pharmacies, and it is not only pharmacies.

Mr. AZAR. Yes.

Senator MURKOWSKI. But it also those who help us navigate through the insurance side.

Mr. AZAR. Right.

Senator MURKOWSKI. We do not have insurance companies on every corner as well. I will look forward to discussion on that.

Very quickly, there has been a lot of focus also on women’s healthcare, preventive care, eliminating the risk of unwanted pregnancies. I happen to believe that the more we can make contraception available and affordable to women, the better off we are.

I have long wondered why we are still these many, many, many decades after prescription birth control was made readily available, why we have been so reluctant to move to over the counter products for birth control. It not only makes the product more expensive as we continue to see. It is just kind of a flat amount out there, but you also have the requirement for a medical appointment in order to get that prescription.

Do you see a way or an opportunity for us to reduce the barriers for more affordable birth control pills, contraception, and in a way that can really help women in gaining greater access to contraception?

Mr. AZAR. The over the counter regulatory regime, as you know, is this OTC monograph procedure that Commissioner Gottlieb, I am very glad, has said was probably out of date in the 1970’s and needs updating, needs a lot of work. whether legislatively, or at FDA, to really speed the approval of products for over the counter for the reasons you said in terms of cost, available, cost to the system, et cetera.

Of course, there are standards. There are scientific and legal standards that have to be met by the sponsors of a product in terms of the ability, if I remember correctly, usually the ability to self-diagnose, self-treat. There are user studies that basically need to be conducted. It would be driven by that, would be my view on any product that the FDA would have to decide on.

But I think the regulatory system really needs a close look at and I would be delighted to work with Commissioner Gottlieb on how we just generally think about over the counter and improving availability of OTC products for people.

The CHAIRMAN. Thank you.

Senator MURKOWSKI. Well, I would encourage you and we will have an opportunity to continue our conversation.

Mr. AZAR. Yes.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murkowski.

Now, Senator Casey.

Senator CASEY. Thank you, Mr. Chairman.

Mr. Azar, good to be with you. We had some opportunity to talk in my office yesterday. I am grateful for that. Grateful for your willingness to put yourself forward again for this work that is difficult.

I want to especially thank your family and your extended family for their commitment. Often as much as public officials work hard, their families often sacrifice more. I appreciate that commitment your family has made.

You and I have a home state in common in terms of where we were born, not where we were raised, but I know you are a Johnstown native. I am a Scranton native and still live there, but we have a lot of disagreements on public policy issues, especially around healthcare, and I will get to those.

But I want to start with something fundamental and I wish we did not have to start here. But because of the interaction between Dr. Price, Secretary Price and this Committee, I have to ask this question.

When Dr. Price came before this Committee prior to his confirmation, Members of this Committee submitted a number of questions to him to answer on the record in writing and he did not provide a lot of responses. I am going to be very precise in this question.

Do you commit to provide answers to all—operative word “all”—all the questions you receive following appearances before this Committee?

Mr. AZAR. I will certainly be happy to comply with the Senate’s nomination procedures in the nomination setting and then, of course, in ongoing appearances before the Committee with the protocols and procedures of the Committees in the Senate.

Senator CASEY. But do you agree that answering questions for the record posed by Committee Members during the nomination process is part of that compliance?

Mr. AZAR. Senator, what I do not know is just what the protocols are between the HELP Committee and the Finance Committee there in terms of questions for the record. I just apologize. I am just not familiar with the customs.

When I was, as General Counsel and as a Deputy Secretary nominee, the hearing before the HELP Committee did not occur there. I am just not knowledgeable.

I would be happy to get back to you on that question. I do not know the protocols. I am sorry.

Senator CASEY. Well, I will take that as a tentative yes for now, but I hope you would familiarize yourself with those rules and then respond accordingly.

We should not have to engage in a back and forth on basic questions for the record.

I wanted to ask you about, in light of the debate on healthcare, the substantial debate that has been undertaken over the last number of months on the Affordable Care Act, and especially Medicaid, at least from my point of view, especially Medicaid. In addition to that debate, some of the statements you have made. I will not catalog the statements you have made that have been critical in one way or the other of the Affordable Care Act and commenting on the process.

Now, you are seeking appointment, a confirmation vote on HHS Secretary and that, of course, would confer on you responsibilities you do not currently have.

In light of that, and in light of the debate, and just to be very clear, I want to be very precise in asking this.

Do you commit to faithfully implementing the Affordable Care Act?

Mr. AZAR. If I am confirmed as Secretary, 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 in ways, and my hope would be to implement it in ways, if it remains.

I obviously believe, the Administration believes that statutory changes would be good and appropriate to replace that system.

But if it remains the law, my goal is to implement in a way that leads to affordable insurance, leads to choice of insurance, insurance that leads to real access not a meaningless insurance card, and insurance that has the benefits that people want, not what we say in D.C. for them.

Senator CASEY. Let me ask you as well about an issue that, frankly, does not get enough attention. It is the efforts that have been made by the Administration to undermine the Affordable Care Act. That is my view of it. I use the word "sabotage," and I think that is an appropriate description.

Let me define more specifically what I mean. When I say "sabotage" of the Affordable Care Act, I mean the following.

No. 1, drastically cutting funding for advertising and outreach activities.

No. 2, terminating cost sharing reduction payments.

No. 3, spending funds meant to promote enrollment on a P.R. campaign to, instead, undermine the law and support repeal of the ACA. Dollars should not be spent for that.

No. 4, spreading falsehoods and misinformation about the health of the marketplaces. It is one thing to be critical and concerned about it, it is another thing to spread falsehoods.

No. 5, working to rollback health insurance protections and undermine coverage.

That is the predicate for the question. Would you oppose those efforts knowing that you have a responsibility to faithfully implement the law? Would you oppose those efforts that I described broadly as sabotage? Yes or no.

Mr. AZAR. Well, I would disagree that there is any effort to sabotage the program. People want to make the program work.

The CSR's was a legal decision that Congress had not appropriated the money. Other elements, I can speak for myself about how I would approach.

Senator CASEY. How about cutting funding on advertising and outreach activities? Is that appropriate or inappropriate?

Mr. AZAR. The advertising cuts, actually, put the advertising for this program, now many years into it, at the level of Medicare Part D and Medicare Advantage.

At some point, these insurance companies have to do their own doggone job to fund their own advertising.

Senator CASEY. But are you asserting that the advertising dollars were not cut?

Mr. AZAR. No, they are cut. They were cut to the level now that, I believe, is comparable to Medicare Part D and Medicare Advantage annual advertising funding.

The CHAIRMAN. We are running out of time.

Mr. AZAR. I think these insurance companies should stand there on their own two feet.

Senator CASEY. We will have more time to engage in this.

Mr. AZAR. Okay.

Senator CASEY. Thank you very much.

The CHAIRMAN. Thank you, Senator Casey.

Senator Kaine.

Senator KAINE. Thank you.

Mr. Azar, good visiting with you yesterday. I have one question about each of your four goals, but before I do, I will tell you what I said to you yesterday.

What I am looking for from you is a commitment to the healthcare safety net broadly defined. I voted against your predecessor because he had commented negatively about Planned Parenthood, CHIP, Medicaid, Medicare, and the Affordable Care Act.

His brief tenure at the HHS proved that he was not kidding and I do not think we can have an HHS Secretary who does not support the healthcare safety net. That is what I am looking for from you.

Your first goal in your written testimony, you say drug prices are too high. As a Member of the Aging Committee, I kind of became convinced, Senator Collins was our leader, that there is a new model out there that is "patients as hostages". Patients who need drugs—who cannot afford to go without them, without risk to their life or health—are treated as hostages by pharmaceutical companies in some circumstances.

There was a story in the "Washington Post," "Why treating diabetes keeps getting more expensive," in October 2016, and this is a quote.

"According to the Washington Post's analysis of Truven Health Analytics's data, over the past two decades Eli Lilly and Novo Nordisk raised prices on their human insulin 450 percent above inflation, closely in sync."

Convince me that Eli Lilly's pricing activity on insulin was not part of this "patients as hostages" business model.

Mr. AZAR. Senator, as I said in my remarks in response to Chairman Alexander earlier today, insulin prices are high and they are

too high. This system that we have got, it may fit for the stakeholders behind the scenes, but for the patient that you are talking about, we have to recognize it is not working.

Senator Kaine. Do individual actors in the system have no culpability? Do the drug companies themselves have no culpability for this?

Mr. Azar. They are making the decisions. The choices are happening. I think everybody, everyone shares blame here. Everyone shares blame here throughout and we need, what we have got to do is I want to be a productive engine, if I can be Secretary, to work with you on solutions to fix that for the patient.

Senator Kaine. Let me ask you about your second goal.

“Second, we must make healthcare more affordable, more available, and more tailored to what individuals want and need in their care.” Amen, amen.

Then you have a sentence that is interesting. “We must address these challenges,” you cite 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.”

That is your only reference to the ACA in your testimony, and I think it was interesting that you talk about people who have been pushed out or left out of the market by the ACA. Of course you know that the uninsurance rate has dramatically reduced in the country following the passage of the Affordable Care Act.

I am not arguing that it is perfect, but if you just read your statement, it suggests that there are fewer people insured because of the ACA.

We had the Surgeon General, Dr. Adams, in here recently from Indiana, a Hoosier just like you. He said the uninsured rate in Indiana has gone dramatically down because of the Affordable Care Act because of the combination of Medicaid expansion and the availability of premiums to help folks afford.

In looking at this question, are you going to execute and be part of the wrecking crew? I do not think that is really an accurate or a really very fair statement.

Mr. Azar. Well, I am happy to explain. I believe we can do better.

Senator Kaine. I do too.

Mr. Azar. I believe both for the folks that are in the individual markets right now that too many of them are paying too much for insurance. Too many of them have insurance that is not really useful.

Senator Kaine. But was that your opinion before the Affordable Care Act passed?

Mr. Azar. I thought that would happen. I thought that would happen given how it was structured in statute, unfortunately.

Senator Kaine. Yes, but the numbers of people uninsured in this country were dramatically higher than they are now when you were at HHS in your first term.

Mr. Azar. I have always been, and I would want to work with you, our goals are the same in the sense that we want to improve access to affordable insurance. The President wants this. I want this. I think we may only differ about tactics and approaches.

Senator Kaine. Let me.

Mr. AZAR. My point was the forgotten man and woman who is not in that individual market because the insurance was not affordable for them.

Senator Kaine. Let me ask you.

Mr. AZAR. I want solutions for them.

Senator Kaine. "Third, we must harness the power of Medicare to shift the focus on our healthcare system from paying for procedures and sickness to paying for health and outcomes." Amen.

Why did you not mention Medicaid? I mean, Medicaid is a very important part of your portfolio, and I found it interesting, in reading that sentence, that you did not say a word about Medicaid, nor do you mention Medicaid at all in your entire testimony.

Mr. AZAR. The only reason I do not mention Medicaid in that context, Senator, is not a lack of any kind of commitment to Medicaid. It is really that Medicaid does not have the same kind of payment rules that Medicare has at the national level. That was my focus. It is not a lack of commitment.

Senator Kaine. Can I say this? I was a Governor, and I ran a Medicaid program, and am an ex-Governor.

Mr. AZAR. Yes.

Senator Kaine. But it is interesting, why would you not—

Would you not also agree that we can focus the paying for procedures and sickness, shift that focus to paying for health and outcomes? The Medicaid program can be part of that as well.

Correct?

Mr. AZAR. It certainly could. To Governors, if Governors are willing partners to try and drive that, absolutely. Medicare, as the Secretary, has more levers in his or her control to do that.

Senator Kaine. Would you try to do the same thing in Medicaid?

Mr. AZAR. Absolutely. Of course.

Senator Kaine. Okay.

Mr. AZAR. If we can make Medicaid better, it will let us serve more people.

Senator Kaine. Thank you.

The Chairman. Thank you, Senator Kaine.

Senator Murphy.

Senator Murphy. Thank you, Mr. Chairman.

Congratulations on your nomination, Mr. Azar. I enjoyed our conversation, and I was very open to your nomination.

I am very, very concerned about your answer to Senator Casey's series of questions, and so, I just want to state it to you one more time and give you a second chance here.

This Administration has shortened the open enrollment period by half. It has cut outreach funding by 90 percent. It has cut funding for Navigators by 40 percent. It has pulled out of state enrollment partnerships.

Is your testimony here today that this is all in service of an effort to make the ACA better? Do you really believe that the goal of this Administration is to help people sign up for the Affordable Care Act?

Mr. AZAR. Obviously, I am not in the Government. I do not have access to all of the data.

My understanding is, and I cannot validate this from the outside, was that the choices made were about what is working and what

is not working, and there is no sense funding any aspects of the program that are not working well. Also a policy decision around advertising that it is time for that to be regularized in its amount of funding around advertising.

Senator MURPHY. You think President Trump is taking these actions in the goal of making the Affordable Care Act work better?

Mr. AZAR. I do not know that President Trump was involved in those decisions. Those are probably decisions made at the HHS level or made as a matter of budgeting.

But I think the goal is with the program you have got, do as best you can. This one has a lot of problems in it. If the Alexander-Murray bipartisan package here helps, it is a good stopgap.

Senator MURPHY. But what has cutting the open enrollment period in half to do help?

Mr. AZAR. I do not know. I was not, again, involved nor did I study the comments on the enrollment period change.

But the enrollment period, my understanding, went from 90 days to 45 days which, I do not know about the Senate, but most of us have 45 day open enrollment periods for shorter, more efficient programs to allow for certainty of beneficiaries, and let the plans then know who is in their plan so they can plan predictably for the following year.

If you run right up to the end of the year there, it is harder for the plans to set their actuarial basis for the open enrollment period and the pricing. Then if you run that open enrollment period right up to the end there, I know this from when we launched Part D and Medicare Advantage that first year, the closer you run up to January 1 on that one, it is very hard to implement effectively and efficiently in the coming year.

Senator MURPHY. Yes, my understanding is that this is not the insurers begging for the open enrollment period to be cut in half.

Mr. AZAR. I do not know.

Senator MURPHY. Put that next to an evisceration of all of the programs that would help people understand the fact that the open enrollment period has been cut in half. Listen, I just think it is strange.

Mr. AZAR. I was not involved in that.

Senator MURPHY. Okay. You said that there are things that the HHS Secretary could be doing to make the open enrollment period work better.

What do you think that you could do in the face of these changes to make open enrollment work better, to make sure that people have the ability to choose wisely within the exchange? If you say that these are changes that are made in the service of making the open enrollment period better. What else are you thinking can be done?

Mr. AZAR. Just to clarify. I do not believe I said that these were changes to make it better, but rather to eliminate what, I think—

Again, I am on the outside. I am not sitting there at HHS looking at data, running the program. I do not know the status of thinking on each individual element there. My point is if something is not working, why are we funding it?

If the view was that the Navigator program, if certain of those vendors are not delivering, delivering one beneficiary enrolled and receiving a lot of money, say, why keep funding that? That would be my perspective in looking at it. Then using your resources to put it on whatever the most effective outreach and enrollment programs happen to be. That would be the approach I would follow.

I do not know. I am not there. I have not been involved. I have not been at HHS for the Affordable Care Act initiation or implementation. I just have not studied each of the individual programs there.

Senator MURPHY. Let me follow-up on some questions that Senator Warren was asking.

I agree with her. Experience in the private sector should not be disqualifying. What we want to make sure is that you are not simply bringing your advocacy on behalf of the industry you used to work for into Government.

Pharma has a number of major legislative priorities, faster FDA approval processes, continued prohibition of Medicare negotiating directly with drug companies, continued legalization of direct to consumer advertising.

I know you have been critical of specific practices of individual drug companies.

Is there any major issue on Pharma's legislative advocacy list that you disagree with?

Mr. AZAR. Well, Senator, if I get this job, my job is to enhance and protect the health and well-being of all Americans. It is not to—

Senator MURPHY. I get it.

Mr. AZAR—implement pharma's agenda.

Senator MURPHY. Just to give us an example of where you will oppose?

Mr. AZAR. I do not have pharma's policy agenda.

Senator MURPHY. But you worked?

Mr. AZAR. That is how little focus. I have been gone for a year. I do not know what their list of agenda items is, Senator.

Senator MURPHY. Okay.

Mr. AZAR. That is not my area of focus.

My area of focus is the President's agenda, and how I can work with this Congress to try to make the programs of HHS better in the interest of all Americans, and not the interest of any trade group. Not the interest of any company.

This is the most important job I will ever have in my lifetime and my commitment is to the American people, not to anywhere that I have worked in the past or any industry I have been connected to in the past.

Senator MURPHY. I thank you for that answer.

Thank you.

The CHAIRMAN. Thanks, Senator Murphy.

I think we have some Senators who want to ask additional questions, so we will have a second round.

Mr. Azar, let me begin.

Senator Cassidy asked, Senator Whitehouse would have, and others of us would too about Electronic Healthcare Records.

We can do some things about that in the Congress, but I think most of what needs to be done, you will have to do because it is a matter of administration. I had urged the previous Administration to delay Meaningful Use Stage 3 because it was implementing it at a time when it was also changing the way doctors and providers are paid.

I thought it would be wise to slow that down and get it right, and build confidence among the physicians and other providers about what we were trying to do. I said that based upon visits with hospitals like Vanderbilt University where they said Meaningful Use 1 was helpful, No. 2 was Okay, and No. 3 was terrifying.

We ended up with six different hearings and a lot of bipartisan interest in this.

One thing that seemed to me to make some difference would be pretty simple. There was an AMA study that showed that doctors believe they are spending 50 or 60 percent of their time on documentation.

It seemed to me that a good thing, a good approach for this would be—if that is true or not, at least that is the perception—might be for the Secretary to work with the doctors in Medicare. There are a half a million of them to say, “Okay. If you think you are spending that much time on documentation, either you are not doing your job right or we are not doing our job right. Why do we not work together and set a goal to bring that from 50 or 60 percent,” whichever it is, “Down to some other goal in the next three or 4 years,” and change the reality and the perception over time.

It would seem to me that some managerial technique like that is essential because the interoperability is one problem, excessive documentation is another. It is a big mess still.

I mean, if you are even at a sophisticated hospital, and you want to take your own medical records to some other place, the best thing you can do is Xerox them yourself, put them in your briefcase, carry them over, and hand them to the next doctor. Even in a sophisticated place, after we have spent \$30 or \$35 billion.

Can you make it a priority, and can you use some of this skillful managerial and executive experience background you had to help us improve, (A) interoperability, and (B) reduce excessive physician documentation both in reality and in perception?

What are your thoughts on that?

Mr. AZAR. I think in both of those areas that is a very sensible approach, Mr. Chairman.

Interoperability, again, it is ridiculous if we have a system now where you have to collect your paper records to go to a different facility. That is a betrayal of the vision Secretary Leavitt laid out originally when we started down that journey and we were working toward.

He would talk about the railway system and if you do not get a single gauge, it does not work and how in Australia, they never decided on a gauge. You have three different railway gauges to get around Australia now. My brother-in-law can tell you about that. That is where he is from.

We need to work on that and get that fixed.

On the regulatory burden, or just the burden on Electronic Health Records with physicians, that would be my style of how to

work is to the affected individuals. They know what is wrong. They know what is happening. Get the input from them to see if there are appropriate changes that can be made.

The CHAIRMAN. You might get your father to help you with that.

Mr. AZAR. He probably has some ideas.

The CHAIRMAN. Secretary Burwell actually changed something in her administration where she believed the reality was different than the perception.

It was the patient satisfaction survey that many of us were convinced was causing doctors and hospitals to prescribe more opioids in order to get a higher score on patient satisfaction. She was convinced that was not true, but it was true that people believed that. She persuaded President Obama to change the policy.

I do not know exactly the amount of time that physicians are spending on documentation, but they are really fed up with it. That, for a whole variety of reasons, which you understand well, we need to change that.

I would think some simple initiative working with physicians especially and hospitals to say, if it is 60 percent, and the perception is 60 percent, let us agree on a goal. Let us take it a step at a time. Let us take it to 50 percent. Or if it is 50, let us take it to 40. Or if it is 40, let us take it to 30 and let us all see what is being done about that.

We cannot do that well here. We can monitor it. We can encourage you. We can make some changes in the law, but basically it is an administrative challenge. It is one I hope you will take up, and then we will let the Senators here who are interested in that work with you in a way that would encourage that.

Senator Murray, do you have additional questions?

Senator MURRAY. I do.

Thank you, again. I am very concerned about some of the responses, particularly to Senator Casey and Senator Murphy, who talked to you about what many perceive as this President directly, and his direction to the administration of HHS, has been to make sure that ACA does not work.

The reason that we very adamantly support that is because many people are now getting access to care through insurance that did not get it before. Those are the harder to reach people, lower income, tougher populations. They end up, we all pay for them at the end of the day if they are not covered by insurance.

The goal is to have as many people as possible insured, have access, get their preventive care, and do not show up in emergency rooms costing everybody else, taxpayers and other folks, who own insurance.

Part of making sure, a critical part of making sure that they get access is through the outreach and through the longer enrollment.

Now, you answered a question about the open enrollment to make it in half had to do with the actuarials. The exact opposite is true. Insurance companies put their prices out. They have already figured that out. The open enrollment does not change their prices or their actuarial costs.

What it does is make sure that we have time for those harder to reach people to get enrolled and that they know what they are doing. They often have not bought insurance before or have dif-

ferent kinds of access problems. It takes time to reach them and to make sure they understand what they are buying.

That is the intent of the longer enrollment, which this Administration has cut in half and made it more difficult.

The second thing is the outreach and I was surprised to hear you answer Senator Casey by saying that insurance companies should pay for that outreach.

They have a very different goal here. They are not looking for the tougher, sicker, harder to reach, more rural folks to sign up. They have a very different goal. As a country, as other people who pay for insurance see our premiums go up, we have that goal and that is why it is so imperative.

In fact, in the Murray-Alexander Bill, which you have been asked about, we reinstate that outreach money for that exact purpose.

You will be HHS Secretary if you are confirmed. You will be responsible for making sure that outreach money is used, used effectively, and the enrollment period works so that we reach that.

Do I hear you that is not what you are going to do?

Mr. AZAR. Senator, I share your commitment. Any program HHS has, I want it to run as efficiently and effectively as possible and serve the beneficiaries of the program. That is my style. That is my commitment to you and how I would work.

Any particulars here. I am not there. I have not studied the particulars of why changes were made around the enrollment period. I simply offered an hypothesis around what might have been a reason around the cutting in half of that to the 45 days to a more normal enrollment period. Pricing before, and then implementation afterwards.

I did see that with Part D that when you bump up against January 1 just the insurance companies have to time getting people, the churn at the end of the year, getting them cards, getting them up and running.

Senator MURRAY. I have not seen that problem at all.

Mr. AZAR. Again, I do not know. Just Senator, I do want to be really clear. My style. I want the programs to work for people and I want to work with you if there are ideas to make them work, the programs to work. I want to make that happen.

Senator MURRAY. Do you share the goal of making sure as many people as possible, who may be sicker, who may be harder to reach, more rural, or communities that have not been reached before should be part of what we are working on?

Mr. AZAR. Of course, I do. I want to make sure that as many people have affordable insurance as possible. Absolutely.

Senator MURRAY. Who do you think is best equipped to do that, to reach them?

Mr. AZAR. Oh, so if the question that you would ask there around advertising. Advertising budgets, that money, my understanding is at the level of Part D and Medicare Advantage. That is my understanding. It is television. I do not think that is your rural outreach or your hard to reach.

That was just your television is my understanding on it, but I may be wrong. That was my understanding there. Not about trying to reach potential beneficiaries, get people enrolled into the pro-

gram. That and it may just be talking past each other on that issue or my misunderstanding the nature of that part of the program.

Senator MURRAY. Okay. Well, I am confused by your answer, I will just say that.

I want to ask one more quick question. I know my colleagues do as well and that is, will you advocate for women to be able to make their own healthcare decisions by supporting a broad safety net and ensuring all women are able to see a willing, able, and qualified provider of their choice?

Mr. AZAR. Senator, the Administration has, I believe, you are asking a question about a particular provider that would be at issue. The Administration has a perspective about whether that should be funded or not. That is a legislative choice.

If I am Secretary, I will implement what Congress has passed, and whatever Congress has passed and the laws that we have there faithfully.

Senator MURRAY. I am out of time, but that does concern me and I will turn it over to my colleagues.

The CHAIRMAN. Thank you, Senator Murray.

Senator Franken.

Senator FRANKEN. Thank you.

Mr. Azar, on Monday, the "L.A. Times" published an analysis of the Senate Republican Tax Plan, which repeals the individual mandate, or the Federal requirement that Americans have health insurance coverage.

The analysis shows that repealing this provision, quote, "Threatens to derail insurance markets in conservative, rural slots of the country and could lead consumers in these regions, including most or all of Alaska, Iowa, Missouri, Nebraska, Nevada, and Wyoming, as well as parts of many other states with either no options for coverage or health plans that are prohibitively expensive."

Mr. Azar, in your opening statement, you said that you want to make healthcare more affordable and available to individuals.

Given this new data, do you support repealing the individual mandate as part of the Republican Tax Plan knowing that it puts rural Americans' coverage in jeopardy?

Mr. AZAR. Senator Franken, what I do not support is forcing 6.7 million Americans to pay \$3 billion of penalties to not buy something they do not want to buy through a mandate upon them and 90 percent of whom make \$75,000 a year or less. That I do not support.

Senator FRANKEN. Well, I think you understand the structure of the ACA, which is that you guarantee that you are not discriminated against for having preexisting conditions.

Mr. AZAR. Yes.

Senator FRANKEN. Then if you are not discriminated against, because you have preexisting conditions, then the motive for someone to get care, to get insurance, buy insurance, we have to mandate it. This is my understanding of the logic behind this.

To mandate it, you have people do not wait until they get sick to get insurance, and that is just the way. Then you give subsidies to people who do not have the means to buy it. That is sort of the three-legged stool of this.

If the individual mandate is repealed, the Congressional Budget Office estimates that 13 million more people will be uninsured and that premiums will go up by 10 percent.

The Alexander-Murray deal—which I worked on those negotiations, and thank the Chairman and the Ranking Member for that—it is helpful, but it is a temporary measure that cannot offset these estimated price increases or coverage losses.

Given this and given that people living in rural areas tend to be older and have greater healthcare needs than average populations, what specifically will you do to make sure that people living in rural areas are not hurt by all these current efforts by the Trump administration to undermine the Affordable Care Act?

Mr. AZAR. As you articulate it, I think you articulate it well. The theory of the mandate was a mechanism to pool insurance risk to create an insurable risk pool for the insurance companies to be able to do their actuarial business. That was the theory.

The challenge was human behavior decided otherwise. Twenty-eight million people are not in that pool and it eroded the risk pool there.

What I would love to work with you and Congress on is coming up with systems that create effective risk pools so that we can insure them. That your rural citizens can actually have affordable care that gives them access, gives them choice, real choice. Half of our counties have one plan available to them.

Senator FRANKEN. Right.

Mr. AZAR. I worry about that.

Senator FRANKEN. The fact of the matter is that under the ACA, over 20 million people who were not insured have insurance. It feels to me that everything that this Administration has been doing is basically aimed at undermining the markets, and undermining the ACA, and undermining it so that we can throw away these gains.

But everything that is getting rid of the individual mandate, putting out plans, temporary plans, short term plans that will not cover that basic, the ten basic health guarantees. It just seems that this is a conscious effort to undermine the health of Americans.

I think that as we go forward, we have to find ways to make sure that people are not discriminated against because they have pre-existing conditions, and that we have the largest pools possible, and we spread the risk, and we make sure that people have, as many people have healthcare. If you repeal this, 13 million more people will be uninsured and premiums will rise.

Mr. AZAR. Senator, I think we share so many of the same goals, and just disagree about the approaches and tactics to get there. But my heart and my goals share so much of what you are talking about in terms of affordable care for people.

The CHAIRMAN. Thank you.

Senator FRANKEN. Thank you.

The CHAIRMAN. Thank you, Senator Franken.

We will continue with our second round of questions. We will conclude the hearing after the second round. I think there may be at least one other Senator who wants to come back.

We will go next to Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

I share the concerns that have been raised by a number of colleagues, that this Administration has spent the first 11 months of this year trying every trick in the book to destroy the health insurance system in this country.

Mr. Azar, you are being considered now for the top job to oversee key parts of the Affordable Care Act and Medicaid. I want to start by asking about a basic principle.

Mr. Azar, would you agree that it is important that we have a system that allows for every single American to have access to the kind of coverage they need?

Mr. AZAR. I think we all share the goal that we want all Americans to have access to affordable insurance that they desire.

Senator WARREN. So is that a yes?

Mr. AZAR. As I framed it, yes.

Senator WARREN. Okay, good. Here is the problem. Those are the exact words that Dr. Price used during his confirmation hearing before this Committee. He sat exactly where you are sitting right now and said exactly that.

He pretended that he cared about people being able to get their healthcare coverage, and then he got confirmed, and spent 8 months doing everything he could to take away people's healthcare coverage, and crash the healthcare system.

I think that is the reason we are trying to be very specific about what it is you will and will not do.

I want to follow-up on Senator Murphy and Senator Murray's question. They asked about shortening the time period for the enrollment and you said you wanted to be very data-driven about that, and you thought maybe there was a data reason for doing that. That is, that it was ineffective and that somehow that had not worked.

Let me ask the question this way.

Mr. Azar, if you are confirmed as HHS Secretary and there are no data showing that cutting the enrollment period improves enrollment, will you commit to going back to a 3-month long period for health insurance enrollment?

Mr. AZAR. My view would be that if the enrollment period does not make sense and work for the efficacy of the program, for the insurers that have to work in it, and for the beneficiaries, I would certainly be open to changing that back, if confirmed as Secretary.

I cannot commit. I am not in the Government. I cannot commit to Government action not having seen everything there.

Senator WARREN. But that is the question I am asking. You have used data as an excuse. You said, "I care about the facts. I want to be data-driven." You had a good exchange with Senator Alexander about the importance of data. I agree with that.

I am just asking. If there is no data to support your hypothesis that cutting the time period somehow might improve enrollments, will you commit to going back to the 3-month enrollment period?

Mr. AZAR. I would need to look at the data and if the data drives in that direction, then I am going to push to ensure that the program is effective, and if a long period is needed and effective. I do not know what counterbalancing factors there might be. I am not on the inside.

Senator WARREN. It is not all about data for you, then.

Mr. AZAR. There is data, but I do not know what the other elements, I have not seen the decision.

Senator WARREN. I will take that as a no.

Mr. AZAR. Okay.

Senator WARREN. Let me ask another question. When Secretary Price was in office, he supported Republican bills to repeal major portions of the Affordable Care Act.

If confirmed as Secretary, will you oppose such bills?

Mr. AZAR. Senator, I and this Administration support legislation that, various forms of legislation, that would have a system that leads to more affordable insurance, more choice, and more access. There has not been any support—

Senator WARREN. I asked a very—

Mr. AZAR—of getting rid of; it is a repeal and replace.

Senator WARREN. I asked a very specific question—

Mr. AZAR. Yes.

Senator WARREN—because I am trying to get this. This is what Price said when he was in here, so I am trying to get a very specific question.

Would you publicly oppose Republican bills to repeal the ACA like the ones we have seen so far this year? Are you saying we should just wait and see what you will do?

Mr. AZAR. I would work with this Congress and within the Administration to build a system that helps people get affordable insurance.

You and I will differ fundamentally, Senator, I guarantee you, on what the contours of a system—

Senator WARREN. You will not make a—

Mr. AZAR—that do that will lead to.

Senator WARREN—commitment to oppose those bills that we have heard so far? All right. Let me ask another one.

What about turning Medicaid into a block grant? Secretary Price pushed that idea while he was in office.

Would you do the same?

Mr. AZAR. I have actually said before that I think looking at block granting and empowering states to be fiscal stewards there can be an effective approach; the contours of that, the amount of funding, the size, what the baseline is.

Senator WARREN. Do you support block granting?

Mr. AZAR. I support it as a concept to look at. One needs to look at block granting as an abstract. The question is instead, what is the precise program? But the notion of a state being empowered to run a program and having all of the incentives to run an efficient program—

Senator WARREN. Mr. Azar, you could own up to the fact that you want to cut Medicaid and gut the Affordable Care Act like every other Member of the Trump administration, but you want to smile and pretend otherwise until you get the job.

Yet, you say exactly the same things that would let you pick up right where Tom Price left off in trying to gut the Affordable Care Act.

Tom Price lied through his confirmation hearing, and now you come in here, and say the same things he said.

No one should be fooled.

The CHAIRMAN. Thank you, Senator Warren.

Senator HASSAN.

Senator HASSAN. Thank you, Mr. Chair.

I wanted to pick up where we left off on the question about the case of Jane Doe, the young woman I asked you about. At the end of that question, you said that, yes, you agreed that you have an obligation to follow the Constitution and all of the laws of the United States, even if you do not personally agree with it.

Is that correct?

Mr. AZAR. That is correct. Yes.

Senator HASSAN. I am glad to hear that.

As you know, under the Supreme Court decisions in "*Roe v. Wade*," women have a constitutional right to make their own reproductive healthcare decisions.

Yes or no, will you commit to upholding those constitutional rights as well?

Mr. AZAR. I would always work to ensure implementation of the Constitution and laws as currently interpreted by the courts. Yes.

Senator HASSAN. Okay. Thank you. I am glad to hear that.

Now, I want to return to the issue of essential benefits for a second. You have said that you would make the opioid addiction crisis a priority if you are confirmed, and I appreciate that, but we need a lot more than lip service to make a dent in this epidemic.

One of the key tools to combat this crisis is the set of Ten Essential Health Benefits under the ACA requiring that insurance cover substance use disorders.

In October, CMS proposed their 2019 Notice of Benefit and Payment parameters which, if finalized, could let states seriously erode the Essential Health Benefits, including the substance use disorder services benefit.

If states develop their own benchmark, the rule would set a ceiling on the generosity of benefits that states can include in their plans. Before the ACA was passed, more than one-third of plans on the individual market did not provide coverage for substance use disorder services.

I am very concerned that under the rule that has been proposed now, states would decide to limit this critically important benefit.

Given your stated commitment to addressing the opioid epidemic, yes or no, will you commit to rejecting the harmful changes to the Essential Health Benefits in the proposed rule?

Mr. AZAR. I believe that states are most effective in determining. They are most effective in determining the benefit packages for their citizens and the circumstances you described earlier. Even with New Hampshire, the unique circumstances of each state.

Senator HASSAN. But the problem, of course then, is when they do that, the insurance companies come in and charge much more for that benefit, and that is one of the advantages of the Essential Health Benefits.

I will tell you, nobody in my state plans to get an illness that their insurance does not cover. Nobody plans to become addicted to prescription drugs after surgery, let us say, and then says, "Oh, too bad. I did not buy insurance coverage for that treatment."

The advantage of the Essential Health Benefits is that millions and millions of people, not only got coverage through the ACA, but they got coverage that actually addressed their needs.

As Governor, and before when I was in the State Senate, it was often the case that insurance companies kept dropping coverage for things they could not make money on and eventually the public picks up that cost.

I would ask you to look at that issue very, very closely because the Essential Health Benefits under the ACA has been critical to fighting the epidemic in our state.

Last topic I wanted to touch on with you, and you have heard a lot about it. It is about drug pricing and some of it is about your past employment as President of the U.S. part of Eli Lilly.

I want to read a quote of yours from the "The New York Times" article because there is a reason that people are skeptical about your commitment to lowering drug prices. This is what you are quoted as saying in "The New York Times."

"All players, wholesalers like McKesson and Cardinal, pharmacies like CVS and Walgreens, Pharmacy Benefits Managers like Express Scripts, and CVS, Caremark, and drug companies make more money when list prices increase. The unfortunate victims of these trends are patients."

Basically in that quote, you are admitting that high list prices are hurting consumers and creating profits for drug companies. But yet, you continue and you did this just last spring to push the blame. Here you have said it is everybody. Everybody has got a part to play.

But last May at a conference, you pushed the blame on everyone but pharmaceutical companies for high list prices saying even though setting list prices is something that manufacturers directly control.

You have also blamed insurance plan designs for high drug prices, but it is really the list price set by manufacturers that is driving the increases in what consumers are paying because requiring lower cost sharing for drugs will just lead to increased premiums; again, all at the expense of consumers.

I want to ask now that you will be taking off your pharmaceutical company hat and will be responsible for advocating for consumers, do you think it is time that the Federal Government take action to limit the profit drug companies can make off of setting high list prices, much the way we limit insurers right now with loss ratio?

Mr. AZAR. In my earlier remarks, I certainly did not mean to be suggesting that list price was irrelevant or that pharma does not have a piece of this also.

The challenge is, as we think about the burden on the patient when they walk into that pharmacy, if the list price is \$500 and they have to bear that \$500, or if the list price is \$250 and they have to bear that \$250 under a high deductible plan, both of those can be unaffordable for that patient.

My point is, and where I want to work is, so I think both can be helpful.

Senator HASSAN. I am way over.

The CHAIRMAN. We are running out of time.

Senator HASSAN. My point is without some action by us, it will just be passed on and the insurance premium will also become unaffordable. Thank you.

Thank you, Mr. Chair.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Baldwin.

Senator BALDWIN. Thank you.

I, too, want to continue along the same lines that Senator Hassan was asking you about, and also what we were talking about in round one of questioning.

You mentioned your example at \$500 a month. I told you a story earlier about Greg from Stoddard, Wisconsin, but did not mention Diane, who lives in western Wisconsin, and has M.S., has taken a medication for over 23 years to slow the progression of her M.S. She became Medicare eligible, and therefore the way in which the family was insured and paying for medication.

She and her husband had a heartbreaking discussion at the beginning of this year whereby she and he decided that she would stop taking the medication. It had reached \$90,000 a year.

No change as far as I know in the ingredients, the manufacturing process, or anything else. It just had crept up, crept up, crept up over all of that time.

I want to return to this issue of transparency. We talked a little bit about this when we met yesterday.

I have offered, along with my colleague Senator John McCain, the Fair Drug Pricing Act which would require basic transparency from drug corporations. Again, understanding that it is a complex system, but that the list price setting starts with the drug corporation.

It would require disclosure to the Department of HHS on elements like executive pay, investment in research and development, investment in marketing, stock buybacks, et cetera as a way to inform policymakers so that we can take better and stronger approaches to this crisis in many respects.

What are your views on requiring drug companies to make basic information public when they are intending to increase the list price of existing drugs?

Mr. AZAR. Even as I referred to in my opening remarks, I generally am in favor of increased transparency within our healthcare system. I think it generally is a good thing.

We always need to look to see if there might be any counterproductive aspects to transparency as you and I discussed in your office. I think we always have to be careful there.

But as a general matter, I think transparency can be good and useful, and I would be very happy to study that more and work with you as part of all the options that need to be on the table to think about this. To see does it help with reducing what a patient pays out of pocket? Does it help with reducing list prices? Does it help with reducing what the system ends up paying?

I am very open to looking at all of these kinds of options with you.

Senator BALDWIN. One note that I want to make.

Often times, the difference between pharmaceutical product prices in the U.S. and overseas has pointed back to the investment

in research and development. But in recent years, the investment—if you can call it that in stock buybacks and dividend payouts—has surpassed that of R and D.

Is that a troubling trend in your opinion?

Mr. AZAR. I do not know. I do not study the financials of the companies on buybacks, for instance. But I certainly believe that one of the bedrocks of the R and D based pharmaceutical industry is that kind of heavy investment.

I think where I was employed, it was upwards of 20 to 25 percent of revenue was invested in R and D, a large percent of that here in the United States.

As we talked a bit earlier at the hearing in reference to some of those entities that simply buy a product and increase the price, I am very supportive of that type of intensive R and D work. Obviously, if I am in this role, I will have NIH, which plays such a key role in the basic foundational science there and is a partner in all of that work.

I do not know the particulars of that issue. I have not connected those two things, but I am very supportive of an R and D based industry.

Senator BALDWIN. It is quite striking. In an academic report, I think earlier this year, in aggregate, I think over half a trillion dollars invested in stock buybacks and less than that now in R and D. It is certainly not specific to the pharmaceutical industry, but very pronounced in the pharmaceutical industry.

The last point I would make is just to note for the record that I actually agree with President Trump regarding his emphasis on authorizing the Secretary of HHS to negotiate directly with pharmaceutical companies for lower drug prices in Medicare. Hope that is something that you will embrace, if confirmed.

Mr. AZAR. Thank you.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator WHITEHOUSE.

Senator WHITEHOUSE. Thank you, Chairman.

Mr. Azar, we talked in our last conversation about Accountable Care Organizations and the ways that we can deliver better care at less expense.

There is another, much more particular area where, I think, there is another bipartisan opportunity to improve care. In this case, it probably would lower expense, but that would not be the point, and that area is end of life care, advanced care.

There is a very good group that you may be familiar with called the Coalition to Transform Advanced Care that has very, very broad corporate institution support that is focusing in these areas.

Rhode Island has been very active in this space. We have enormous support from—we are the most Catholic state in the country—the Catholic diocese has been very helpful. The State Council of Churches has been helpful. Our major hospital groups and our medical society have all been extremely helpful.

What we see is that from time to time, we bump up against problems within the Medicare and Medicaid billing systems which, in a general arbitrary world, might make some sense.

But once a state or a community has decided that it is going to undertake a path to deal more humanely with people near the end

of their lives, suddenly those prescriptions become obstacles. I think, do more harm than good to the patient, and probably to the public fisc as well.

Here are some examples that we are trying fix.

Medicare and Medicaid patients are not supposed to receive both hospice care and curative care at the same time. If you are seriously focusing on the care of an end of life patient, that is a completely stupid distinction to force into that situation.

Nurse practitioners have way too small a role and their role could be increased.

The whole two night-three day in-patient stay rule before somebody can be moved into a nursing home is nonsensical in the context of somebody who is operating under a good end of life care base or hospice plan.

Home health services ought to be provided without having to meet the full regulatory definition of being homebound. Very often a dying patient can still move around for a while and is not fully homebound. But it would be cheaper for the system, better for the family, easier for the loved ones who are providing care to get home health services. That rule, again, backfires.

Finally, caregivers often need respite and respite care is a very valuable thing because without that, you wear out the caregiver and now the system has to come in at a vast expense and pick up with potentially an in-patient treatment.

Home-based respite care where you do not have to put your family member into an in-patient place, while you get your couple of days of respite, would seem to make a ton of sense.

None of those things are being done and the result is that this very precious time of life toward the end, states want to make it better. They want to make sure that the wishes of the patient are honored and that it is clear around the family what those wishes are, so there are not horrible fights at the end of life.

All of those things can be made so much better. Here is the Government with all of these rules that may make sense, again, in isolation. But once you start to deal with end of life care in any kind of a comprehensive and humane fashion, they begin backfiring in your face.

Will you work with us, particularly with Rhode Island, to try to support models?

We do not need to get rid of them entirely, but what we really want to do is to support waivers so that when a state or a community steps forward with a really good, humane—

I am saying this sitting next to Senator Baldwin, whose state is legendary for end of life care planning, by the way. I should give Wisconsin some props here as well.

Would you help us with that?

Mr. AZAR. Senator, I just want to thank you for those very thoughtful comments and reflections.

As I mentioned in my opening remarks, my stepmother Wilma died just in July and it was a blessing that she was able to be in her house, in her bed for the whole time.

Senator WHITEHOUSE. Yes.

Mr. AZAR. I want to make sure people have that chance and so, happy to work with you.

Senator WHITEHOUSE. I think what we will find is that it actually helps the public fisc as well.

But to be perfectly blunt, I do not actually care if we have to spend a little bit more money so that people at the very tender time of their life, and the family who are surrounding them at that very tender and important time of life, are not treated disrespectfully and are not pushed to make dumb decisions based on bureaucratic rules that simply do not make sense at that time.

God bless you and thank you.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Murray, do you have any closing remarks or questions?

Senator MURRAY. Again, Mr. Azar, I thank you so much for you and your family patiently sitting through this.

I do have some additional questions.

Senator MURRAY. I would just ask that we do get timely and sufficient answers to our questions. We have had that problem before under Secretary Price, and both before confirmation, and then after your confirmation just really respectfully ask that we get timely answers so that we can do our job as well.

I did want to put one issue on the table that we did not have time to address and that is HHS's plans for implementing the Pre-school Development Grants Program.

We authorized that in our Every Student Succeeds Act. It is something I am very concerned about and I am going to be watching very closely to make sure that really vital program is implemented the way that Congress intended, so that it helps us expand access to high quality, early learning and care for our most vulnerable children.

I will follow-up with you, but know that I will be following that very closely.

Again, thank you for being here. I know you have another hearing to go through, numerous questions. We will be looking at all of those.

But if you are confirmed, I want to know that we will talk to you, work with you, and hope that you will be as responsive as we need you to be.

The CHAIRMAN. Thank you, Senator Murray.

Mr. Azar, thank you for being here, for your willingness to serve, for answering the questions. I do hope you will respond to the Senators' questions. We do not have any limit on the number of those questions, but I hope there will be a reasonable number of questions.

About one-third of the Members of this Committee are also a Member of the Finance Committee, which is the Committee that will vote on your confirmation and report it to the floor of the Senate.

I think you have seen today the diverse points of view on this Committee and some people wonder how we could ever get anything done. But the fact of the matter is we get quite a bit done.

A couple of years ago, we fixed No Child Left Behind in a way that President Obama called, "A Christmas miracle."

Last year was the 21st Century Cures legislation that the Majority Leader said, "Was the most important legislation of the year."

You will have a chance to implement that legislation, as well as the Mental Health Reorganization that was a part of it.

This year we worked, Senator Murray and I, worked to try and see if we could find some area of agreement, even though it is for a short term, on the Affordable Care Act which we were able to do. It is not law yet, but we were at least able to take a step.

There are a number of areas and you have heard many of them today. Senator Whitehouse suggested two major areas of bipartisan cooperation.

We have talked about electronic healthcare records. There is a lot here that we can do working with you and I think you will find that most of us would like to create an environment in which you are able to succeed. We will not be shy about giving you our points of view as you are able to tell today.

My hope also is that we can talk about more and work with you on more than the individual insurance issue. For the last, it seems like forever, we have focused on health insurance and only 6 percent of the Americans who buy health insurance on the individual market, every single one important. But year after year, we give ourselves——

It is like going to college, and taking only one course, and earning a “C,” or a “D,” or an “F” on it every semester. We do not seem to be making very much progress and the important thing about it is there is so much other important things that we should be working on when we talk about health, and healthcare, and the agencies that you work on.

Drug pricing is one this Committee has a great interest in. I, for one, am excited about the fact that you know something about this. Health insurance is complex. I think drug pricing is Byzantine. I think if we had a Secretary who was new to the subject, that he or she would leave after two, or four, or 8 years without having accomplished much of anything because it would take that long to understand what is going on.

You arrive knowing the subject and helping us answer the questions, where does the money go? Do we really need rebates? Can there be more negotiations on drug pricing? Should we really think seriously about finding a way to let Americans buy drugs in the United States that are not approved by the Food and Drug Administration? We have not ever done that before, and several Senators think we should, and we will need to talk about that.

We should be talking about wellness. We have had two or three hearings on that. That offers great promise for reducing healthcare costs. Electronic healthcare records, we have talked about.

Biomedical research, we hear a lot about the President’s budget proposals. We hear less about the fact that Senator Murray and Senator Blunt for 2 years, hopefully for three, have increased funding for the National Institutes of Health, \$2 billion a year, and we added another \$4.8 [billion] in the 21st Century Cures.

We are putting big, new dollars into the National Institutes of Health, as well as big, new authority into NIH and the FDA, all of which you will have a chance to take advantage of and to make something of.

I think it is a very exciting time for someone with your experience, and background, and energy to come to this position. I think

you could help families all over America and I hope, if you are confirmed, which I am confident you will be, that you will look to this Committee, both the Democrats as well as the Republicans, as a resource to create an opportunity in which you can succeed.

I ask consent to introduce four letters of support for Alex Azar into the record, which it will be done.

The CHAIRMAN. If Senators wish to ask additional questions of our nominee, questions for the record are due by 5 p.m., this Friday, December 1.

For all other matters, the hearing record will remain open for 10 days. Members may submit additional information for the record within that time.

The CHAIRMAN. The next meeting of the HELP Committee will be a hearing tomorrow, November 30, at 10 a.m. We will hear from experts on the opioid crisis.

Thank you for being here.

The Committee will stand adjourned.

[Whereupon, at 12:34 p.m., the hearing was adjourned]

[Additional Material follows]

UNITED STATES SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

NOMINATION OF ALEX AZUR TO SERVE AS SECRETARY OF HEALTH AND
HUMAN SERVICES

WEDNESDAY, NOVEMBER 29, 2017

Questions for the Record

Senator Paul

Re-Importation

During the hearing, we discussed the issue of drug re-importation as a way to provide American consumers with more options for purchasing prescription drugs. Are there any circumstances under which you believe that re-importation can be implemented safely? If so, what steps, administrative or legislative, need to be taken to ensure the safety of re-imported drugs?

Response: 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.

Do you believe there are safety concerns with the drugs supply in other developed countries, such as Canada, the UK, and Australia? If the drugs in such countries are considered to be safe, why is there a safety concern with Americans importing drugs from these countries for their use?

Response: The issue is not the safety of drugs approved and distributed within Canada's, the U.K.'s, and Australia's closed distribution systems, rather the challenge is that the opening of U.S. borders to a free-for-all importation of drugs, from even these countries, does not in any way guarantee that the drugs entering into our country are the actual drugs that would be available in those countries through their closed and legitimate distribution systems. It is my understanding that many websites that purport to be Canadian online

pharmacies, or other sources of drugs from developed countries, may actually be merely Canadian-registered web sites that actually are sourcing from less developed countries, or are in fact fraudulent, with prescription drugs being offered for sale to American consumers through such sources may not have been subject to review by regulators in developed countries. In recent years, HHS has worked with the Department of Justice and foreign law enforcement agencies to take down and pursue enforcement actions against those who market counterfeit, unsafe, and/or substandard drugs through such sources. Such criminal enterprises continue to pose a significant risk to American patients and consumers, and it is important that any policy on imports not unintentionally expand this risk.

Patent/Exclusivity Issues

One of the issues frustrating competition, especially complex and combination products, is the seemingly limitless ability for a company to “evergreen” their patents to prevent competitors from coming to market. What solutions or further changes to these patent barriers would you suggest to further promote competition?

Response: 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.

Tobacco

Each year, approximately 1,200 dark tobacco farmers grow 23,650 acres (for a total of 66 million pounds) of dark tobacco. Most of that is grown in western Kentucky. The cash value of this crop is \$173 million annually, a major economic driver in the region. A proposed rule from the Obama Administration could shutter these plants. The rule, entitled “Tobacco Product Standard for N-Nitrososonornicotine Level in Finished Smokeless Tobacco Products” (21 CFR Part 1131) (Docket No. FDA-2016-N-2527), intends to limit N-nitrososonornicotine (NNN) levels to 1 part per million in finished smokeless tobacco products. NNN is naturally occurring in tobacco, and it may form during the growing, curing, manufacturing, or retail stage of the product. While farmers and manufacturers continue working to limit NNN levels in tobacco, as I understand, this proposed standard is currently not technically achievable.

I am opposed to this rule and wrote President Trump on January 26th asking that it be withdrawn. Do you agree this rule needs to be withdrawn?

Response: If confirmed, I look forward to reviewing this proposed rule and the comments received on it, in order to determine how best to proceed on this issue. It is important that regulations be workable and not place undue burden on the American people and American business.

Senator Collins

1. In June, Secretary Price wrote to Congress concerning the discovery of glass fragments in injectable drugs, which can present a public health risk to patients. The Secretary noted that FDA is aware of this problem and, due to potential health risks, issued an Advisory to the industry back in June 2011. The Agency also initiated a study to compare various types of glass products intended for use in injectable drug products, and determine the superiority of new types of glass products to current products. The Secretary indicated that he is “hopeful that the study results and discussions will provide valuable information with which to update the 2011 advisory.” Despite our understanding that the FDA study will be completed this year, the timeline on the review and advisory remains unclear. Will the study be completed this year and when will FDA decide whether to update the Advisory?

Response: At this time I cannot comment on the status of the review; but if confirmed I will work with FDA’s leadership to ensure industry has the most up to date guidance at the earliest practicable time.

2. As a co-founder of the Diabetes Caucus, I was pleased that Medicare began covering continuous glucose monitors (CGMs) earlier this year. Yet despite advancements, I remain concerned that CMS continues to place unnecessary barriers and restrictions to coverage of new and existing diabetes technologies.

On November 28, I received a response to a letter that Senator Jeanne Shaheen and I sent CMS regarding coverage of an insulin delivery device that replaces the tubing of a conventional insulin pump with wireless technology. This product was approved by the FDA over 12 years ago and is covered by nearly every private insurance carrier. The response letter suggests that this coverage issue is “complicated by the need to look across multiple parts of Medicare.” What are the barriers to resolving these types of coverage questions in a more expeditious manner?

Separately, it has come to my attention that Medicare has a policy that prohibits beneficiaries from using a free smartphone app to share data and alerts from their otherwise coverable CGM. The data enables family members and caregivers to intervene before a beneficiary’s blood glucose levels become dangerously high or low. What will you do to ensure that Medicare encourages, rather than inhibits, innovative tools?

Response: 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 reimburses 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 the CMS recently issued guidance allowing Medicare Part D Plan Sponsors to cover the Omnipod system. Regarding CGMs, there was a CMS Ruling issued earlier this year recognizing therapeutic CGMs under the Medicare durable medical equipment benefit category. The definition of durable medical equipment is defined in regulation and items must meet this definition to be covered by Medicare.

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.

Senator Young

1. Welfare Reform

President Trump has recently stated that he hopes to tackle welfare reform after tax reform because changes were “desperately needed in our country.”

With so many of our welfare programs housed within HHS, what are some ideas that you have for welfare reform?

In the short term, White House officials have stated that they have been working on welfare executive orders looking at what federal agencies, like HHS, can do on their own.

What kinds of changes would you consider as HHS Secretary if this executive order comes to fruition?

Response: 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.

2. Healthy Indiana Plan (HIP) Waiver

Indiana is currently awaiting approval of its Healthy Indiana Plan waiver at CMS. This will be the third iteration of a successful State-initiated healthcare plan that does well to provide greater access to care while remaining accountable to state budgets and taxpayers.

However, the State is quickly approaching deadlines for notifications regarding HIP access.

Can I have your commitment that this waiver application and others like it will receive thorough and timely reviews, so that innovative states like Indiana can get to work on providing these needed services?

Response: Yes. 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.

Ranking Member Murray

Affordable Care Act

1. What measures will you take to ensure that the newly insured population does not lose quality, affordable coverage? What measures will be taken to reach the current uninsured population with quality, affordable health care coverage?

Response: We must make healthcare more affordable, more available, and more tailored to what individuals 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.

2. How will you ensure women will have access to healthcare? How will you protect and improve coverage and access to healthcare for elderly, rural, and indigent populations? How will you protect and improve coverage and access to health care for communities of color?

Response: The mission of the U.S. Department of Health and Human Services (HHS) is to protect the health and well-being of all Americans. I believe that everyone should have access to quality, affordable healthcare and insurance coverage that works for them and that meets their needs. If confirmed I will work to support that goal for all Americans.

3. About half of Americans get coverage through their employer, which means that changing jobs, starting new business ventures, or deciding to retire or work part-time put people at risk of losing their coverage. The marketplaces ensure that people can buy coverage on their own, without the risk of being discriminated against for having a pre-existing condition. This prevents job lock, where an employee remains in a job solely because of the need for health insurance for herself or her family. Do you fear that the Administration's recent actions to destabilize the market are limiting coverage options and will stunt entrepreneurship, prevent family members from providing care for elderly parents or children with special needs, or lock more workers into jobs they are unhappy with?

Response: I do not agree with the characterization that the Administration or the Department has made an effort to destabilize the market, nor that the marketplaces are delivering on the promise articulated above. Right now, we have a system where Washington is too often in the driver seat and defining what is healthcare, 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 healthcare 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.

4. Section 2901 of the ACA prohibits cost-sharing for Indians with incomes below 300 percent of federal poverty level who are enrolled in qualified health plans offered through the exchange and stipulates that health programs operated by the Indian Health Service, Urban Indian or tribal organizations, or Indian Tribes (as those terms are defined in 25 USC 1603) are the payers of last resort for any services they provide to eligible individuals. Do you support repealing this provision? Are you concerned that the President's recent decision to stop paying cost-sharing reductions will jeopardize access to coverage and care for American Indians?

Response: I defer to the Congress regarding any legislative changes along the lines described above. With respect to the CSRs, the Administration conducted a legal review and received an opinion from the Attorney General concluding that since the Congress did not appropriate the money for Cost Sharing Reductions, the Administration could no longer legally make the payments.

5. Thanks to Medicaid, the Children's Health Insurance Program (CHIP) and the ACA, over ninety-five percent of children in the United States have health coverage – a historic high. Over the past 50 years, it has been clearly demonstrated that there are strong economic reasons to preserve and protect children's health coverage. The return on investment is high. Children with health coverage are more likely to attend school, graduate from high school, go to college, and become healthier adults, with higher taxable earnings than uninsured children. Identifying and treating conditions early, before they become expensive long-term liabilities, is effective. Research also demonstrates that when parents have health insurance, children are more likely to get the care they need, one of the key reasons why the Medicaid expansion is so crucial for the health of children and families. You have been quoted as being supportive of the various ACA repeal bills being considered throughout 2017 that would reduce the historic gains we've made as a country to reach the historic rate of insurance coverage of children. While health care stakeholders and families spoke out against the changes being contemplated to the ACA and Medicaid over the summer and fall, the Administration and many in Congress have continued to pursue legislation that would strip millions of children and families of health insurance coverage thereby denying them access to life-saving vaccines, health and developmental screenings, and care. Do you think that's an acceptable scenario for millions of children?

Response: It is important that every child has access to high-quality health coverage. CHIP plays 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 the families in communities. Each state is different. HHS should work with states to ensure that the CHIP program provides the best possible coverage to their residents. If confirmed, I will work with Congress on CHIP reauthorization with these principles in mind.

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 healthcare system that is more affordable and accessible.

6. The ACA included Section 1557, an important civil rights provision that prohibits discrimination on the basis of race, color, national origin, sex, age or disability. The law also enhances language assistance for people with limited English proficiency. The law aims at increasing access to health care for all individuals and reducing health care disparities. Under former Secretary Price, there were various efforts to undermine or restrict the scope of Section 1557. If confirmed, will you work to ensure full implementation of Section 1557 so that all individuals are protected from discrimination in health care on the basis of race, color, national origin, age, disability, and sex, including someone's gender identity?

Response: If confirmed as Secretary, I will faithfully implement laws written by Congress and the regulations issued by the Department. It is essential that healthcare services be available to all people with the highest level of quality, affordability, and respect for their human dignity.

7. In March, when the House of Representatives introduced its first ACA repeal bill, the American Health Care Act (AHCA), former HHS Secretary Price falsely claimed "no one will be worse off financially." Secretary Price made these statements despite the fact that he had no reputable source of information to back up the claims. The following day on March 13, 2017, the Congressional Budget Office (CBO) score of the AHCA estimated that by 2026, the ACHA would have resulted in 26 million more uninsured people. Additionally, CBO determined that the AHCA would have significantly increased premiums in the near term and imposed disproportionate costs on seniors. Once the CBO analysis was released, Secretary Price announced that he disagreed strongly with the CBO analysis and criticized the agency. In the summer, CMS used federal funds to produce the July 15, 2017 analysis, "Estimating the Effects of the Consumer Freedom Amendment on the Individual Market," rather than waiting for the CBO estimate of this provision. The analysis made claims that many experts contradicted. Do you share Secretary Price's view of the CBO analysis? Do you support the non-partisan Congressional Budget Office in its role of scoring potential legislation and will you commit to supporting their analyses in the future? Can we rely on you to speak with credibility, backed by reliable data and information, in your role as Secretary of the Department of Health and Human Services?

Response: I respect the work of the dedicated and hardworking individuals at the CBO, and I fully appreciate the Office's role to provide non-partisan analysis and scoring of legislation. I have also seen firsthand the CBO miss the mark, repeatedly and reliably, in accurate prediction of human behavior, and inability to take other dynamic scoring factors into consideration. The work products of the CBO are essential, but real-world data must inform assumptions in predictive products going forward. It is wise to verify information in an evidence-based, data driven process to help inform the deliberative process.

8. In October, President Trump signed an executive order that required consideration of regulations to expand access to association health plans. In the 1980s and 1990s, a number of association health plans failed, sometimes as a result of fraud, leaving millions

in unpaid medical bills across a variety of industries. What types of protections would you require in the association health plan regulations to ensure that these plans do not fail and leave unpaid medical bills in their wake?

Response: Oversight and regulation of AHPs are under the purview of the Department of Labor, but if confirmed, I'll be happy to assist Secretary Acosta in helping to deliver affordable insurance options for as many Americans as possible.

9. President Trump's October executive order also encouraged expanding the use of short-term and limited-duration insurance. Expanding the use of STLDI as a substitute for other individual market coverage will reduce the pooling of risk, especially among people with pre-existing conditions. Will you commit to enacting policies that improve the affordability of coverage for those with pre-existing conditions by promoting the single risk pool in the individual market?

Response: Predictable and stable risk pools are critical to the success of any health insurance system. The ACA's structure has been fundamentally flawed in this area. If confirmed I pledge to work with Congress on healthcare reforms that create or enable effective risk pools. I should note that the recent proposed changes to the short-term and limited-duration insurance options would restore the status quo that was in place during almost all eight years of the Obama Administration, changed only in the waning hours of that Administration.

Immigrant Youth, Trafficking Survivors, and Refugees

10. In 2016, two defendants were sentenced for their role in a forced labor scheme that exploited Guatemalan minors. According to the indictment, members of the labor-trafficking conspiracy recruited workers from Guatemala, some as young as 14 or 15 years old, falsely promising them good jobs and a chance to attend school in the United States. The traffickers then smuggled and transported the workers to a trailer park in Marion, Ohio, where they ordered the children to live in dilapidated trailers and to work at physically demanding jobs at Trillium Farms egg farm for up to 12 hours a day for minimal amounts of money. The indictment identified eight minors and two adults as victims of the forced labor scheme. This is just one example that illustrates that unaccompanied immigrant minors are especially vulnerable to trafficking. If you are confirmed, will you support comprehensive programs that provide follow up services to ensure the protection of immigrant youth?

Response: The Administration for Children and Families provides assistance for unaccompanied minors who have experienced human trafficking through the Office of Refugee Resettlement (ORR) and the Office on Trafficking in Persons (OTIP). I agree that keeping unaccompanied alien children safe from traffickers and others who may harm them when they are released to sponsors is an important part of ORR's work.

11. Immigrant and refugee women experience unique difficulties in obtaining services following an instance of intimate partner violence because of language barriers, confusion over their legal rights, and new and different cultural and social structures. HHS's Office of Refugee Resettlement (ORR) plays a critical role in addressing these

challenges faced by immigrant and refugee survivors of violence. Do you support HHS's role in providing necessary services to immigrant and refugee survivors? Do you intend to impose any income or immigration status eligibility requirements in order for survivors to access HHS-funded services related to intimate partner violence? If you would make changes, what specifically would you change? Will you work to improve sensitivity and response to intimate partner violence issues through the Office of Refugee Resettlement at HHS? If so, how?

Response: If confirmed, I will support effective and efficient implementation of laws pertaining to the provision of services to refugees, asylees, and other arriving populations by HHS' Office of Refugee Resettlement.

12. ORR serves an extremely vulnerable population-- unaccompanied immigrant minors. Many face sexual violence in their home countries, during their journey to the US, or in custody, and are in need of urgent reproductive care. These young people have critical and time-sensitive reproductive health needs including abortion, emergency contraception, and longer-term contraception needs. There are many young women in federal custody who are being or will be denied access to constitutionally-protected care and who will be coerced and shamed by HHS for their decisions. Will HHS, under your leadership, continue to apply this unconstitutional HHS policy to prevent young women throughout the country from getting abortions and other reproductive health care?

Response: If confirmed, I will commit to ensuring 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.

13. ORR Director Scott Lloyd has used a variety of tactics to block abortion access for the young women in ORR custody. He has instructed his staff to prevent minors seeking abortion from meeting with attorneys, has personally visited pregnant minors to pressure them to continue their pregnancies, and has directed ORR and shelter staff to notify parents and sponsors of minors' pregnancies, even when they have received judicial authorization to make their own medical decisions.
- a. Are you concerned that Lloyd is violating a 1997 federal settlement in the *Flores v. Reno* case, which requires ORR to provide emergency health care and family planning services?

Response: If confirmed, I will ensure that the Unaccompanied Alien Children (UAC) program in the Office of Refugee Resettlement is run in accordance with all applicable Federal statutes and regulations and the *Flores* settlement agreement as applicable.

- b. Are you concerned that Lloyd is violating the constitutional rights of these young women by effectively banning abortion for them, which the Supreme Court forbid the government from doing more than 40 years ago in *Roe v. Wade*?

Response: ORR understandably keeps confidential information about the UAC in its care,

whose protection and well-being is the responsibility of ORR. I am not able to comment on ORR Director Lloyd's management of the UAC program, but, if confirmed, I will ensure that the program is managed in accordance with all applicable Federal statutes and regulations and the *Flores* settlement agreement as applicable.

- c. Is it appropriate for a political appointee like Scott Lloyd to override the determination of a Texas state judge who ruled that Jane Doe was mature enough to make her own medical decisions?

Response: The case that you refer to continues in litigation, and I cannot comment on ongoing litigation.

14. The Department of Health and Human Services is responsible for ensuring that trafficking victims are provided with resources needed to recover and rebuild their lives. In addition, the Department helps spearhead the federal government's prevention efforts to address vulnerabilities that can lead to trafficking. Based on data from the National Human Trafficking Hotline, one particularly vulnerable demographic is Latinos and Latinas, which represent the highest total percentage of human trafficking victims identified by the Hotline in the United States since 2015. Will your Department prioritize outreach to this population in the United States to inform them about human trafficking and the resources your Department provides, including the Hotline? Are you willing to work with Congress and advocates to find ways to limit the opportunity foreign labor recruiters have to abuse workers on temporary work visas?

Response: It is critical to reach at-risk individuals to prevent human trafficking and to come to the assistance of victims of trafficking. Key factors to reach populations that may become vulnerable to trafficking include working with faith- and community-based organizations that can provide culturally and linguistically appropriate outreach and resources. If confirmed, I look forward to working within HHS and with our interagency partners to improve the federal response to human trafficking in the United States.

15. The Trafficking Victims Protection Act created the President's Interagency Task Force to Monitor and Combat Trafficking (PITF, a cabinet-level entity, which consists of several federal agencies responsible for coordinating United States government-wide efforts to combat trafficking in persons). As Secretary, you will represent the Department of Health and Human Services at the annual PITF meetings and designate senior officials to the Senior Policy Operating Group, which handles the day-to-day activities for the PITF. Do you agree that no child should be at risk of trafficking, including immigrant children? How will you ensure the Office of Refugee Resettlement has the funding necessary to combat human trafficking, and how will you coordinate with other federal agencies to address all aspects of human trafficking, such as developing victim identification and protection measures, strategically linking the Office of Refugee Resettlement services to leverage United States diplomacy, and enhancing public-private partnerships?

Response: I agree that no child should be at risk of trafficking, and if confirmed, I will work within HHS and in coordination with interagency partners to address all aspects of human trafficking under the authorities provided to HHS by Congress, including the

trafficking of children, regardless of nationality, as authorized under the Trafficking Victims Protection Act of 2000 and its subsequent reauthorizations, the Preventing Sex Trafficking and Strengthening Families Act, and the Justice for Victims of Trafficking Act.

Upon confirmation, I look forward to participating in the PITF and I am committed to lending my full support to existing efforts within the Department dedicated to supporting and leading systems that prevent trafficking through public awareness and training; and that protect victims through identification and assistance, helping them rebuild their lives and become self-sufficient.

16. The Office of Refugee Resettlement provides crucial services to refugees, asylees, trafficking survivors, torture survivors, Special Immigrant Visa recipients targeted due to their work with United States military and diplomatic personnel, Cuban and Haitian entrants, and unaccompanied children. The Office of Refugee Resettlement funding is critical not only to these individuals and families rebuilding their lives, but also to the communities that welcome them across the United States, including local and community-based charities, schools, and state governments. Unfortunately, the Office of Refugee Resettlement budget has not kept pace with its mandate, nor the cost of living and inflation. Accurate and timely information is essential for Congress and its Committees to fulfill its Constitutional and other legal functions, including appropriations. Will you communicate in a clearly and timely manner, when requested by Congress and its Committees, regardless of party, about the financial information, management, policies, practices, and plans of these programs, including budgeting projections and refugee flows?

Response: Yes, if confirmed I will communicate in a clear and timely manner, when requested by Congress and its Committees, regardless of party, about the financial information, management, policies, practices, and plans of these programs, including budget projections. The Department will also continue its current practice of communicating with Congress, in coordination with OMB, when issues arise impacting the sufficiency of appropriations. Refugee admissions are handled by the Department of State and the Department of Homeland Security, and I defer to those agencies to communicate about refugee flow issues.

Child Welfare and Early Childhood Education

17. The Every Student Succeeds Act represents the first time that our nation's K-12 education law includes dedicated funding for early learning. Our new Preschool Development Grants (PDG) program will be administered jointly by HHS and ED. I have heard significant concerns that leadership at HHS is planning to manipulate the PDG program to defocus the program on expanding access to high-quality early learning and care programs. If confirmed, will you commit to implement PDG the way that Congress intended, including respecting the law's allowance to use funding for slots during the renewal period?

Response: 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 five and their families with supports to assist these children to be successful in school and beyond.

18. Head Start is one of our nation's strongest anti-poverty programs. Since its inception, Head Start has served over 32 million children and families.¹ Not only does Head Start provide our youngest learners with vital skills, but it provides for a two-generational approach, strengthening parenting skills as well. If confirmed, will you commit to recognizing the importance and the effectiveness of the Head Start program, and requesting an increase in funds to increase the number of children and families served?

Response: I agree with you as to the importance and effectiveness of the Head Start program. If confirmed, I will work to ensure that HHS appropriately implements the Head Start statute to ensure the program is operated in an effective and efficient manner.

19. The Early Head Start-Child Care Partnerships program has been very successful in raising the quality of child care and promoting collaboration between Early Head Start and child care programs. As Secretary, how do you intend to build upon the program's successes?

Response: If confirmed, I will implement the laws passed by Congress as effectively and efficiently as possible. I look forward to working with the leadership of the Administration for Children and Families to identify ways to build upon what they have learned to ensure Early Head Start-Child Care Partnerships are as successful as possible.

20. In 2016, the Department of Health and Human Services worked collaboratively with the Department of Education to provide guidance to states, local educational agencies, and child welfare agencies concerning the new requirements to support students in foster care in the Every Student Succeeds Act and Fostering Connections to Success and Increasing Adoptions Act.² If confirmed, how do you plan to collaborate with ED to ensure that states, local educational agencies, and child welfare agencies follow through with their commitments to support students in foster care?

Response: 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.

21. Under the Obama Administration, there has been enhanced collaboration between HHS, HUD, and ED regarding the intersection between homelessness and education. Will the Department of Health and Human Services continue that collaboration under your direction, if confirmed – if so, how will HHS continue that collaboration?

¹ <https://www.acf.hhs.gov/ohs/about/history-of-head-start>

² <https://www2.ed.gov/policy/elsec/leg/essa/edhhsfostercarenonregulatorguide.pdf>

Response: The Family and Youth Services Bureau (FYSB) within the Administration for Children, Youth and Families (ACYF) at the Administration for Children and Families (ACF) has a long-standing relationship with the Department of Housing and Urban Development (HUD), Department of Education, Department of Justice (DOJ), and the US Interagency Council on Homelessness (USICH) . If confirmed, I look forward to working with ACF to continue this intergovernmental collaboration.

22. In September, I introduced the Child Care for Working Families Act, a bill that would ensure that low- and moderate-income families have access to high-quality, affordable child care and early learning. The bill also includes numerous policies to strengthen the child care workforce. What are your views on the issues we face when it comes to the child care workforce, and what can be done to ensure that child care workers have access to the training and compensation they need to take care of our youngest learners?

Response: A well-trained child care workforce is necessary to provide children with safe and nurturing environments. There are several promising options for providing child care workers with the support they need to be good caregivers, including coaching and mentoring for teachers, and a shared-services model, where smaller providers may come together to leverage economies of scale to access training, consultants, and business supports. If confirmed, I look forward to furthering our research into best practices and supporting states as they implement different strategies based on their priorities.

23. The number of children receiving access to child care assistance through the Child Care and Development Block Grant has fallen significantly in the past decade. From 2006 to 2015 alone, the average monthly number of children served fell by 373,100.³ Do you believe that additional funding is needed to ensure that parents, and particularly mothers, are able to work?

Response: 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 all available resources to provide access to child care for the working families who need it.

24. Congress came together to pass a bipartisan reauthorization of the Child Care and Development Block Grant (CCDBG) Act in 2014 that took significant strides to improve the quality of child care across the country. As Secretary, how will you support efforts at the Department to support states and communities in order to implement these reforms? Will you commit to ensure that all states are in full compliance with the law?

Response: If confirmed, I will work with states to ensure full compliance in the implementation of the CCDBG Act of 2014. A majority of states have implemented most requirements included in the CCDBG Act of 2014. Where states have yet to meet the requirements, HHS has granted statutorily allowed temporary waivers to provide states the

³ <https://www.clasp.org/sites/default/files/publications/2017/08/CCDBG-Reauth-Guide-Updated.pdf>

time they need to come into compliance with those requirements, along with technical assistance as appropriate.

25. Hurricanes Maria and Irma have devastated early learning and care programs in Puerto Rico and the U.S. Virgin Islands. However, OMB's supplemental request included no funding for the Child Care and Development Block Grant, Social Services Block Grant, or Head Start program.⁴ Please send the most recent estimates of the needs when it comes to early learning and care in Puerto Rico and the U.S. Virgin islands. Given the current situation, do you believe that OMB's request to Congress is adequate to address these urgent needs?

Response: The United States faced an unprecedented hurricane season in 2017 with multiple category four or stronger hurricanes making landfall in a short period of time. Without being privy to specific information related to the recovery and response, I cannot provide an update on the current needs. If confirmed, I look forward to working with ASPR to learn about the recovery process and plan to ensure that the needs of those impacted by the hurricanes are met.

26. In 2016, Congress passed the bipartisan Comprehensive Addiction and Recovery Act, which included important amendments to the Child Abuse Prevention and Treatment Act regarding plans of safe care for substance-exposed infants. If confirmed, how will you make compliance with these important provisions a priority, including by providing technical assistance and conducting thorough oversight?

Response: If confirmed, I plan to fully implement all laws passed by Congress, including the Comprehensive Addiction and Recovery Act. I look forward to learning more about HHS efforts to implement these specific provisions and working with the various agencies to see that they are implemented correctly.

Older Americans

27. The issue of linguistic and cultural competence is critically important in reaching our growing, hard-to-reach, and vulnerable populations. Ensuring that as a nation we are able to reach these populations is especially critical in the areas of health, where there remain significant disparities. For example, robust, inclusive outreach to elderly populations ensures that they do not fall through the cracks of service provision and education. How will you ensure that federal aging programs are most effective and able to support all aging populations?

Response: If confirmed, I will work with the HHS Administration for Community Living to continue to adhere to the Older Americans Act (OAA) goals and requirements, and ensure services and supports offered through State Units on Aging, tribes, and Area Agencies on Aging are targeted to those with the greatest social need, including low-income minority older individuals, older individuals residing in rural areas, and individuals with limited English proficiency, consistent with the law.

⁴ https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/Letters/fy_2018_hurricanes_supp_111717.pdf

Disability

28. You support converting the Medicaid program to a block grant. Previous Republican proposals to establish Medicaid block grants would substantially cut funding compared to current law. Under this scenario, states would likely cut services and employ severe service rationing, including for the services used by individuals with significant disabilities. With nursing homes and other institutions frequently “carved out” of managed care pools, funding cuts can push individuals with significant disabilities into institutions instead of the community. In your view, does the federal government have an obligation to ensure through oversight that federal dollars are not used in a way that promotes unnecessary institutionalization of individuals with disabilities? Doesn’t this type of block-granting conflict with the goals of the ADA?

Response: Promoting community integration for older adults and people with disabilities is a high priority for me and for the Administration. For that reason, states and territories must be given the flexibility they need to provide the highest quality healthcare they can to their own unique constituencies and be empowered to be fiscal stewards of taxpayer dollars. If confirmed, I will work to help provide health insurance that works for patients and meets their unique needs.

29. In 1999, in the Olmstead case, 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 in an institutional setting. Since the Olmstead decision, HHS has used the Medicaid waiver system to encourage states to shift away from institutional care and to instead expand home and community-based services. Will you continue this longstanding federal policy? If yes, what steps will you take? If no, why do you believe the federal government shouldn’t use federal funds to provide people with disabilities community options for their care?

Response: Promoting community integration for older adults and people with disabilities is a high priority for me and for the Administration, and the Administration has worked with state partners and other stakeholders to implement provisions of a final regulation defining a home and community-based setting. In the upcoming years, the Administration will also be examining 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. If confirmed, I would continue the Department’s work with states on home and community based programs.

30. Since the Olmstead decision, Congress has authorized several programs to incentivize states to meet their obligations under Olmstead by increasing federal dollars for providing community-based services. These 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. Is it your view that the Administration should continue these types of programs? Why or why not?

Response: I 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.

31. Medicaid contains numerous employment supports and programs such as the Medicaid buy-ins under the 1997 Balanced Budget Act (BBA), Ticket to Work and Work Incentives Improvement Act (TWWIA), or Section 1115 waivers. Currently, 46 States provide Medicaid eligibility through the TWWIA Buy-in, the BBA Buy-in, or a Section 1115 waiver. Over the past decade, more than 400,000 individuals with disabilities have taken part in the Medicaid Buy-In program. Total earnings among all Medicaid Buy-In participants in 2011 were about \$1.15 billion. For these Americans, retaining access to benefits such as Medicaid is essential for them to be able to go to work. Will you commit to preserving these vital work incentives policies? How will you as Secretary coordinate with the Department of Labor, the Centers for Medicaid and Medicare Services, and the Social Security Administration to support these efforts and maintain important work supports in Medicaid?

Response: I am supportive of options in our programs that enable and empower people to work and avoid cliffs in benefits that disincentivize employment. The best way to improve the long-term health of low-income Americans is to empower them with skills and employment. If confirmed, I look forward to supporting programs that aid in that empowerment.

Gender-based violence

32. Before the ACA passed, insurance companies were allowed to charge victims of domestic violence more for the same benefit package, or even deny them coverage outright because they had experienced violence and abuse. Prior to the ACA, seven states allowed health plans to deny coverage based on a history of domestic violence, and only 22 states protected against plans considering domestic violence a pre-existing condition. Today, no victim of domestic violence will be charged more because she has experienced abuse or violence. No survivor will be financially penalized for wanting to access the same benefits at the same cost as her peers. How will you ensure that health plans will never again be permitted to consider domestic violence a pre-existing condition? How will you ensure that health plans will not be allowed to charge survivors more for an identical benefit package simply because they experienced violence or abuse?

Response: As I previously stated, the mission of the U.S. Department of Health and Human Services (HHS) is to protect the health and well-being of all Americans. I believe that everyone should have access to quality, affordable healthcare and insurance coverage that works for them and that meets their needs. If confirmed, I will work to support that goal

for all Americans. Everyone ought to be treated fairly and with compassion – particularly when it comes to their healthcare needs. HHS must follow Congress’s lead in defining and enforcing nondiscrimination laws, and HHS will comply with all statutory and judicial requirements in doing so. No one should be financially penalized for being a survivor of abuse.

Drug Pricing

33. CMS has taken a number of steps to increase the transparency of Medicare drug costs in recent years, such as publishing the CMS Drug Spending Dashboard and releasing data on spending for most individual Part D drugs, including cost trends over time, rebates across drug classes, and prescriber information. Do you commit to continuing these transparency efforts? Will you continue to collect and publish this data?

Response: As I said during my opening statement to the Committee 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, manufacturing, 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 and innovation so Americans have access to high quality care.

I commit to continuing transparency efforts related to drug pricing.

34. During your time as head of a major pharmaceutical company, you advocated for market solutions to bring down the price of drugs. However, drugs with market monopolies – which are extended by drug manufacturers as long as possible by exploiting loopholes in the system – are immune from these forces. You stated in your HELP Committee hearing that you want to prevent this sort of “gaming” by the drug industry. Therefore, what specific legislative proposals do you plan to send to Congress that target the length of drug manufacturers’ market monopolies, or otherwise bring down the prices of drugs for which a monopoly persists?

Response: To clarify, branded companies secure the exclusive rights to practice a patent for a limited period of time or the exclusive use of approval data for a limited period of time. This is different from a monopoly, in that we see extensive competition and rebating even where patents remain valid, as a result of therapeutically substitutable molecules and treatments.

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.

Drug, Device, and Cosmetics Regulation

35. The Food and Drug Administration (FDA) assures that drugs meet the gold standard of being both safe and effective based on a scientific, non-political review before they are marketed to consumers. Do you support upholding this gold standard?

Response: Yes.

36. Patients, health care providers, and medical product manufacturers trust that the non-partisan, non-political, scientific independence of FDA ensures that only the integrity of scientific data supporting safety and efficacy drives approval decisions for drugs and devices. Are you committed to upholding this trust at the FDA?

Response: Yes.

37. While the FDA gold standard of approval helps to ensure the safety and efficacy of new products, we know that many new drugs and devices have not been studied on adequate numbers of women, people of different races and ethnicities, nor all age ranges. By implementing provisions of FDASIA, the FDA has taken a number of steps to improve the data required to be submitted for a new drug, and is reporting through Drug Snapshots the summaries of who was included in trials and whether there are safety or efficacy differences among subpopulations. The actions are just a first step and much more remains to be done.
- a. Do you support requiring inclusion of women and minorities in clinical trial data submitted to the FDA?

Response: Yes, I support the inclusion of women and minorities in clinical trial data submitted to the FDA and implementation of FDASIA, which requires the results of NIH funded clinical trials that include women and minorities be submitted to NIH's clinical trial data base.

- b. Are you committed to supporting additional work by the FDA to improve the diversity of clinical trials used to support medical product approvals?

Response: Yes, as appropriate.

- c. How will you ensure that doctors have information they need about how a new medication works in these subpopulations?

Response: If confirmed, I look forward to working with FDA’s senior leadership to ensure that sponsors have clear guidance on the ways in which truthful and non-misleading information regarding medical products may be shared with healthcare providers.

38. Biologic drugs are extremely important to patients, but the historic absence of competition has limited access and affordability to these important medicines while driving up health care costs. One of the best opportunities to help address this is to not only support for timely review and approval of biosimilars, but their introduction into the market.

a. Do you support the biosimilars pathway?

Response: Yes.

b. Do you believe that the development and approval of biosimilars is critical to a competitive market, and can benefit patients across the country?

Response: Yes.

c. What plans do you have for FDA and for CMS to encourage and speed their development and availability to patients?

Response: 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.

d. How do you plan to help educate physicians and the public about biosimilars to increase their uptake in the market?

Response: 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.

e. How do you plan to prevent gaming of exclusivities and the patent system by brand biologic makers to keep biosimilars off the market?

Response: 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.

39. In 2013, an outbreak of fungal meningitis took the lives of 64 people and sickened 751 in more than 20 states, including Georgia, Tennessee, North Carolina, Illinois, Rhode Island, Minnesota, and Pennsylvania. Congress responded by passing the bipartisan Drug Quality and Security Act (DQSA), which clarified and enhanced FDA's authority to regulate drug compounding. There has been broad-based support for FDA's implementation of the DQSA, and in inspecting pharmacies since the law was passed FDA has found disturbing violations and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently halted sterile operations as a result of these violations.

- a. Do you commit to protecting patients who need compounded drugs by continuing to implement and enforce this important public health law as written, including the requirements imposed by 503A?

Response: Yes.

- b. It is important that compounded drugs be used only for patients who have a medical need. These drugs have not gone through the full FDA approval process, which establishes the safety and efficacy profile of a drug, therefore, they should be used only for those patients for whom there is no available approved product. The availability of compounded drugs must not undermine the very important drug approval process. Will you commit to implementing the compounding law in a way that will not create a loophole in the FDA approval standards?

Response: Yes.

- c. Dr. Gottlieb has announced that in the interest in of encouraging pharmacies to register as outsourcing facilities, he is considering changes to certain FDA requirements governing how compounded drugs are manufactured. As FDA considers ways to address access issues around certain compounded drugs, to you commit to ensuring that FDA will maintain standards and processes that give providers a safe supply of sterile drugs?

Response: Yes.

- d. There is a growing concern about drug compounders misusing bulk drug substances to copy FDA-approved drugs and therefore undercutting the market. Will you take an active role in ensuring that FDA effectively implements the statutory limits on the use of bulk drug substances for compounding and enforces the statutory prohibition on copying approved drugs?

Response: Yes, I will work with FDA leadership to implement the compounding provisions of the Drug Quality and Security Act.

40. I believe that precision medicine relies on effective and meaningful lab tests to inform treatments, and that this area of innovation should be fostered. However, there are many recent examples of lab tests being marketed to physicians and patients that have no real clinical meaning. Are you committed to supporting a regulatory framework that would give patients and their providers confidence in the quality and veracity of their tests, and level the playing field for innovators?

Response: LDTs play a critical role in patient care, and it is important for both patients and their healthcare providers to have confidence in these tests. If confirmed, I will work closely with Administrator Verma and Commissioner Gottlieb to ensure we have a risk-based regulatory approach that supports patient access to reliable tests and advancing innovations in this area on behalf of patients.

41. The Fred Hutchinson Cancer Research Center develops treatments for serious diseases and has been on the forefront of advancing immunotherapy. An important part of the Fred Hutchinson mission is to get cures to patients and the FDA's Breakthrough Therapy Designation has been important as they drive towards this goal. As Secretary of HHS, how will you work with the FDA to ensure that the agency is supporting the approval of breakthrough therapies while also guarding patient safety?

Response: I support the breakthrough therapy approach and, if confirmed, look forward to being briefed by Commissioner Gottlieb on the FDA's efforts to balance approval of breakthrough therapies in a risk-based approach that also appropriately balances patient safety and access to breakthrough and potentially life-saving medicines.

42. The Fred Hutchinson Cancer Research Center is home to HICOR (Hutchinson Institute for Cancer Outcomes Research) which uses data to assess the economic burden of chronic disease in patients. This work provides powerful evidence that could help shape the discussion around health care and, importantly, the financial burden of treatments but the center's work is dependent on access to quality data from CMS. How will you work with CMS and other HHS agencies to ensure that data is accessible and actively informing policy? What priorities will you set to ensure access to high-quality data about health outcomes and spending?

Response: Data can be a very powerful tool to help identify and address challenges and opportunities across the healthcare delivery system. Program improvement is a continuous process, requiring continuous evaluation of data, and HHS has made significant progress in making data available to providers and researchers, like those at the Fred Hutchinson

Cancer Research Center. If confirmed, I will work with CMS and other HHS components to make sure appropriate data is made available and accessible to researchers and to the public, consistent with applicable laws.

43. In 2013 in my home state of Washington, 32 patients were sickened with antibiotic resistant infections that were traced back to contaminated duodenoscopes. An investigation by my office found that duodenoscopes around the country were harboring these bacteria, and that the cleaning protocols issued by the manufacturers were not sufficient. Since then, it has come to light that other reusable medical scopes have harbored potentially harmful bacteria—putting patients at risk. My investigation of contaminated duodenoscopes revealed that for medical devices, “FDA’s reliance on self-reporting of adverse events by manufacturers and hospitals is unworkable and outdated, particularly when contrasted with the active post-market surveillance system for drugs.” I believe that the FDA needs to do more to improve post-market surveillance for medical devices.
- a. Section 3059 of the 21st Century Cures Act requires the Secretary to publish a list of reusable devices, like medical scopes, that are required to have validated cleaning, disinfecting, and sterilization information for 510(k) clearance, and publish a guidance to clarify the when device modifications require the submission notification under 510(k). As Secretary, are you committed to publishing these documents by their statutory deadlines?

Response: Yes.

- b. The FDA has recently engaged with external stakeholders to establish the National Evaluation System for Health Technology, which acts as a hub for electronic data sources for medical device outcome and safety information. The NEST is also supported by the medical device industry in the MDUFA IV agreement, however, only for uses to improve pre-market review and approval of devices. Do you support the utilization of NEST for post-market surveillance activities? If so, do you commit to requesting funds in your budget for these activities?

Response: If confirmed, I look forward to being briefed by FDA on NEST and the opportunities to modernize the Agency’s post-marketing activities.

44. The Office of the Inspector General of the Department of Health and Human Services recently found that taxpayers spent more than \$1.5 billion for Medicare beneficiaries to receive treatment as a result of the failure of seven cardiac implants. Additionally, seniors spent \$140 million on out-of-pocket expenses to obtain care to treat these failures. To detect these problems sooner, the Inspector General recommended the addition of medical device identifiers to insurance claims—a commonsense reform that can prevent avoidable expenses to Medicare and seniors. That solution has also been endorsed by the Medicare Payment Advisory Commission and across the healthcare industry, including from health plans, clinical societies (including the Society of Thoracic Surgeons, American College of Cardiology, and American Academy of Orthopaedic Surgeons), patient groups, and hospitals, along with bipartisan support in Congress. While CMS and

FDA have both indicated support for this policy in the past, CMS has recently given conflicting responses as to its position, including indicating that it would review whether clinicians would be burdened by this policy change. Many healthcare providers have indicated and research has shown that adding device identifiers to claims would not place an undue burden on hospitals and clinicians. If confirmed, do you plan to advance this commonsense reform that has broad support and can simultaneously improve safety while reducing costs?

Response: If confirmed, I look forward to learning more about this issue, and working with the CMS team and other stakeholders to understand the potential benefits and costs. As you mention, there are two significant concerns at stake here: the integrity of the Medicare payment system and ensuring that we do not over-burden hardworking providers who care for beneficiaries and others. I take both concerns very seriously, and, if confirmed, I will work with CMS to ensure the agency carefully evaluates this proposal.

45. In December 2015, the FDA published final guidance that overturned the long standing ban on blood donations from men who have sex with men (MSM). The old policy was discriminatory, based on stereotypes, and scientifically unfounded. In addition, it prevented many healthy people from donating blood, while allowing some high-risk donors to donate. The 2015 guidance replaced the lifetime ban with a one-year deferral, but the one-year deferral remains an arbitrary time-based deferral not based on risk or science. Since the guidance was released, the FDA, in collaboration with other HHS agencies, has been working to collect the data necessary to implement a true risk-based deferral system for all donors, which will lead to a more robust and safer blood supply for American patients. Do you commit to continuing the studies and data collection necessary, including monitoring of behavioral risk factors of viral infections through the Transfusion-Transmissible Infections Monitoring System (TTIMS), to support the goal of transitioning to a risk-based blood donation deferral system for all blood donors?

Response: One of FDA's greatest public health responsibilities is ensuring the safety of our Nation's blood supply. If confirmed, I look forward to working with FDA to ensure that the Agency's regulation of our Nation's blood supply is science-based and fulfills the Agency's mission to protect public health.

46. I strongly support the Precision Medicine and the Beau Biden Cancer Moonshot Initiatives in order to improve patient outcomes by delivering "the right treatment to the right patient at the right time." How would you ensure continued multi-agency coordination and commitment to these initiatives including support of their regulatory oversight and recognition of their value to the broader health care system?

Response: Coordination and collaboration among agencies is essential to the progress of the Cancer Moonshot and the Precision Medicine Initiative. If confirmed, I look forward to working with all of the leaders and staff at HHS to ensure that these initiatives reach their full potential. I commit to reviewing the current progress and identifying any barriers to success for these projects, including support that can be provided from a regulatory perspective.

Food

47. Most of the sodium Americans consume is already processed into the food they buy, whether in a grocery store or at a restaurant. Researchers have found that reducing sodium intake to 2,300 milligrams per day would save an estimated \$10 billion to \$24 billion in health-care costs and 44,000 to 92,000 lives annually. Do you accept the scientific consensus and Dietary Guidelines for Americans recommendation that Americans should reduce their sodium intake to no more than 2,300 milligrams of sodium per day? Many food companies have undertaken sodium-reduction initiatives, but for industry leaders in this area, there is currently an uneven playing field. Do you support the FDA issuing voluntary sodium-reduction guidance to food companies to provide a level playing field for industry, as well as saving lives and reducing health-care costs?

Response: I agree that 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 healthcare costs. If confirmed, I will work with FDA leadership to make sure that the Agency's sodium policy advances the public health in a manner that takes into account all available information, empowers consumers in their decision making, and does not unnecessarily burden food manufacturers or increase costs for consumers.

48. For seven years my colleagues and I in the Senate have called on FDA to issue advice to pregnant women about seafood consumption based on the latest nutrition science, and consistent with the Dietary Guidelines for Americans. The FDA has researched this topic exhaustively and has concluded that maternal seafood consumption offers significant neurodevelopmental benefits for children. Despite commitments to complete the advice in 2011, final advice was not issued until January 18, 2017. I understand that the seafood advice issued on January 18th was published without OMB interagency review, is now inconsistent with the Dietary Guidelines, and was not tested with consumers to ensure the intended message was conveyed through the text. Will you commit to review, reevaluate, and submit the FDA seafood advice for interagency review to ensure that pregnant women receive the latest nutrition science about what to eat during pregnancy for their health and the health of their children?

Response: If confirmed, I will work with FDA leadership to ensure all consumers have the information they need to make informed decisions on what they are consuming.

49. The Dietary Guidelines for Americans provides an expert review of nutrition science every five years and is a critical public health document. It creates a strong, science-based foundation for nutrition advice and education, and it forms the basis of nutrition standards for government programs at the national, state, and local levels. In the last several years, there has been unprecedented political and industry pressure on the Dietary Guidelines, pushing the U.S. Department of Health and Human Services and the Department of Agriculture, to disregard science presented by outside experts on the Dietary Guidelines Advisory Committee.
- a. The National Academy of Medicine has now reviewed the process and issued two reports: one on how to select the advisory committee, and a second on how to improve the process of developing the guidelines. Will you ensure that the DGA

process remains transparent, science-based, and free from undo political influence?

Response: Yes.

- b. Will you commit to publishing substantive “deviations” between the report of the advisory committee and the final guidelines as recommended by the National Academy?

Response: If confirmed, I look forward to being briefed on this matter in greater detail.

50. The Department of HHS can have an important public health impact through efforts to support access to healthy food and sound nutrition policies and regulations. Former Secretary Price named childhood obesity prevention as a priority but nonetheless persisted in weakening, rather than strengthening, important protections that help keep kids healthy. And FDA Commissioner Gottlieb has indicated that the Trump Administration is working on a “broader policy initiative” on nutrition but the details remain unclear.

- a. What are your primary goals regarding food, including food safety, nutrition, and public health?

Response: Advancing the goals of food safety and nutrition is vital to HHS’s mission of protecting and promoting the public health. One of my goals in this area, if confirmed, is to continue implementation of the Food Safety and Modernization Act in a manner that is consistent with Congressional intent, advances the public health, ensures appropriate and fruitful collaboration with state and local partners, and does so in a manner that is not unnecessarily burdensome on our Nation’s food system. If confirmed, I also look forward to working with FDA leadership on policies to promote the use of nutritional information as a way to prevent disease and death by empowering consumers with information regarding their food choices.

- b. How do you plan to address the obesity epidemic, with regard to both children and adults, and to use your authority to reduce the incidence of diet-related diseases in the American population?

Response: If confirmed, I intend to maintain the Department’s commitment to addressing this issue. I would look forward to learning more about the work already underway on this issue and exploring how we can amplify this work to reach more individuals.

51. Forty-eight million Americans get sick every year from a foodborne illness, and 3,000 die as a result. Foodborne illness strikes hardest at our most vulnerable citizens: the elderly and children. When it comes to foodborne pathogens, no individual can see the risk, since the contamination is microscopic. So prevention measures, like those in the Food Safety Modernization Act (FSMA), are essential. The FDA has now proposed delaying important FSMA regulations that are intended to keep dangerous amounts of animal feces out of the water that is used on produce. The first Trump Administration budget would have effectively reduced funding for FDA’s food program. Will you fight to maintain or increase FDA funding to keep food safe and protected, particularly funding to implement

FSMA?

Response: Food safety is critically important for public health. If confirmed, I look forward to working with senior leaders in the Administration to make sure these vital activities are properly resourced.

52. Nutrition facts labels are designed to make it easier for consumers to be better informed about the food they buy and eat. Nutrition facts labels are especially important for people with certain medical conditions, including those with high blood pressure who rely on labels to check sodium levels and those with diabetes who rely on labels to manage their blood sugar and know how much insulin to pump. In October, the FDA proposed delaying the compliance deadline under the May 27, 2016, final Nutrition and Supplement Facts Label Rule. In response, FDA received thousands of comments, including comments from more than 40,000 people, twenty major public health and consumer groups, and even the Coca-Cola Company opposing the delay. I have also encouraged Commissioner Gottlieb to quickly issue guidance to support industry efforts to comply with the final rule and expedite implementation of the updated Nutrition Facts panel. Will you consider reversing this unnecessarily lengthy delay? And if not, why not?

Response: 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. If confirmed, I look forward to supporting a successful implementation of the nutrition fact labeling updates.

53. Menu labeling in restaurants and other establishments where people buy restaurant-like food is critical to providing people with the information they want to make healthy choices. Eighty percent of Americans support menu labeling, and it's especially important information because people are eating out more than ever before. The restaurant industry and over 100 nutrition and public health organizations and professionals supported the menu labeling law, which was the result of a bipartisan compromise. After repeated delays in the implementation of the final menu labeling rule, FDA recently issued new draft guidance for menu labeling, to address key concerns from industry. Do you support FDA's position not to further delay or weaken menu labeling and to meet the new implementation date in May 2018?

Response: It is important for regulations implementing the menu labeling statute to strike a balance, within the bounds established by Congress, to realize the public health benefit of providing information to consumers so they can make informed choices, while doing so in a workable manner that does not place unnecessary burdens on businesses without any public health benefit. If confirmed, I will work with FDA leadership to more fully understand the current state of implementation of these important menu labeling requirements.

LGTBO

54. There is consensus from the medical community that anti-LGBT conversion therapy has no treatment value and, in fact, is harmful. The Substance Abuse and Mental Health Services Administration recognized this consensus in a 2015 report. I want your reassurance that you will respect the medical community's judgment on conversion therapy. Do you commit that under you, HHS will continue to oppose conversion therapy? If not, justify your response using scientific, peer-reviewed studies or literature as evidence to back this viewpoint.

Response: As I mentioned during my confirmation hearing, I am committed to following medical, clinical, and scientific evidence.

55. Suicide is the second leading cause of death among young people ages 10 to 24. The rate of suicide attempts is four times greater for lesbian, gay, and bisexual youth than for others. For transgender youth, the rate is even higher. Do you agree that this is a national crisis requiring a priority response? Do you agree that the LGBT community must play an important part in developing that response? Will you commit to making this a national priority?

Response: Suicide is a serious issue that deserves our attention and response. Any individuals that can help us better develop a response should be involved.

56. Government-funded discrimination, in any guise, is counter to our nation's laws and values. The government should not discriminate in whom it hires or serves, and the government should not let groups that are paid to provide government services discriminate using federal funds either. Do you agree with the principle that federal contractors and grantees should not use taxpayer money to subsidize discrimination?

Response: I believe Americans have equal rights under the law, without distinction, and that the government should follow the law and not discriminate.

Maternity and family care

57. Two-thirds of births from unintended pregnancies are paid for by Medicaid or CHIP. In 2010, these publically funded unintended pregnancies cost state and federal governments \$21 billion dollars. Publicly funded family planning allows families to prepare for pregnancies and build healthy families. Given your interest in improving the efficiency of government, will you acknowledge the efficacy of investing in contraception and the need to continue the Medicaid state option to expand family planning services? Do you intend to continue to work with states to implement such programs?

Response: I support ensuring access to health care for all Americans. If confirmed, I will also work to promote a healthcare system that will provide access to quality care while ensuring patients are able to make decisions that work best for them. 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.

58. According to the CBO, repealing the ACA will increase the number of uninsured people by 32 million (to a total of 59 million people under the age of 65). Cutting access to vital Medicaid services for low-income women by block granting Medicaid will increase the U.S. maternal mortality rate. What will you do to reduce the U.S. maternal mortality rate, which is three times higher than in other developed nations?

Response: 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 Medicaid financing and payment proposals in order to hold states accountable to ensure patient access to high quality health care.

Medicaid and CHIP

59. The Children's Health Insurance Program (CHIP) program provides health coverage for children in low income families and has earned bipartisan support since it was first approved in 1997. The 2009 reauthorization of CHIP included important measures to strengthen the quality of care and improve health outcomes of children in Medicaid and CHIP. States are running out of CHIP funding because Congress failed to extend the program, which expired on September 30. Some states are already planning to send termination notices to families. Do you support extending CHIP and what steps will you take to extend funding as quickly as possible?

Response: It is important that every child has access to high-quality health coverage, and CHIP plays an important role in accomplishing this objective. CHIP can only be reauthorized by Congress and if confirmed, I will work with Congress to extend this important program.

60. Many children with extremely medically complex conditions are living today when just a decade ago, they would not. The vast majority of these children are Medicaid enrollees, and they benefit from Medicaid's EPSDT services. If these children lose Medicaid, they will face life threatening conditions. Will you support continued Medicaid and coverage of EPSDT services for these children?

Response: Medicaid has been the safety net for so many vulnerable American children. If confirmed, I will support continued coverage of EPSDT services for children in Medicaid consistent with the Department's statutory obligations

Medicare

61. The Centers for Medicare & Medicaid Services (CMS) recently rolled back and canceled Medicare demonstrations designed to advance payment models tied to value rather than volume. For instance, in August, CMS issued a proposed rule to cancel the Episode Payment Models and Cardiac Rehabilitation Incentive payment model programs. In addition, CMS is reducing the number of geographic areas participating in the Comprehensive Care for Joint Replacement model and making the remaining participation voluntary in the remaining geographic areas. Given its size, Medicare should be a leader in testing new payment models, but this Administration is pulling back from that role. Under your leadership, how will you ensure that CMS remains a leader in payment reform?

Response: As I made clear in my opening statement, 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 healthcare 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 the details or deliberative process behind the most recent actions cited in this question, but if confirmed, I look forward to coordinating with CMS and CMMI as they work toward their goal of fostering an affordable, accessible healthcare system that puts patients first. It is my understanding that CMS recently issued a Request for Information seeking feedback on a new direction for CMMI to promote patient-centered care and to test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes.

As I said during my opening statement to the Committee, we must make healthcare more affordable, more available, and more tailored to what individuals want and need in their care. If confirmed, I look forward to working with CMS to explore payment models that reduce costs and increase quality for Medicare beneficiaries, taking full advantage of the stakeholder input CMS receives through the recent RFI.

Mental Health and Substance Use Disorders

62. There is a critical shortage of mental health providers in the United States. For example, a recent survey from the American Association of Medical Colleges found that almost 60 percent of psychiatrists are aged 55 or older, making psychiatry the fourth oldest medical specialty in terms of practitioner age. The AAMC further noted that while the number of active specialty physicians grew 7.7 percent between 2010 and 2015, the number of active psychiatrists fell by 1.4 percent—from 38,289 to 37,736.⁵ Shortages are particularly acute in subspecialties. For example, according to the American Academy of Adolescent and Child Psychiatry there are only 8,300 practicing child and adolescent psychiatrists.⁶ As a result, wait times to see a child or adolescent psychiatrist average 7.5 weeks. These facts are especially troubling considering approximately 44,000 Americans annually die by suicide; individuals with serious mental illness often wind up in a jail or prison rather than receiving appropriate mental health care; and approximately 100 million Americans live in areas with inadequate access to mental health professionals.⁷ How would you sustain and expand federal investment in mental health workforce training? Will you commit to proposing budget requests for the Department of Health and Human Services that invest in the mental health workforce rather than cutting it as you proposed as a member of Congress?

⁵ *Active Physicians by Age and Specialty, 2015*. (2017). *aamc.org*. Retrieved 1 December 2017, from <https://www.aamc.org/data/workforce/reports/458494/1-4-chart.html>

⁶ *Workforce Issues*. (2017). *aacap.org*. Retrieved 1 December 2017, from http://www.aacap.org/aacap/resources_for_primary_care/Workforce_Issues.aspx

⁷ *FastStats*. (2017). *cdc.gov*. Retrieved 1 December 2017, from <https://www.cdc.gov/nchs/fastats/suicide.htm>;

Radnofsky, L. (2017). *Where Are the Mental-Health Providers?* *WSJ*. Retrieved 1 December 2017, from <https://www.wsj.com/articles/where-are-the-mental-health-providers-1424145646>

Response: The shortage of skilled mental health professionals across the nation is of critical importance and demands our attention. The shortage impacts the provision of services to address serious mental illness and serious emotional disturbance. We need to support efforts that not only leverage the skills of the current behavioral health workforce, but also support new clinicians in entering the field. If confirmed, I look forward to working with agencies, such as SAMHSA and HRSA, to ensure that we are addressing the shortage.

63. The substance use treatment workforce cannot currently meet the demand for substance use disorder prevention, treatment, and recovery services. How would you as HHS Secretary incentivize physicians and other providers to join that workforce treatment workforce?

Response: We must ensure that physicians and providers have the tools needed to provide adequate prevention, treatment, and recovery services. This includes working to ensure that HHS is not creating unnecessary regulatory burdens on practitioners that make it difficult to provide care to patients. If confirmed, I look forward to working with agencies, such as SAMHSA and HRSA, to ensure that we are addressing the shortage.

64. The Comprehensive Addiction and Recovery Act (CARA) permits Nurse Practitioners and Physician Assistants to prescribe buprenorphine to treat substance use disorders for five years. Would you support making this permanent? Do you believe that rulemaking is necessary to implement this change?

Response: Expanding access to medication-assisted treatment (MAT) is a primary goal of HHS's opioid strategy, and Nurse Practitioners (NPs) and Physician Assistants (PAs) play an important role in meeting that goal.

I have not reviewed this provision in order to make a determination about whether rulemaking is necessary, but I would certainly commit to looking into this should I be confirmed. I do know that this Administration is committed to reducing regulatory burden and supporting providers, and I would seek to continue this, if confirmed.

65. You have indicated that addressing the opioids crisis is one of your priorities, but also suggested that you are not sure if additional resources are necessary. The President just donated a portion of his annual salary to HHS to the opioids crisis. Do you believe that amount will be helpful? If not, why not. If so, do you believe that \$100,000 is approximately the correct additional amount of funding that is necessary for the nation to address the opioids crisis?

Response: As you note, the opioid crisis is one of the top four priorities I will be working on if confirmed as Secretary. If confirmed, I plan to ensure that all components of the agency are dedicated to advancing the five-point strategy developed to address this issue. While I am not familiar with all of the efforts currently underway at the Department, I plan to review all actions to address the opioid crisis, if confirmed. Ultimately, funding decisions will be made by the Congress. I do believe that any additional funding to address the

opioid crisis is helpful, and I would plan to ensure that the \$100,000 donated by President Trump is put to good use, if confirmed.

NIH, Scientific Research, and Research Funding

66. Are you committed to the world-class peer review process that has helped NIH, FDA, and other HHS agencies make such important strides in developing cures for disease and improving health through the federal funding of scientific research? If no, what specific changes do you envision?

Response: I am deeply committed to the peer review process that has served biomedical research well for many years. The core values of peer review drive the NIH to seek the highest level of ethical standards, and form the foundation for the laws, regulations and policies that govern the NIH peer review process.

67. Given significant evidence of health disparities in communities such as racial and ethnic minorities, women, people with disabilities, and LGBT people, do you believe the government has an interest in funding research that addresses the needs of subpopulations? Do you believe that NIH-funded research should be designed in such a way that it is of equal benefit to all people? How would you ensure effective implementation of the provisions of the 21st Century Cures Act that seek to address this?

Response: I believe Dr. Collins, the Director of NIH, has spoken on this many times. NIH has a strong interest in funding research that identifies and reduces health disparities, and furthermore, NIH is investing quite heavily in precision medicine, which is designed to target interventions to smaller and smaller subgroups. I look forward to working with Dr. Collins to implement the provisions of the 21st Century Cures Act that are aimed at improving inclusion and data sharing so that research benefits all people.

68. What actions do you plan to take to coordinate with the Secretary of Energy to utilize the Department of Energy's (DOE) national laboratories' scientific, technological and supercomputing capabilities noted in the 21st Century Cures Act's provision on advancing the Precision Medicine Initiative? Do you view the DOE national laboratories' scientific, technological and supercomputing capabilities as having a role in contributing to HHS' mission needs?

Response: I do firmly believe in the potential of harnessing big data, supercomputing, and advanced and predictive analytics to help HHS fulfill its mission. The Department of Energy (DOE) national laboratories play a role in contributing to the HHS mission needs. If confirmed, I look forward to continuing implementation of the 21st Century Cures Act, including the Precision Medicine Initiative, and would work to leverage resources at DOE that could be beneficial to our work.

Public Health

69. As the nation faces tragic increases in opioid abuse, we are also seeing a parallel increase in hepatitis C (HCV) infections and HIV infections among those who inject opioids and share syringes, often the tragic culmination of a growing addiction. One of the starkest examples of this is the HIV outbreak in Scott County, Indiana, the home state of Vice President Pence. In response to this, a public health emergency was declared and the Vice

President changed positions and allowed Syringe Services Programs to operate in his state. Syringe Services Programs (SSPs) have been shown to be effective in reducing needle sharing and reducing transmission of HCV and HIV, without increasing drug use. The CDC, Institute of Medicine, and many other scientific bodies have stated unequivocally that SSPs are highly effective in stopping the spread of HIV/AIDS and Hepatitis C. For this reason, Congress recently lifted the restrictions on use of federal funds for SSPs. Do you support continued availability of federal funds for SSPs, based on local public health department determination of need?

Response: I know that the Department and the Administration are committed to bringing everything we have to bear to address the opioid crisis. 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 as intended.

70. An important part of the Department of Health and Human Services' mission is to protect Americans from chronic and infectious diseases. Investments in evidence-based, cost-effective preventive services such as tobacco cessation and immunizations can reduce the risk of developing cancer, heart and lung diseases, and other serious illnesses. The guarantee of no-cost access to recommended clinical preventive services has been key to increasing access to these critical tools. Do you believe that all patients and families should have access to comprehensive, affordable clinical preventive services? How would you utilize these and other preventive tools to help Americans avoid diseases as HHS Secretary?

Response: I believe that all Americans should have access to the healthcare they need. Individuals 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 work to support that goal for all Americans, and I look forward to implementing the laws passed by Congress.

71. In November 2016 Health Affairs published a study based on 16 years of data from a large cohort of U.S. communities showing that "deaths due to cardiovascular disease, diabetes, and influenza decline significantly over time among communities that expand multi sector networks supporting population health activities. The findings imply that incentives and infrastructure supporting multi sector population health activities may help close geographic and socioeconomic disparities in population health." These findings support the growing momentum in the public health and medical community to invest in what has been termed community prevention: evidence based strategies based on community needs that address the underlying determinants of health. Community prevention has been a successful hallmark of the ACA's Prevention and Public Health Fund under the leadership of the Centers for Disease Control and Prevention (CDC). What is your vision for continuing these types of community-based upstream investments in the public's health?

Response: Working at the community level promotes healthy living, helps prevent chronic diseases and brings the greatest health benefits to the greatest number of people in need. If confirmed, I would support CDC's work to identify the unique needs, assets, and opportunities of communities and empower those communities to implement what works in chronic disease prevention.

72. You once stated that we can accrue real benefits by preparing now before the next pandemic strikes and that *"Preparation runs along a continuum. We won't ever become completely prepared or finished and done with our preparation efforts. Preparation is like money or friends. Some is good, but more is better."* In FY 17, the Prevention and Public Health Fund supported over \$324 million in funds – about half of the program's total – from the CDC to states, counties, and city and tribal health departments to support the public health immunization infrastructure and outbreak response for vaccine preventable diseases. Yet the Prevention Fund has repeatedly been proposed for elimination by the Trump Administration, including in every Trumpcare bill.
- a. What role do you see for the federal government in supporting states, counties, and city and tribal health departments in strengthening the public health immunization infrastructure?

Response: 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.

- b. What impact do you believe repeal of the Prevention and Public Health Fund, which accounts for 12 percent of CDC's budget, would have on public health?

Response: I am not familiar with CDC's budget or the particulars of how the agency has used the Prevention and Public Health Fund (PPHF) resources. If confirmed, I look forward to ensuring that the Department has the resources to carry out its mission.

73. In the last few years, our nation has confronted immediate public health crises including natural disasters, Zika, Ebola, and H1N1—all of which required a quick and significant government response in order to protect Americans. How will you educate the President, White House staff, and other members of the Cabinet about the importance of public health, public health preparedness, and research?

Response: There are multiple existing mechanisms for high-level cross-departmental work to create Administration policy for preparedness and response to public health threats whether naturally occurring or man-made including biological, environmental, chemical, or radiology emergencies. I commit to full participation of the Department of Health and Human Services in all existing and newly created policy groups. Likewise, when there is a developing public health emergency, I will brief the President, White House offices, and other cabinet members as needed. HHS offices/agencies specializing in public health and public health preparedness, including ASPR, CDC, and NIH will inform these briefings and provide both high-level and subject matter expertise from the public health arena on a given topic of emergency.

74. In November 2016, President Obama issued an executive order to advance the U.S. Global Health Security Agenda, which works to strengthen health systems globally to prevent, detect, and control emerging infectious diseases. This has implications for both global health and American health security, by preventing global pandemics with potential to directly affect the health of Americans. Given that HHS agencies have led many of these programs, as Secretary, how would you support and enhance Global Health Security efforts to detect, prevent, and respond to diseases internationally? What are your priorities to shape the next phase of health security programs? The initial Global Health Security Agenda commitment was for five years; how will you work with Congress to sustain the Global Health Security commitment and ensure that there is sustained and stable funding to prevent the spread of future pandemics?

Response: 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.

75. Antimicrobial resistance continues to be a serious public health threat, exacerbated by modern travel that allows pathogens to travel quickly and efficiently. Hospitals face challenges with travelers who return home from other countries and introduce drug-resistant bacteria to hospital settings, putting other patients and medical staff at risk. The November 13 Presidential Message on Antibiotic Awareness Week included the important commitment to implementing the National Action Plan for Combating Antibiotic-Resistant Bacteria. It specifically identified the need to focus on both the scientific investments required to prevent, diagnose, and treat infections, and well as the need to improve prescribing and use of existing drugs.
- a. What will you do to ensure the CDC has the resources it needs to provide the guidance and technical assistance needed to improve antibiotic stewardship in the US? What will you do to ensure the CDC has the resources it needs to maintain and expand the capacity of its regional lab network to strengthen national surveillance of antibiotic resistance?

Response: 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.

- b. As you know, BARDA has played an important role in incentivizing drug development and NIH is conducting and funding critical basic research to help overcome some of the scientific barriers impeding drug discovery. If confirmed, will you commit that the agency continues this critical work and prioritizes the discovery and development of new antibiotics?
- c. Under your leadership, how will you ensure the FDA, in cooperation with the CDC and USDA, has the resources it needs to both promote stewardship in the agriculture industry?
- d. Under your leadership, how will you ensure the FDA, in cooperation with the CDC and USDA, can enhance its data collection on antibiotic use on the farm?

- e. How will you ensure that the federal government partners with both domestic and international partners to surveil the origination and global spread of drug-resistant bacteria?

Response to b-e: With the expansion of international travel, antibiotic resistant infections can spread quickly between countries, including the United States, requiring all countries to take steps to stop this spread. If we continue to act aggressively, we can slow transmission of AR infections. If confirmed, I look forward to working with CDC to ensure that we are doing all we can to partner with other countries to stop the spread of drug-resistant bacteria. In addition, I would look forward to working with BARDA and the NIH to continue work on the discovery and development of new antibiotics. The FDA also plays a critical role in this space by working with the agricultural community, and I intend to continue this work, if confirmed, as well as important coordination with the USDA.

- f. Are there areas where you believe the federal government could improve its surveillance and response efforts to antimicrobial resistance?

Response: If confirmed, I look forward to learning about HHS's current surveillance and response efforts and working to strengthen our efforts to respond to antimicrobial resistance.

76. According to the Administration's National Action Plan update released earlier this month, the agency has made progress in strengthening one-health surveillance efforts. Under your leadership, what will the agency do to enhance capacity in state and federal veterinary and food safety laboratories to conduct antibiotic susceptibility testing and characterize zoonotic and animal pathogens?

Response: HHS's surveillance work is critically important, and I am pleased to know that the agency has made progress in this area. I have not been privy to the specific work ongoing in this area, but I look forward to learning about the efforts underway and supporting work to ensure that this progress continues.

77. In 2016, the Zika outbreak was accompanied by an exceptionally high rate of related birth defects, including a much higher than average rate of microcephaly. Fortunately, the immediate threat posed by the Zika virus seems to have waned, but the extent of the outbreak and its effects are still unknown. If confirmed, will you commit to continuing the fight against the spread of Zika and its devastating birth defects? How will you ensure that children born with microcephaly and their families continue to get the care and support they need? Do you commit to prioritizing public health investments in access to contraception and family planning services, as primary tools to prevent Zika-associated birth defects by allowing women to time their pregnancies?

Response: Despite the lower number of Zika cases in 2017, the threat posed by this virus remains of concern and there is still much we do not know about Zika and its long-term impacts. I know that the HHS agencies, including CDC and NIH, have been involved in research and surveillance of the Zika virus, and I look forward to being involved in these

efforts, if confirmed. We must continue our vigilance and ensure that the public is armed with the best information to protect against this virus.

78. Gun violence is a leading cause of premature death in the U.S., killing almost 30,000 people and causing 60,000 injuries annually. Do you view gun violence as a public health issue? How would you address this public health threat? Would you support lifting restrictions on CDC for funding for research into gun violence and its effects on public health?

Response: I am not aware of any prohibition on gun violence research. I believe we must better understand why individuals commit violence and seek to address the causes of this violence.

79. After the Sandy Hook shooting, NIH issued a new funding opportunity for “Research on the Health Determinants and Consequences of Violence and its Prevention, Particularly Firearm Violence” that supported 22 projects, but closed it on January 8, 2017. Despite a letter from more than half of the Senate Democratic Caucus urging NIH to renew this funding the agency continues to keep the opportunity closed. Do you agree that gun violence is a pressing public health challenge that warrants further investigation?

Response: I believe that mental health and serious mental illness is a public health issue that is of top concern. In addition, I agree that we need to better understand what is causing individuals to commit violence independent of the tool used to cause harm.

80. There is growing evidence that health-related social needs such as stable housing can dramatically affect health outcomes, especially for those incurring some of the highest health care costs in Medicare or Medicaid. There are now a number of demonstration projects being undertaken either directly through programs such as the State Innovation Model Grants and the forthcoming Accountable Health Communities program or through the use of Medicaid 1115 waivers, like in my home state of Washington, to test different approaches to addressing health-related social needs of beneficiaries. Will you assure that CMS continues to support such innovation that sufficient resources will be available to states to continue these experiments?

Response: I support continued efforts to use CMS’s innovation authorities to test and evaluate demonstrations that support Medicare and Medicaid benefits with other services and supports that can lower health care costs or improve quality, as the statute requires. 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. 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 the continued support and the timely review of all state waivers received by HHS.

81. Globally, tuberculosis remains one of the leading causes of death, particularly in low-income countries. Fortunately, after a slight increase in national TB cases in the United States in 2015, the number of cases declined again in 2016. Yet, in 2013, CDC identified drug resistant TB as a serious public health threat. The President's FY18 budget request proposed cutting funding for CDC's domestic TB program, and the CDC has stated that are our response to TB "has stalled." What do you see as the role of HHS in addressing TB, both domestically and internationally? Will you seek to strengthen our response to this infectious disease, including the drug-resistant forms of the disease?

Response: The U.S. has been highly successful over the past two decades at reducing domestic tuberculosis (TB) cases and rates. In addition, successfully addressing TB in the United States requires global attention. CDC works with partner countries to enhance platforms and activities critical for successful TB control. If confirmed, I look forward to continuing HHS' work to address TB.

82. Vaccination is considered one of the most important public health achievements of our time and continues to offer great promise for Americans. Through timely vaccination, nearly 20 million cases of infectious diseases and 42,000 deaths are averted every year in this country. And yet the President has often cited discredited, anti-scientific claims with regards to vaccines. First, do you believe vaccines are safe and effective? If confirmed, will you be a vocal proponent of vaccination? How will you ensure CDC and state health departments have sufficient funds to ensure immunization coverage if the Prevention and Public Health Fund is repealed? What steps do you think can be taken to increase vaccine uptake, including vaccines that have been disproportionately underutilized, such as the HPV vaccine?

Response: Vaccines are one of the greatest success stories in public health and are among the most cost-effective ways to prevent disease. If confirmed, HHS will continue to advance the best science and advocate for use of vaccines.

83. How can we better ensure that drugs, devices, food, and other products regulated by the FDA – that are developed and produced outside our borders – meet the quality and safety standards that consumers in this country trust?

Response: I appreciate that FDA's responsibilities span critical areas with an increasingly complex and global footprint. If confirmed, I look forward to working closely with the FDA to make sure that the Agency is properly resourced to fulfill its critical public health mission.

84. Hurricanes Harvey, Irma, and Maria cost lives and decimated homes, infrastructure, and public health resources in states and territories including Florida, Louisiana, Texas, Puerto Rico, and the U.S. Virgin Islands. Congress has since passed two emergency supplemental bills adding up to over \$51 billion, which helped fund immediate needs like temporary housing and restoring critical services. However, the long-term response is ongoing: communities are in need of critical medicines; property is irreparably damaged with water and mold; and debris has destroyed power systems, water systems, and roads. In Puerto Rico and the U.S. Virgin Islands, the Administration's response has been

particularly insufficient in helping survivors of the crisis who struggle to access power, food, potable water, and medical care.

- a. How would you evaluate the Administration's response to the hurricanes and the lives they affected?

Response: The United States faced an unprecedented hurricane season in 2017 with multiple category four or stronger hurricanes making landfall in a short period of time. Without having access to all of the information on the response activities, it is difficult to offer a complete evaluation of the response. If confirmed, I will support an evaluation of the response activities so that successes can be built on, and shortfalls can be fixed. The recovery from the storms will take years, and I believe HHS should continue to partner with the states, commonwealth, and territory impacted by the storms until recovery is complete.

- b. What lessons were learned from these disasters?

Response: Without having access to internal department information, it is difficult to know what lessons have been learned. During my previous time at the Department, I assisted in developing hurricane after-action reports. As Secretary, I will ensure after-action reports are compiled and that the recommendations are appropriately implemented in a timely fashion.

- c. What specifically can be done now and in the future to ensure community resiliency and adequate federal response, including public health and medical response, to natural disasters?

Response: During my previous time at HHS, I was fortunate to participate in establishing the Office of the Assistant Secretary for Preparedness and Response (and its predecessor), which assists in ensuring we prepare for, and respond effectively to manmade and naturally occurring public health emergencies. Programs within HHS assist state and local public health agencies and healthcare facilities in preparing for public health emergencies. This hurricane season has shown the successes from investing in community resilience, as were evidenced in the quick recovery of hospital systems in Houston; as well as the work we still need to do, as evidenced in the Florida Keys, Puerto Rico, and the U.S. Virgin Islands.

Tobacco

85. More than 16 million Americans are currently living with a tobacco-caused disease, and treating tobacco-caused disease costs the nation approximately \$170 billion a year. Yet, until 2009 no federal agency had authority over cigarettes and other tobacco products. As Secretary of the Department of Health and Human Services, you would oversee the FDA. Do you believe FDA should have authority over cigarettes and other tobacco products, such as e-cigarettes? Do you support the steps FDA has taken so far to regulate tobacco products? Are you committed to fully implementing the Tobacco Control Act and the FDA's recently finalized deeming rule and supporting tobacco prevention and cessation initiatives at FDA and CDC which have been so successful at driving down smoking rates among adults and children? Would you support FDA taking additional steps to regulate tobacco products if the agency found that such regulations would reduce youth

use of tobacco products and reduce tobacco-caused death and disease? What additional steps to you think are needed at this time?

Response: 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 soon see the end of addictive cigarettes, something which was viewed as impossible in the not-so-distant past.

86. Recent data from the Centers for Disease Control and Prevention reveals that youth are using tobacco products like e-cigarettes and cigars at alarming rates – in 2016, 11.3 percent of high school students reported that they had used e-cigarettes in the past 30 days and 7.7 percent reported that they had smoked cigars in the same timeframe. While Congress has prohibited the use of flavors other than menthol in cigarettes, e-cigarettes and cigars are still available in kid-friendly flavors like gummy bear and cotton candy. The Food and Drug Administration’s Population Assessment of Tobacco and Health (PATH) study found that 71 percent of cigar users ages 12-17 had used a flavored cigar in the past month, and 73 percent of those users mentioned the flavor as the reason that they used the product. Similarly, 85 percent of e-cigarette users ages 12-17 had used a flavored e-cigarette in the past month, and 81 percent of those users again cited the flavor as their reason for using e-cigarettes. Do you believe that the use of flavorings contributes to kids’ use of e-cigarettes and cigars and is helping to addict another generation of youth to tobacco products?

Response: Yes, I am extremely concerned about this issue, and I support Commissioner Gottlieb’s recent efforts to review kid-appealing tobacco flavors as part of FDA’s comprehensive approach to tobacco and nicotine regulation.

87. The FDA’s Tobacco Products Scientific Advisory Committee found, in 2011, that menthol cigarettes have an adverse impact on public health. In 2013, FDA’s own staff scientists issued a report finding that menthol cigarettes pose a public health risk greater than non-menthol cigarettes. Based on these findings, over four years ago, FDA issued an Advance Notice of Proposed Rulemaking on menthol in cigarettes, yet the agency has taken no further action. Given that research shows that menthol in cigarettes increases youth initiation of smoking by masking the harshness of smoke, and makes it harder for some smokers to quit, will you commit to having FDA within the next year issue a proposed rule prohibiting menthol as a characterizing flavor in cigarettes and report back to this committee on your plans for addressing mentholated cigarettes within 60 days of your confirmation?

Response: As previously stated, I am extremely concerned about anything that encourages youth tobacco use and that impedes individuals from quitting. If confirmed, I will work with FDA's leadership to better understand how menthol factors into the Agency's tobacco and nicotine regulatory framework.

Women's Health

88. A number of large, peer-reviewed studies have carefully examined the relationship between abortion care and breast cancer, and have almost uniformly determined that no causal link exists between abortion and breast cancer. For example, a Danish study conducted in the 1990s reviewed the medical records of all Danish women born between 1935 and 1978—some 1.5 million women—and found that abortion has no overall effect on the risk of breast cancer. Likewise, a similar study conducted at Harvard in 2007 followed more than 100,000 women for twenty years, and again found that no difference in breast cancer risk for women who had an abortion. As Secretary of the Department of Health and Human Services, would you support evidence-based medicine and support health care that reflects the agreed-on best practices of the medical community?

Response: Yes, I am supportive of evidence-based medicine.

89. Under President Trump and Secretary Price, HHS has supported efforts to permit states to discriminate against abortion providers and prevent them from participating in federally-supported family planning programs. Previous efforts to restrict access providers in this manner has led to substandard access to family planning and other preventive care for women. Do you believe that these women should have access to the provider of their choice? Should states be able to discriminate against providers, like essential community providers like Planned Parenthood?

Response: States have the best read on the level of access available for their citizens and deference should be paid to their judgment, whenever possible, and within the confines of federal conscience protections.

90. As Secretary, how would you respond if a senior official in your agency was promoting or recommending a change in HHS policy that did not reflect evidence-based best practices or well-established medical science?

Response: As I mentioned during my confirmation hearing, I am committed to following the evidence. If confirmed, I will ensure that this is a principle in all of HHS's work.

91. Preventing unintended pregnancy is important to women's health, and can reduce maternal mortality and infant mortality. How do you plan to increase access to the full-range of FDA approved contraceptive methods?

Response: Preventing unintended pregnancy is important to women's health. As I said in my opening statement to the Committee, we must make health care more affordable, more available, and more tailored to the medical care individuals need. If confirmed, I look forward to working with Congress to ensure that such a system is in place.

92. Do you believe health insurance should cover contraceptives and contraceptive

counseling without a copay?

Response: All Americans deserve the power to choose the kind of coverage they need and want, rather than Congress or HHS mandating what they must purchase and at what price. That said, the so-called “contraceptive mandate,” promulgated by HRSA, is still in effect, subject to federal and Constitutional conscience protections.

93. You indicated that you thought there were only a few employers who were interested in utilizing the recently issued IFRs on birth control. As the IFRs apply to practically all for-profit employers as well as universities and could impact coverage for millions of women, will you withdraw the IFRs?

Response: The IFRs only apply to those businesses that have a moral or religious objection to providing contraception. Consistent with the longstanding protections for conscience in health care adopted by Congress, it is critical that we balance individuals’ access to healthcare with the protection of conscience of those with contrary moral or religious beliefs.

94. Will you continue to implement the HRSA women’s preventive services guidelines, including the contraceptive coverage benefit?

Response: If confirmed as Secretary, I will faithfully implement laws written by Congress.

95. As HHS Secretary, would you commit to ensuring that the Title X program continues to make a broad range of family planning methods and services available to the patients that seek care at Title X-funded sites?

Response: If confirmed, I commit to following the statutory language governing the Title X program, which requires Title X projects to offer a broad range of acceptable and effective family planning methods and services.

96. The Title X family planning program requirements, which among other things outline the parameters of the grant program for participating health care providers, are currently set forth in regulation.⁸ To amend these requirements, the agency must use the notice-and-comment rulemaking process prescribed by the Administrative Procedure Act (APA) at 5 U.S.C. § 553, which allows for the most open and transparent exchange between stakeholders and the agency through public comment and furnishes the agency with valuable information about the impact of any changes it proposes. Lesser pronouncements, such as guidance documents and funding announcements, should only be used to explain existing law. This critical distinction between the effect of rulemaking versus the effect of guidance documents was affirmed by the U.S. Department of Justice in a recent memo.

- a. Do you agree that notice-and-comment rulemaking is the most robust means to assure the agency is furnished the best information about the effects of its policy decisions?
- b. Do you agree that notice-and-comment rulemaking is necessary to amend the

⁸ 42 C.F.R. part 59

law, including the Title X program requirements?

- c. As HHS Secretary, do you commit to upholding the rule of law by subjecting any proposed changes or additions to the Title X requirements to notice-and-comment rulemaking as prescribed by the APA?

Response to a-c: The Administrative Procedure Act provides the American people with transparency and the opportunity to participate in the rulemaking process. If confirmed, I commit to following the requirements of the APA to issue or revise any regulations.

97. You have expressed support for reducing health care costs. Preventive health care is one of the best ways to improve health while cutting costs. How will you ensure women have access to affordable preventive health care, such as breast cancer screenings, cervical cancer screenings, HIV testing, STI counseling, contraceptives and contraceptive counseling, screening for intimate partner violence, and well-woman visits?

Response: I do believe that prevention is important, and I look forward to implementing the laws put in place by Congress.

Workforce and Medical Education

98. HHS oversees a portfolio of health workforce training programs. Describe your vision for supporting health workforce training that develops practitioners who are ready to engage in patient-centered, team-based care—particularly in professions with pronounced shortages and in underserved areas. What opportunities do you see to move the currently siloed federal support authorized in Title VII and VIII of the Public Health Service Act and Medicare graduate medical education, toward one that is more focused on interprofessional education and one that meets the needs of vulnerable patient populations?

Response: 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.

99. The Affordable Care Act secured health workforce training investments in order to meet the increasing demand on our delivery system, including loan repayment and forgiveness programs, scholarships, residency slots and workforce planning to improve the distribution of health workers in underserved areas. How will you support workforce training programs to ensure access to quality care, and leverage your authority to build on these programs to address shortages in health professions shortages and the specialized cultural and linguistic needs of different patient populations?

Response: I understand the critical importance of having a strong health workforce in order to meet the varied health care needs of the American people. The nationwide shortage of physicians and more general health care workforce policy questions are central to the health care challenges our country faces. If confirmed, I look forward to working with Congress and other stakeholders to expand career options and paths for all healthcare professionals.

HIT

100. One of the top priorities in the 21st Century Cures Act was preventing information blocking by technology developers, providers, and other organizations. The President's budget request for the Office of the Inspector General, which is responsible for investigating allegations of information blocking, did not include any request for funding to carry out these investigations. Will you commit to providing adequate resources to stop the practice of information blocking?

Response: I support the goals of the 21st Century Cures Act in respect to health information technology. I agree that preventing information blocking should be a top priority. It is a crucial to achieving interoperability of health information technology. If confirmed, I look forward to working with Congress to make sure this important provision is implemented.

101. One of the most important ways that the 21st Century Cures Act promotes interoperability of health information technology is establishing a new set of criteria for certification. These criteria require free flow of information among users of the technology, real-world testing, and the use of open application programming interfaces. Will you make implementing these new criteria a top priority?

Response: I agree that interoperable health information technology is one of the key enablers for improving cost, quality, and value in our healthcare system. I believe that all individuals, their families, and their healthcare providers should have appropriate access to electronic health information that facilitates informed decision-making, supports coordinated health management, allows individuals and caregivers to be active partners and participants in their health and care, and improves the overall health of the nation. Application Programming Interfaces (APIs) will be key to opening the data according to the appropriate access described above. As required in the 21st Century Cures Act, I will ensure that implementation of the conditions of certification, including the publication by developers of APIs and the availability of data through APIs, will be a priority.

102. The President's proposed budget would cut funding to the Office of the National Coordinator for Health Information Technology—or ONC—by more than a third. At the same time, Congress through the 21st Century Cures Act has instructed your department and ONC in particular to advance the exchange of healthcare data—known as interoperability—and support enhancements to the efficient use of electronic health records. Improvements in both these areas can lead to higher quality and safer patient care by giving patients better access to their own electronic health information and ensuring that clinicians have accurate and up-to-date information on their patients, and

that the design and use of electronic health records does not lead to inadvertent patient harm—such as through patients receiving the wrong dose of a drug. Several approaches to improve safety have been proposed. For example, the Institute of Medicine and ONC have supported the establishment of a health IT safety collaborative where the public and private sectors can work together to detect common safety problems and develop solutions. And, implementation of provisions in the 21st Century Cures Act offer ONC an opportunity to focus on health information technology safety. Given the extreme budget cuts proposed to ONC, how do you plan to prioritize enhancing the safety of electronic health records?

Response: I support the goals of the 21st Century Cures Act in respect to health information technology and if confirmed, commit to prioritizing interoperability. There are a number of safety organizations in the private sector who will be vital partners to help take on this important issue.

103. Health information technology—and electronic health records in particular—have the potential to dramatically improve the safety and quality of patient care. The transition from paper to digital records offers clinicians new tools to warn them of drug-drug interactions, model the progression of a patient’s illness, and provide key data to inform care decisions. Yet, the adoption of this technology can also lead to inadvertent harm—such as where the layout of electronic health records and how they are used contribute to medical errors. We’ve heard many stories, including of patients harmed because they received the wrong dose of a drug based on the design of the health record, or patient test results not being displayed. Provisions in the 21st Century Cures Act encourage your department to improve the use of electronic health records, including by developing measures related to their user-centered design. How do you plan to leverage provisions in the 21st Century Cures Act to improve patient safety?

Response: I support the goals of the 21st Century Cures Act in respect to health information technology and if confirmed, commit to work within the Department and with external stakeholders to improve the use of electronic health records.

Strategic Plan

104. The HHS draft strategic plan for 2018-2022 and a request for information on “Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding” suggest that HHS intends to expand the unsound policy in the SAMHSA regulations regarding hiring discrimination to other forms of discrimination, such as discrimination in the delivery of services. HHS-funded programs exist to benefit the individual recipients of services, not to benefit faith-based contractors or grantees. HHS-funded programs are critical to the health and well-being of many people across the country and therefore they must be as effective, available, and accessible as possible. These programs should be focused on assisting individuals by increasing access to health care and human services. Denying individuals the services they need undermines the purpose of these programs, and expanding religious exemptions will fall hardest on those who already face barriers to accessing services and care. If confirmed, will you guarantee that the Department will not create exemptions

that result in discrimination against beneficiaries or allow contractors and grantees to refuse to provide services they would be otherwise required to provide?

Response: Ensuring that the government does not impose any artificial barriers to healthcare access is an important aspect of HHS's mission. In addition to ensuring that unnecessary regulatory burdens on healthcare providers are minimized, HHS can also work to broaden healthcare access by ensuring that healthcare providers, doctors, nurses, pharmacists, and all of those whose skill and education in providing important medical and wellness care are not driven out of America's healthcare system by being made to feel that they must choose between their deepest moral convictions and the medical profession.

105. HHS recently solicited public comments on its new 2018-2022 draft Strategic Plan, a document that traditionally serves as a roadmap for the department's activities and priorities in the next five years. The current Draft Strategic Plan does not meet the requirements under law to create measurable workplan – instead, it essentially serves as political messaging in support of the Administration's perceived allies, without any measurable performance goals to benchmark qualitative or quantitative progress. Such a plan diminishes government accountability, and drafting an execution plan without measurable benchmarks to determine success is likely to simply waste valuable government resources. As Secretary, do you intend to attempt to implement the Draft Strategic Plan as written, or will you be issuing a new Draft Strategic Plan that more properly complies with the statutory requirements?

Response: The development of the Department's strategic plan proceeds in stages with the requirements and deadlines for each stage set by statute or OMB guidance. It is my impression that the draft strategic plan met the requirements for the relevant stage when published in September. I am sure that the Department's final Strategic Plan will meet the requirements of the statute. If confirmed in time to have an impact on the Strategic Plan, I will ensure that the 2018–2022 Strategic Plan is able to serve as a measurable work plan to guide HHS's progress over the coming four years and can be used to hold HHS to appropriate standards of accountability – and as I did when I was Deputy Secretary, I will work to ensure that the Department successfully implements the Strategic Plan using the established benchmarks to measure its progress in each area.

106. The draft strategic plan also includes language defining an individual's lifespan from "conception" to "natural death," and states that it will respect "the inherent dignity of persons from conception to natural death." As you know, well-established constitutional caselaw explicitly rejects the idea that legal personhood begins at conception. Forty years ago, in their *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 holding has been consistently upheld and reaffirmed by the Supreme Court, including just last year in *Whole Woman's Health v. Hellerstedt*. The draft strategic plan would undermine this fundamental right by advancing an unconstitutional definition of persons as beginning at conception, which has no basis in science. As Secretary, would you stand by this harmful, unconstitutional, and non-medical definition remaining in the HHS strategic plan?

Response: The mission of HHS is to enhance the health and well-being of all Americans, and this includes the unborn.

Senator Sanders

1. Do you believe health care is a right, not a privilege, and the quality of care you receive should not depend on where you live or how much money you have?

Response: All Americans ought to have access to quality, affordable healthcare. We must make healthcare more affordable, more available, and more tailored to what individuals want and need in their care.

2. President Trump stated during the campaign “I’m not going to cut Medicare or Medicaid.” Do you agree with this statement?

Response: I share the President’s commitment to making Medicare and Medicaid as effective and efficient as possible for the people that we serve. 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.

If we can move to a more value-driven system of health care, we will do two things that are really important. One of them is that we will actually stretch out the resources in the Medicare and Medicaid programs to sustain the programs. Secondly, we will allow Medicare to better serve more beneficiaries, as the baby boomer generation ages into the program.

3. Yes or no, do you believe high drug prices restrict access to medicines for U.S. consumers? If yes, can you explain why Eli Lilly consistently raised the price of its insulin products while you were the president of the US division?

Response: As I said at my hearing drug prices, including insulin 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.

4. Do you believe that prescription drugs are unaffordable for seniors? To what factors and influences do you attribute these costs?

Response: Part D has worked to make prescription drugs available and affordable for 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, or a Medicare Advantage prescription drug plan, as they choose. 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.

5. During your prepared remarks in the first hearing, you said "drug prices are too high." Do you stand by that statement? You went on to testify that, thanks to your experience implementing Part D and your time in the insurance industry, you believe you have the skills to address the problem and work to ensure all Americans have access to care. While you were president of Eli Lilly's US division, the corporation consistently raised the price of insulin. In last year's annual report, Eli Lilly described the ability of the Department of Health and Human Services to negotiate drug prices in Medicare as a "risk" to the corporation. Given this experience, explain how you are equipped to fight to lower drug prices.

Response: As I said at the hearing, drug prices are too high. The current system of pricing insulins and other medicines may meet the needs of many stakeholders, but that system is not working for the patients who have to pay out-of-pocket. If confirmed I will work to fix this system. My experiences in the public sector, implementing the Medicare Part D program, and through my experiences in the private sector have afforded me an understanding how the system works, how manufacturers, payers, pharmacy benefit managers, pharmacies, distributors all work together. If confirmed, I will hit the ground running to work with Congress to identify solutions.

6. As a result of the ACA's closing the Part D donut hole, 10.7 million Part D beneficiaries saved \$20.8 billion in prescription drug costs from 2010 to 2015. Are you in favor of repealing the ACA provision that closes the donut hole? If so, do you acknowledge that this will increase Medicare beneficiaries' prescription drug costs?

Response: My role as HHS Secretary would be to execute the laws that Congress passes. I look forward to working with Congress on making drugs more affordable for Medicare beneficiaries.

7. With concerns about drug prices increasing significantly year-over-year, a common response from drug makers is that list prices do not take into account rebates. However, these discounts, including those paid to Medicare Part D plans, remain confidential. Will

you take steps, and if so which ones, to improve the transparency of the true prices being paid by taxpayers for drugs in public programs?

Response: 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.

8. While on the campaign trail, President Trump stated, “we are not allowed to negotiate drug prices. Can you believe it?” Do you as Secretary plan on advocating for policies that would allow for CMS to negotiate drug prices?

Response: 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 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.

9. In opposing importation, you’ve stated that “This thing about importing drugs from Canada is a canard. . . These are not American-produced drugs.” As the former president of Eli Lilly USA, you know that many drugs sold in the U.S. are manufactured in other countries, including the drug Jardiance sold by Eli Lilly to treat Type 2 diabetes. It is manufactured in Germany. A three-month supply of Jardiance costs \$1500 in the U.S., however the same drug in Canada costs \$500.
- a. Do you believe that drugs approved and sold in places like the EU, Canada, Australia, and Japan are just as safe as drugs sold in the U.S.?

Response: The issue is not the safety of drugs approved and distributed within Canada’s, the U.K.’s, and Australia’s closed distribution systems, rather the challenge is that the opening of U.S. borders to a free-for-all importation of drugs, from even these countries, does not in any way guarantee that the drugs entering into our country are the actual drugs that would be available in those countries through their closed and legitimate distribution system. It is my understanding that many websites that purport to be Canadian online pharmacies, or other sources of drugs from developed countries, may be fraudulent, and that the prescription drugs being offered for sale to American consumers through such sources may not have been subject to review by regulators in developed countries. In recent years, HHS has worked with the Department of Justice and foreign law enforcement agencies to take down and pursue enforcement actions against those who market counterfeit, unsafe, and/or substandard drugs through such sources. Such criminal enterprises continue to pose a significant risk to American patients and consumers, and it is important that any policy on imports not unintentionally expand this risk.

- b. If you do believe they are just as safe, as Secretary, will you commit to implementing current law and allow for the importation of prescription drugs?
- c. If no, why not? And please describe what you would do as Secretary to create a system to allow Americans to import safe and affordable drugs from other countries.

Response to a & b: 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. 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, when such pilot/model is scaled up to represent the likely level of importation, of no additional risk to the public's health and safety and a significant reduction in costs for American consumers, as Congress has established in the 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 unreasonable 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 information facts to which I do not currently have access.

- 10. A Commonwealth Fund study has shown that nearly 1 out of 5 adults between the ages of 19-64 do not fill a needed prescription because it is too expensive. You know that people who are sick may get sicker, or even die, if they do not take the medicine they are prescribed. Do you believe high drug prices restrict access to medicines for patients?

Response: The current system clearly needs improving. If confirmed, I look forward to working with the various agencies at HHS to come up with strategies to help make drugs more affordable for patients.

- 11. The federal government does not fund Medicaid in Puerto Rico and the U.S. Virgin Islands the same way it funds Medicaid in the states. While total federal Medicaid funding is available to states on an open-ended basis, it is capped for Puerto Rico and the U.S. Virgin Islands. While state Medicaid programs receive federal matching funds based on a formula reflecting their need, federal matching for Puerto Rico and the U.S. Virgin Islands is capped in statute at an insufficient 55 percent. This is particularly troubling due to the high poverty rates in the territories. In fact, by some estimates, if the federal government funded Medicaid in Puerto Rico using the same formula it uses for states, Puerto Rico would receive 83 percent federal matching instead of 55 percent.
 - a. As HHS Secretary, what would you do to ensure not only adequate funding but equitable funding for health care in Puerto Rico and the U.S. Virgin Islands?

- b. Do you support eliminating the Medicaid funding cap and the 55 percent federal matching limit in Puerto Rico and the U.S. Virgin Islands?
- c. In your opinion, what can be done to rebuild and reform the health care system in Puerto Rico and the U.S. Virgin Islands so that it is stronger than it was before the hurricanes?

Response to a-c: 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. States and territories must be given the flexibility they need to provide the highest quality healthcare they can to their own unique communities. Removing unnecessary red tape and requirements would allow states to provide high quality care while also preparing for and responding to their unique challenges and emergency situations.

- 12. Congressional Republicans stand behind a plan that would increase the Medicare eligibility age from 65 to 67 to generate savings for the federal government. It is well documented that these savings ultimately shift costs to the American people, to states, and to employers. Under this proposal, 65 to 66 year olds would have to pay on average \$2,200 more in out-of-pocket costs a year. Medicare beneficiaries, whose average income is less than \$24,150 per year, are already spending 23 percent of the average Social Security check on Medicare Parts B and D premiums and cost sharing alone. Do you agree that seniors should not have to pay more for health care?

Response: 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.

- 13. As Secretary of Health and Human Services you would have the authority to test new payment options through the Center for Medicare and Medicaid Innovation. If you are confirmed, would you use CMMI to test a voucher system for Medicare?

Response: If confirmed, I look forward to coordinating with CMS and CMMI as they work toward their goal of fostering an affordable, accessible healthcare system that puts patients first. It is my understanding that CMS recently issued a Request for Information seeking feedback on a new direction for CMMI to promote patient-centered care and to test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes.

A top priority would be harnessing 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.

14. How can the government support the fast growing senior population who are living in or facing living in poverty?

Response: In addition to programs like Social Security, Medicare, and Medicaid, the HHS Administration for Community Living administers Older Americans Act programs that help make independent living in the community a viable option for many older adults through services such as home-delivered meals, homemaker assistance, transportation, senior centers, and other community-based services. I am committed to eliminating barriers to employment, regardless of age or disability. Older adults should have the opportunity to be employed and live productive lives. If confirmed, I will work with HHS agencies, the Department of Labor, and others to remove barriers to employment for older adults and people with disabilities.

15. More than 30 years ago, Congress implemented protections to ensure that Medicare providers fairly and equally bill people with Medicare, in response to growing concerns that people with Medicare charged over and above the standard Part B coinsurance of 20 percent were going without critical care. One study found that medical spending declined by 9 percent in Medicare households as a result of these protections. Do you support repealing these protections and allowing Medicare doctors to charge patients whatever price they choose?

Response: I support fostering an affordable, accessible healthcare system that puts patients first and support testing 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 as Secretary, I would faithfully implement laws written by Congress and the regulations issued by the Department.

16. The Older Americans Act was recently reauthorized but recommended funding increases haven't occurred. Home based services funded by the OAA have been flat lined or reduced. Will you commit to honoring the increased funding recommendations, and to ensure that OAA services receive – at the minimum – yearly cost of living increases? Further, Seniors are the fastest growing demographic nationally, with growth rates almost double that of younger cohorts. How will you assure that the programs serving seniors, such as nutrition programs, caregiver support, legal services, and job training are effective and remain adequately funded?

Response: I believe that the use of innovation and evidence-based practices will be critical to keeping these programs vital and to meeting the evolving needs of older Americans. 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. To do that most effectively and efficiently, we have to work together across all levels of government and with all potential partners to establish innovative strategies for meeting these goals.

17. Most seniors want to remain at home rather than go into a nursing home. Yet home based services do not always receive consistent funding, and the funding they do receive is insufficient. How can you help shift the balance so that seniors can get what they want and need, in a less expensive way, for the end of their life, rather than have no other option but to move into an expensive nursing home?

Response: I share your concern that HHS's programs support home-based services for those who would need them, as well as institutional care for those for whom that setting is more appropriate. If confirmed, 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.

18. I fought very hard to get more funding for community health centers into the Affordable Care Act. But that was not the only key funding for health centers in the ACA—they get a significant amount of funding from patients using Medicaid, especially those newly eligible under the Medicaid expansion. Community health centers are a key part of the safety net. In fact, one in six Medicaid beneficiaries get care at community health centers, and nearly half of all patients at health centers are covered by Medicaid. Gutting Medicaid funding would be a huge blow to community health centers, especially in rural areas where people have fewer options than those who live in urban areas. How do you plan to help low-income people access care when you take away both their insurance and their doctor?

Response: 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 to nearly 26 million people nationwide and make services available to residents of their service area regardless of ability to pay.

19. The National Health Service Corps is a key HHS program providing loan repayment and scholarships to primary care providers—including dental care and mental health care providers—serving 10 million people in underserved communities in this country. The program is over 40 years old and has regularly received high marks for performance, impact, and cost-effectiveness from bipartisan Administrations. However, the funding for the program expires later this year. In fact, we need an additional 52,000 primary care providers by 2025 and thousands of other health care providers to meet the growing need. And we need those providers to take jobs all over the country, including in very rural communities who do not traditionally attract new graduates. Yes or no, do you support expanding loan repayment and scholarships for primary care providers who are going to work in underserved communities?

Response: If confirmed, I will support primary care providers working in underserved communities. The NHSC continues to serve as a vitally important recruitment tool for community health centers and other health care entities nation-wide operating in underserved areas where shortages of health care professionals exist. I will support loan

repayment and scholarships for primary care providers who are going to work in underserved communities.

20. Our country is facing a shortage of primary care physicians, which is especially catastrophic in rural and traditionally underserved areas. How can we incentivize more medical students and health care providers to go into primary care?

Response: Recruiting and retaining primary care physicians has been a challenge for rural communities, and I agree that this should be an important focus area for the Department. HHS has a number of grant programs that rural communities can apply to for funding to address workforce issues including the Rural Health Outreach, Rural Health Network Development, and Rural Network Planning Programs. If confirmed, I will work to support access to primary care in rural communities.

21. 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. Will you ensure that Medicare covers medically necessary oral health care, as currently allowed by the statute?

Response: Oral health is an important aspect of general health and wellbeing. 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. If confirmed, I will faithfully implement the law to ensure that Medicare covers medically necessary oral healthcare.

22. What will you do to eliminate racial disparities and institutionalized racism in the health care system?

Response: 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.

23. Health disparities have been and continue to be a persistent problem in the nation's healthcare system. Studies confirm that these disparities not only have a negative health impact, but also a negative economic impact – in terms of direct and indirect costs – to this nation. Literature shows that people in rural communities often receive worse healthcare and suffer worse health outcomes than those in urban communities; women

often receive a lower quality of healthcare than men; and individuals from racial and ethnic minority communities often suffer worse health outcomes and suffer from lower quality of care than their White counterparts. Additionally, studies confirm that people with disabilities often receive a lower quality of healthcare than those without disabilities; and that those from the LGBTQ community are treated less well than their heterosexual counterparts. When the Affordable Care Act was signed into law, there were numerous provisions that very directly sought to reduce and ultimately eliminate so many of these types of health disparities. What are your specific plans, if you become the HHS Secretary, to address all of these health disparities and to ensure that the progress that has been made since 2010 continues to move in the right direction?

Response: It is vitally important that the United States healthcare system provide meaningful access to quality medical care, health, and wellness for all Americans. I believe that every person counts, has inherent dignity, and has value. If confirmed, as Secretary I would ensure that the Department addresses health disparities and the disparities that arise from lack of health care providers in certain areas of the country.

I am committed to ensuring that community health centers continue to be funded, so that they can increase access to primary care. In addition, we will work to educate the American people, and especially those in disadvantaged communities about how they can take responsibility for improving their health and wellness outcomes – and to give them the necessary tools for them to help themselves. We 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.

24. I come from a rural state where ambulance services play an absolutely critical role in our health care infrastructure. The GAO has recognized that current Medicare rates fall short of covering the cost of providing ambulance health care services in urban, rural, and super-rural areas. Congress has authorized Medicare adjustment payments for many years now. These add-ons are vital to maintaining ambulance services in this country. They expire at the end of this year. Can you tell me how you will work with the ambulance industry to protect these front-line health care providers and find ways to make sure that Medicare is setting reimbursement rates to cover the cost they incur in providing these services?

Response: I believe that access to ambulance services is important for ensuring that Medicare beneficiaries can be transported to facilities for essential treatment. In communities across the country, particularly rural communities, ambulance services are a critical link in emergency care and the healthcare system. The statute provides add-on payments for ambulance services furnished in urban, rural, and super-rural areas that expire at the end of 2017. Congressional action would be required for these add-on payments to be extended. If confirmed as Secretary, I would be ready to assist Congress with any information you need, and follow the law regarding ambulance add-on payments as written and passed by Congress.

Senator Casey

LGBTQ Issues

1. 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?

Response: 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 healthcare 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

2. 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.
 - a. 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?
 - b. Will you commit to ensuring that we will maintain the current level of insurance among children and young adults?

Response to a & b: 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 healthcare system that is more affordable and accessible.

Pregnancy Assistance Fund

3. 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 one year. I am concerned that HHS has shortened the grant periods from three years to one, 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?

Response: I look forward to working with your office to learn more about this program.

Disabilities

4. 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 verses 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?

Response: Since January, my understanding is that the Administration has worked with state partners and other stakeholders to implement provisions of a final regulation defining a 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 the administration's work with states on home and community based programs that meet the needs of those who rely on them, including those with disabilities.

5. In 2008, Congress passed, by an overwhelming bipartisan majority, the Americans with Disabilities Act Amendments. 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 the ADA Amendments Act. I would like to know where you stand on this issue.

- a. Do you think people who get treatment for disabilities such as epilepsy and diabetes should not be protected from discrimination by the ADA?
- b. Do you think it should be legal to discriminate against people with chronic health conditions?

Response to a & b: As I said in my opening statement to the Committee, we must make healthcare more affordable, more available, and more tailored to what individuals want and 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.

6. 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?
 - a. On a similar note, do you think it should be legal to discriminate against people with chronic health conditions?
 - b. 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.⁹ Will you commit to supporting the ACA's ban on discrimination on the basis of pre-existing conditions?

Response to a & b: The President has made clear that any replacement must make insurance more affordable, have more choices, and provide the insurance coverage that people need. In addition, it 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 healthcare 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.

7. 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

⁹ <http://kff.org/health-reform/issue-brief/pre-existing-conditions-and-medical-underwriting-in-the-individual-insurance-market-prior-to-the-aca/>

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?

Response: As stated above, the President has made clear that any replacement must make insurance more affordable, have more choices, and provide the insurance coverage that people need. In addition, it 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 healthcare 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.

8. With major demographic changes occurring in the United States, are you concerned about the shortage of racial and ethnic minority mental health professionals and the poor quality of mental health services for underserved minorities? If so, are you supportive of federal efforts to increase the numbers of individuals from diverse ethnic backgrounds entering into health professions as well as increasing cultural competence of our health workforce?

Response: 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.

9. 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?

Response: 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.

10. 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 to 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?

Response: 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

11. 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?

Response: If confirmed, I will prioritize working with states to provide families the best opportunities to access quality, affordable child care. In the President's Fiscal Year 2018 Budget Request, HHS requested \$5.7 billion for the CCDF program, which is estimated to serve about 1.4 million children each month. HHS is committed to working with states to help leverage all available resources to provide access to child care for the working families who need it.

12. 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?

Response: I am not aware that Corporation for Public Broadcasting (CPB) is within HHS's jurisdiction.

13. 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?

Response: 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.

14. 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?

Response: 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.

15. 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?

Response: 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.

16. 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 five are ready to succeed in school and life?

Response: 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 we serve are better prepared for success in school and life.

Agency for Healthcare Research and Quality

17. 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 five 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?

Response: Efforts to improve patient safety are important. I have not been privy to budget formulations and cannot speak to AHRQ's funding request.

Maternal & Infant Health

18. 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?

Response: 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.

19. 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?

Response: I believe that all women should have access to quality, affordable healthcare and to services they choose that work for them and that meet their needs.

Viral Hepatitis Elimination

20. 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.

- a. 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?

Response: 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.

- b. 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?

Response: 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.

21. 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?

Response: 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.

22. 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?

Response: 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

23. 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?

Response: Yes.

Public Health Preparedness

24. 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?

Response: 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.

25. 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?

Response: 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.

26. 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?

Response: During my previous tenure at HHS, I was deeply involved in creating mechanisms to support sustainable investment research and development for biomedical countermeasures. I look forward to working with Drs. Kadlec, Fauci, Fitzgerald, and Gottlieb to enhance U.S. preparedness for infectious disease threats.

27. 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?

Response: 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.

28. 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?

Response: 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.

29. 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?

Response: 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 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 biotreats 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.

30. 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, if confirmed, to renew HHS' commitment to fully-funding the SRF, as Congress intended?

Response: 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

31. 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 ten to fifteen 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?

Response: NIH is the world leader in biomedical research, and I will do everything in my power to maintain this tradition.

32. 30 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?

Response: Having worked at HHS previously, I know the agency 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 & Drug Administration

33. 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?

Response: 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.

34. 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?

Response: 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.

35. 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?

Response: If confirmed, I look forward to being briefed on this issue by the Agency leadership and subject matter experts.

36. 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?

Response: 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.

37. 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?

Response: 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. If confirmed, I look forward to supporting a successful implementation of the nutrition fact labeling updates.

38. 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?

Response: 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.

39. 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 two 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?

Response: 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.

40. 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 healthcare 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?

Response: 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 healthcare 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.

41. 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?

Response: Food safety is vitally important, and I will support the Department and the Agency in being properly resourced in this critical public health work.

Rural Health

42. 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?

Response: Telehealth can provide innovative means of making healthcare more flexible and patient-centric. Innovation within the telehealth space could help to expand access within rural and underserved areas. 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.

Grandfamilies and Caregivers

43. 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.

- a. How do you think improved coordination and collaboration across the government and with experts will help these grandparents and relatives?

Response: 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 healthcare, behavioral healthcare, 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 non-duplicative, and financially efficient.

- b. Given the support for this bill, we are confident that it 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?

Response: 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

44. As Americans age, they are often confronted with greater health care needs. Historically, seniors paid up to eleven 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%). 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?

Response: 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. 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 healthcare reforms that create effective risk pools.

45. 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?

Response: 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.

46. Older Americans Act (OAA) Nutrition Programs are serving 23 million fewer meals¹⁰ 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 GAO report¹¹ 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?

Response: The OAA nutrition programs offered through the Administration for Community Living help meet the needs of many of the nation's older adults. The

¹⁰ <http://www.agid.acl.gov/CustomTables/SPR/Data/>

¹¹ <http://www.gao.gov/products/GAO-15-601R>

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% of ACL's nutrition funding for exploring innovative ways to provide these services.

47. 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?

Response: 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.

48. 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?

Response: 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.

49. 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. This flexibility will reduce burden on state administering agencies as well as seniors.

The Administration on Aging also oversees two federally-funded nutrition programs that are critical to the health and wellbeing 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?

Response: If confirmed, I will continue to support the value of these vital nutrition programs for older adults.

50. 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% of hospitalized older adults and 35% to 50% of older adults in long-term care facilities are malnourished. Of hospitalized older adults, an estimated 20% had an average nutrient intake of less than 50% 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?

Response: 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)

51. 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?

Response: 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.

Drug Pricing

52. 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?

Response: 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.

Cooperation with Congressional Requests

53. In order for Congress to fulfill its constitutional duty to conduct oversight, Members of Congress must be able to receive testimony, briefings and other information from the Executive Branch upon request. To ensure that you and your agency fulfill its obligations to respond to congressional inquiries in a timely and comprehensive manner, I ask the following:

- a. If confirmed, do you commit without reservation to comply with any request or summons to appear and testify before committees of Congress?

Response: I will continue to uphold the long-standing tradition of the Secretary testifying presuming a reasonable notification is given.

- b. If confirmed, do you commit without reservation to respond in a timely manner to all congressional inquiries and requests for information from Members of Congress, including request from Members in the minority?

Response: Yes, I will make sure the Department is as responsive as it possibly can be.

- c. If confirmed, do you commit without reservation to take all reasonable steps to ensure that you and your agency comply with deadlines established for requested information?

Response: Yes, I will make sure the Department attempts to meet all relevant deadlines.

- d. If confirmed, do you commit without reservation to protect subordinate officials or employees from reprisal or retaliation for any testimony, briefings or communications with Members of Congress?

Response: Yes.

Senator Baldwin

1. Do you believe patients deserve to know the comparative effectiveness of prescription drugs so that they can take it into consideration, along with price, when determining the right course of treatment? If not, why shouldn't patients and physicians have this information?

Response: I believe it is important for patients to have access to information in order to make informed decisions.

2. Reports show that in 2013, about 40 million family caregivers in the U.S. provided an estimated 37 billion hours of care to an adult with limitations in daily activities. The estimated economic value of their unpaid contributions was approximately \$470 billion in 2013, up from an estimated \$450 billion in 2009. To recognize and support family caregivers, I have co-authored the *RAISE Family Caregivers Act* with my colleague Senator Susan Collins. Do you share my view that family caregivers must be recognized as official members of the long-term care team? As our baby boomers rapidly age, how would you strengthen our long-term care system and support family caregivers?

Response: Caregiving is a labor of love, and families are the major provider of long-term care for older adults and people with disabilities in the U.S. Many caregivers work and regularly experience the conflict of these competing responsibilities. Family caregivers must be engaged in the long-term care planning process and should have access to training and supports necessary to enable them to be successful in this challenging role. HHS should continue to play an important leadership and advocacy role as a facilitator of a national dialogue on how to leverage a variety of resources and coordinate efforts for a more comprehensive approach to supporting family caregivers. If confirmed, I look forward to working with congressional and state leaders to support caregivers.

3. The Centers for Disease Control and Prevention (CDC) reports that in 2015, 33,000 people died from opioids, including heroin, which is tragically a new record high. It is vital that individuals have access to life-saving opioid overdose reversal drugs. Unfortunately, the price of the drug naloxone has increased dramatically in recent years. Narcan, a naloxone nasal spray, costs \$150 for a two pack and a two-pack of Evzio, a naloxone auto-injector, has increased from \$690 in 2014 to \$4,500 today. I agree with President Trump that the Secretary of HHS should be able to negotiate directly with drug companies. Do you agree with me and President Trump and support letting the Secretary negotiate drug prices in Medicare?

Response: As I said during my opening statement to the Committee drug prices are too high. The President has made this clear. In addition, in an effort to expand access, I will work hand in hand with the Administration 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. 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, such as naloxone, leads to lower list prices.

4. In 2016, CDC released safe opioid prescribing guidelines for outpatient settings. These critically important guidelines were developed using the latest science on opioid safety and pain care, and were the result of collaborative efforts among stakeholders and leaders throughout the federal government. I am a strong supporter of these guidelines and other efforts to empower our providers with the latest science and education to help them care for our families. How will you work to ensure that the CDC guidelines are widely disseminated and that providers maintain immediate access to the most up to date science on safe opioid prescribing and alternative treatments to opioids?

Response: Education of providers is a critical element as we look to stem the tide of the opioid epidemic. I am committed to working with Dr. Fitzgerald at the CDC in order to develop strategies to ensure that the guidelines are widely disseminated.

5. How would you support medical research efforts to develop novel therapies to treat opioid addiction, and how would you make such treatments accessible?

Response: Addressing the opioid crisis is a top priority for the Department of Health and Human Services. As just one example, HHS through the NIH is launching a public-private collaborative research initiative to address the opioid crisis. The goal of this partnership is to identify the scientific strategies with the greatest potential. By bringing together innovative experts from government, industry, and academia, the goal is to develop novel therapies to treat opioid addiction but also to develop non-addictive pain medications. If confirmed, I look forward to supporting this initiative.

6. The opioid and illicit drug epidemic continues to ravage my home state of Wisconsin. It is growing so fast that we now need to add fentanyl to what is today a major health crisis. Milwaukee County, Wisconsin, has already seen a record 101 fentanyl-related deaths this year. I am concerned that President Trump has failed to match words with action because he did not call for additional funding to combat the opioid emergency. When I have traveled Wisconsin to talk to families and local leaders, their message is clear: Washington needs to continue to be a strong partner in this fight. If confirmed, would you commit to meaningfully address this emergency by providing the necessary additional and sustained funding to improve prevention, treatment and recovery? Yes or no?

Response: If confirmed, I would look forward to working with the Administration and Congress to address the opioid crisis.

7. Trump's Administration has also called on drug companies that manufacture opioids to do their part in fighting the epidemic. As a former drug company executive, do you believe the pharmaceutical industry has played a role in proliferating the opioid epidemic and overprescribing?

Response: The opioid epidemic is a public health crisis on an unprecedented scale. There are many contributing factors to today's opioid epidemic. Certainly, the pharmaceutical industry played a role in this crisis. If confirmed, combatting this crisis will be one of my

highest priorities.

8. What do you see as HHS's role in collaborating with the Department of Veterans Affairs on efforts to improve treatment of chronic pain, reduce opioid abuse and misuse, and share research and clinical data on safe and effective alternative treatments and services?

Response: The opioid crisis is one of the top four priorities I will be working on if confirmed as Secretary. I plan to continue this work and will look to collaborate with other agencies, including the Department of Veterans Affairs, whenever I can.

9. How will you advance efforts to develop safe and effective opioid treatment alternatives for those living with chronic pain?

Response: As mentioned above, the public-private partnership is an important effort underway at NIH to spur the innovation and development of non-addictive opioids and other treatment alternatives. In addition, CDC has issued guidelines to help guide prescribers as they treat patients with pain. Ongoing education of providers about alternatives to opioids can play an important role in addressing the crisis. If confirmed, I would look forward to working across the agency to ensure the development and availability of these alternatives.

10. What other efforts would you implement or seek to advance to increase opioid and other Substance use disorder prevention and treatment services?

Response: Addressing the opioid crisis is a top priority for the Administration. HHS has developed a five-point strategy to guide its work and, if confirmed, I plan to continue the great work already underway there. Of course, if confirmed, I would review the current efforts and ensure that we are using our resources and expertise to the fullest.

11. Contraceptive use has enabled women to make fundamental decisions about childbearing, delay when they first become parents, avoid the health risks associated with short pregnancy spacing, and achieve better birth outcomes when they do have children. For all these reasons, the CDC identified the development of and access to effective contraception as one of the top 10 public health achievements of the 20th century. Given these facts, do you think contraception is health care for women that should be covered under public and private insurance in the same manner as other preventive services?

Response: Contraception and family planning are an important part of women's healthcare. I believe that all women should have access to quality, affordable healthcare and to services they choose that work for them and that meet their needs.

I defer to Congress as to the requirements imposed on health insurers.

12. Most American women will seek health care services related to pregnancy and childbirth at some point during their childbearing years. Prior to passage of the Affordable Care Act, more than 60% of plans offered in the individual market explicitly excluded coverage for pregnancy and childbirth. In Wisconsin, not even one individual health plan offered maternity care for families before the ACA. Do you agree that all women should have access to guaranteed insurance coverage for prenatal care and delivery as an essential health benefit?

Response: The mission of the U.S. Department of Health and Human Services (HHS) is to protect the health and well-being of all Americans. I believe that everyone should have access to quality, affordable healthcare and insurance coverage that works for them and that meets their needs. Individuals 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 work to support that goal for all Americans.

13. Title X of the Public Health Service Act requires Title X-funded projects to provide a broad range of effective family planning methods and services, and women who obtain care from such service sites must be given the same options. A recently leaked White House memo detailed plans to refocus Title X to provide “fertility awareness methods” or natural family planning to patients, while excluding the broad range of methods that are currently offered and available. As Secretary, would you commit to ensuring that Title X-funded sites continue to make a broad range of family planning methods and services available to patients? Are you aware that fertility awareness methods and natural family planning are less effective than other forms of birth control?

Response: If confirmed, I commit to following the statutory language governing the Title X program, which requires Title X projects to offer a broad range of acceptable and effective family planning methods and services and which expressly includes natural family planning methods, and services for adolescents.

14. The Title X program requirements give patients at Title X-funded centers the right to receive non-directive pregnancy options counseling, information, and referral upon request for prenatal care and delivery. The information provided is consistent with the recommendations of medical experts. As Secretary, would you commit to ensuring that patients receive complete and medically accurate information about their pregnancy options? Can you guarantee that HHS would uphold the existing Title X program requirements that ensure women are given comprehensive, medically accurate information by doctors and health care providers at Title-X funded centers during the course of their pregnancy?

Response: If confirmed, I commit to implementing the Title X program in accordance with its statutory requirements.

15. You have publicly stated that you support making changes to the ACA. How would you go about ensuring that health plans cover pregnancies and maternity care, given that approximately half of pregnancies are unplanned?

Response: I believe that all women should have access to quality, affordable healthcare 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.

16. On September 26, 2017, HHS issued a draft Strategic Plan which eliminates language from previous strategic plans about support for LGBT individuals. I have long fought to ensure equal rights and access to health care for all individuals, including LGBT Americans. In 2011, I helped advocate for an IOM report to study the health of LGBT Americans, which

found that as a nation we lack sufficient understanding of the health disparities and unique health needs of this community. In your role as Secretary, what would you do to reduce stigma and foster a more inclusive health care environment for LGBT Americans? Would you support making changes to the draft Strategic Plan?

Response: If confirmed, I will work to enhance and protect the health and wellbeing of all Americans. I am not aware of how far along the draft HHS Strategic Plan is in the comment process, but I look forward to reviewing feedback received, if confirmed, and using it as a tool against which to measure the Department's progress towards fulfilling its mission to enhance the health and well-being of all Americans.

17. While we have made progress in preventing and treating HIV infections, there are still 37,600 new cases of HIV each year. In addition, nearly 20,000 people in the United States die from hepatitis C (HCV) and its complications each year, and HCV-associated deaths now exceed the number of deaths from 60 other nationally notifiable diseases. As a result of the opioid crisis, the rate of new cases of HCV has increased since 2010 and there are rising concerns about clusters of HIV outbreaks. How will you support HIV prevention and treatment services in order to continue the progress made on reducing new infections, improving access to care and treatment outcomes, and reducing health disparities as outlined in the National HIV/AIDS Strategy? As Secretary, how will you work to combat the increasing rates of HCV that we are seeing across the nation?

Response: 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.

18. The 21st Century Cures Act directs the Secretary of HHS to work with stakeholders to reduce the regulatory demands associated with physician documentation. As Secretary, how would you work with the Office of the National Coordinator for Health Information Technology (ONC) to fully implement this provision and effectively reduce the regulatory demands associated with physician documentation?

Response: I understand the need to reduce clinician burden in respect to the use of electronic health records (EHRs). As the son of a physician, I have heard first hand clinician challenges in using health IT. Physicians should spend more time with patients and less time in front of a computer screen. If confirmed, I look forward to working across the department to address this priority.

19. Wisconsin has a large number of home durable medical equipment (DME) suppliers, including a vibrant community of small businesses that have been serving Medicare patients and health systems for decades. I believe it is critical to ensure that the current competitive bidding program is designed in a way that does not disadvantage Wisconsin small businesses that provide valuable medical products or the families that rely on these important services. I have long supported efforts to provide relief to rural DME providers under competitive bidding. On December 7, 2016, I supported passage of the 21st Century Cures Act (P.L. 114-255), which delayed applying competitive bidding rates for DME suppliers in non-competitively bid, or rural areas. While this delay helped avoid immediate disruptions in

beneficiary access, lower reimbursement rates have now gone into effect. As such, I have joined my bipartisan colleagues in urging CMS to provide further relief for rural areas. How would you address the challenges faced by rural DME providers? And, can you please provide an update on any pending CMS regulations or efforts that would help mitigate the reimbursement cuts for home medical equipment providers to ensure patients maintain access?

Response: I agree that maintaining access for Medicare beneficiaries to durable medical equipment and other items and services in rural areas is important. I understand that CMS is closely monitoring beneficiary access and their health outcomes to ensure that they are not negatively impacted by the Medicare payment rates. CMS recognizes the importance of ensuring access to durable medical equipment and is considering ways to strengthen the competitive bidding program and payment in non-competitive bidding areas. If confirmed, I look forward to working with you on this important issue.

20. Eating disorders have the highest mortality rate of any mental illness, and affect over thirty million Americans during their lifetime. I led the passage of the Anna Westin Act as part of the bipartisan 21st Century Cures Act, which clarifies insurance coverage of eating disorders treatment, enhances public information and resource sharing, and increases education and training to improve early detection and treatment for eating disorders. It has been almost a year since we passed the 21st Century Cures Act, and HHS has not fully or meaningfully implemented these essential and historic provisions. How would you implement these provisions and provide our medical professionals the tools they need to identify and intervene? How do you envision HHS enforcing mental health parity for eating disorders in order to ensure that Americans to receive coverage for residential, intensive outpatient, and partial hospitalization treatment?

Response: Eating disorders have a major impact on millions of individuals, families and communities across the nation. We need to build on the recent work that has been done in this area. I am committed to fully implementing the laws passed by Congress and would ensure the 21st Century Cures Act and the provisions related to eating disorders are properly carried out, if confirmed.

21. I am concerned that the President's FY18 budget request proposed eliminating funding for the Paralysis Resource Center, the only federally funded program specifically tailored to mobility impaired Americans. This critical program provides information specialists, a national peer-to-peer network, and a military and veterans program designed to support the unique needs of current service members and veterans. Will you commit to continuing to support the Paralysis Resource Center and other programs for mobility impaired Americans?

Response: The mission of the Paralysis Resource Center (PRC) is to improve the quality of life for people living with paralysis through grants, information, and advocacy. The PRC provides comprehensive information for people living with spinal cord injury, paralysis, and mobility-related disabilities and their families. I am interested in seeing how we can leverage our existing efforts with other federal partners, including the VA and others, to expand our impact on individuals living with paralysis and spinal cord injury, including veterans and current military service members.

22. I have long supported efforts to ensure access to comprehensive, quality maternity care to promote the health and well-being of mothers, and I believe that it is critical that we look for ways to improve our public health infrastructure to better support mothers and infants. Breastfeeding plays a vital role in promoting healthy outcomes and preventing higher healthcare costs. Providing access to comprehensive breastfeeding support, supplies, and counseling is essential to helping women more effectively breastfeed their babies for longer periods of time, which can reduce additional costs and help foster healthy families. If you are confirmed as HHS Secretary, how will you expand access to breastfeeding support, supplies, and counseling to guarantee that women have the resources they need to adequately breastfeed their babies?

Response: 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.

23. You agree that we need to make insurance more affordable, but I am frustrated that you have not clearly articulated whether or not you support the bipartisan Health Care Stabilization Act of 2017. Do you specifically support restoring the cost-sharing payments and the investments in enrollment assistance that are needed to help mitigate Trump's sabotage?

Response: I do not agree with the characterization that the Administration or the Department has made an effort to destabilize the market. The Administration conducted a legal review and received an opinion from the Attorney General concluding that, since the Congress did not appropriate the money for Cost Sharing Reductions, the Administration could no longer legally make the payments. Ultimately, Congress will need to act to make the broader reforms that are needed in order to create a health insurance system that is more affordable and responsive to the needs of individuals and their families. I am encouraged by the efforts ongoing in Congress to address the issues, and if confirmed, would look forward to working with you to support these efforts. If confirmed I will faithfully execute the laws as passed by Congress.

24. In July, the Trump Administration unilaterally decided to end – two years early - the five-year projects for all grantees of the Teen Pregnancy Prevention Program (TPPP) in 2018. This critical program has helped contribute to a decline in teen birth rates. These cuts undermine the important work of grantees who relied on HHS to stand by this program, including those in Milwaukee, Wisconsin, who have a long-record of serving our vulnerable youth. Do you agree with the Trump Administrations' actions to cut short its commitment to these quality, evidence-based programs that work to prevent unintended teen pregnancy?

Response: If confirmed, I am committed to faithfully implementing the law. Any grant programs will be operated in accordance with any statutory requirements and the grant making rules and procedures of the Department. 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.

Senator Murphy

1. In October, President Trump continued his sabotage of the Affordable Care Act by issuing an executive order directing the Department of Labor to consider proposing regulations on association health plans, and for the Secretaries of Labor and Treasury to examine efforts to expand short-term, limited-duration insurance.

A recent estimate found that the best-selling short-term plans sold on eHealth in 14 states exclude pre-existing conditions, mental health, substance use treatment, prescription drugs, and maternity expenses. Not only do these plans *not cover* these vital essential health benefits but the out of pocket maximums and deductibles are often not the same. For example, the best-selling plan in one state comes with a \$10,000 deductible and a \$10,000 out of pocket maximum, for an effective out of pocket maximum of \$20,000.

In my home state, one of the best-selling short-term plan is offered by National General Accident & Health and includes no outpatient prescription drug coverage, has a \$7,000 out of pocket maximum. This plan excludes mental health, substance use treatment, outpatient prescription drugs, maternity/pregnancy care (except for complications) and pre-existing conditions.

The willful expansion of these plans will leave Americans who use these plans holding the bag when they try to access services, and will increase costs in the individual market overall as the risk pool deteriorates.

If confirmed, you would be responsible for implementing this latest executive order with respect to expanding these insurance plans and association health plans, which have been opposed by the National Governors' Association and the National Association of Insurance Commissioners.

Do you agree with the executive order? Can you outline the steps that you will take to determine whether these skimpy plans should be expanded? How will these plans ensure that Americans have peace of mind when these plans do not cover such basic services like prescription drugs, maternity care, mental health and substance use treatment? As a former pharmaceutical executive, do you believe that prescription drug coverage is an essential part of insurance?

Response: Short-term limited duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other forms of insurance, or who are otherwise priced out of the unaffordable ACA insurance markets. Americans need more insurance options, and they need less federal micromanagement of their insurance options.

The status quo is not working for millions of Americans – whether it is those who are in the insurance market or those who have been left out of it. Although there are many Americans who may not be best served by a short-term limited duration plan, expanding the availability of such plans creates affordable options for those who understand how to

choose and use these flexible, short-term products. 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 healthcare 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.

2. In October 2016, the previous administration's White House Task Force on Parity issued a report making several recommendations to improve enforcement of the Mental Health Parity and Addiction Equity Act and its implementing regulations. More recently, this administration's President's Commission on Combating Drug Addiction and the Opioid Crisis recommended full enforcement of the Mental Health Parity and Addiction Equity Act to ensure that health plans cannot provide less favorable benefits for mental health and substance use diagnoses than physical health ailments. For example, the final report stated, "The Commission recommends that federal and state regulators should use a standardized tool that requires health plans to document and disclose their compliance strategies for non-quantitative treatment limitations (NQTL) parity. NQTLs include stringent prior authorization and medical necessity requirements. HHS, in consultation with DOL and Treasury, should review clinical guidelines and standards to support NQTL parity requirements. Private sector insurers, including employers, should review rate-setting strategies and revise rates when necessary to increase their network of addiction treatment professionals."

Can you describe which of the recommendations from the previous White House Task Force on Parity you support and which you are not prepared to support? In addition, do you support the recommendation from the Opioid Commission that HHS should work with other agencies to review clinical guidelines and standards to support non-quantitative treatment limitations parity requirements?

Response: I believe mental health parity is an important issue as it is critical for individuals to have access to quality healthcare, including mental healthcare. I am committed to implementing the laws passed by Congress with respect to mental health parity, including those in the 21st Century Cures Act. If confirmed, I would work with my counterparts at the Departments of Labor and Treasury to ensure we are able to provide the best possible guidance to states and insurers in the implementation of parity.

3. In Connecticut, 1 in 6 residents are providing care for a relative, and 70 percent believe they will at some point. A recent report by the National Academies of Sciences, Engineering and Medicine found that close to 18 million Americans of working age help older family members or friends with activities of daily living on an ongoing basis. The report forecast that the numbers of family caregivers will continue to rise.

Family caregiving obligations have an economic impact, as workers in this situation often have to take time off from jobs, cut back on working hours, or leave the paid workforce

altogether. Unfortunately, this lowers their future Social Security benefit, threatening their own retirement. Studies indicate that on average, total wage, private pension, and Social Security losses due to caregiving add up to more than \$300,000. In Connecticut, an estimated 459,000 caregivers in 2013 spent 427 million hours providing nearly \$6 billion in unpaid caregiving.

I believe that family caregivers deserve our gratitude, not punishment for taking time off to care for a loved one. That's why, after hearing concerns from family caregivers around Connecticut, I introduced the *Social Security Caregiver Credit Act*, which would add a credit to caregivers' lifetime earnings to determine how much they should receive in Social Security benefits. By creating a Social Security Caregiver credit, caregivers who had to leave the workforce entirely, or continue to work with significantly reduced hours, would receive modest retirement compensation.

What initiatives will you, as Secretary of HHS, undertake to facilitate family caregiving?

Response: HHS is responsible for administering a number of programs to help support and empower those caring for older adults and children and adults with disabilities. For example, the National Family Caregiver Support Program funds a variety of supports that help family and informal caregivers care for older adults in their homes for as long as possible. This program also permits states and communities to use a portion of program funds to serve older relative caregivers who may be raising their grandchildren or adult children with disabilities. If confirmed, I look forward to working with Congress, states, and the broader Administration on how to further strengthen and enhance our national support for family caregivers.

4. The National Institute for Occupational Safety and Health (NIOSH) Total Worker Health (TWH) Program promotes and protects the health and productivity of the American workforce through research and dissemination of innovative and cost effective tools and intervention program for American businesses.

TWH Centers funded by NIOSH are leading national research on integration of health promotion and health protections program. Current research suggests that these integrated programs increase employee participation and decrease healthcare and lost productivity costs. However, there are only six NIOSH funded Centers of Excellence across the country, including one at the University of Connecticut, devoted to building the evidence base and disseminating these innovative approaches and programs for American Businesses.

Although the TWH Program is relatively new, it is having a major impact on the NIOSH transition from its traditional focus on disease and injury prevention, to its current health-based focus. Given the growing recognition of the TWH Program, and the centrality of the TWH Program for US employers who are now responding to the need to improve the health status and productivity of their workforce through worksite prevention and wellness programs, there are clear benefits of preserving the Total Worker Health Program.

How will you support the work of the Total Worker Health Program to improve the health of the American workforce?

Response: Thank you for raising this program to my attention. I am not familiar with the Total Worker Health Program, but I look forward to being briefed on it, if confirmed.

5. Since 2013, Americans have died from incidents involving firearms and automobiles at almost identical rates. There were 33,804 motor vehicle traffic deaths and 33,636 firearm deaths in the United States in 2013. Over the last two decades, the federal government has spent \$240 million a year on motor vehicle safety research, and virtually nothing on research into gun-related injuries and deaths after an appropriations rider was added that prohibits the CDC from “participating in advocacy or promotion of gun control.”

The CDC recommends the use of seatbelts, for example, because its research has found seatbelts and appropriate car seats and booster seats for children reduce motor vehicle deaths by half. Motor vehicle deaths plummeted nearly 25 percent from 2004 to 2013 thanks to data supporting new policies.

With about 100,000 Americans injured or killed each year by guns, including over 2,000 in 2016 from accidental shootings alone, should the CDC resume its research into guns as a means of death and injury?

Response: I am not aware of any prohibition on gun violence research. I believe we must better understand why individuals commit violence and seek to address the causes of this violence.

6. In a September 29th Presidential Memorandum, President Trump set a Presidential Determination on Refugee Admissions for Fiscal Year 2018 of 45,000 refugees. What specific measures will you take at HHS to ensure the number of refugee admitted in FY 2018 meets the 45,000 target?

The Office of Refugee Resettlement (ORR) awards a variety of grants and provides a variety of services to help resettle new refugees. These programs are vital lifelines for refugees and refugee resettlement agencies. How will you support the work of the ORR? What specific measures will you take to ensure ORR funding is disbursed regularly and quickly?

Response: The Office of Refugee Resettlement in the Administration for Children and Families does not determine the number of refugees admitted annually, however if confirmed, I will work with leadership in ACF and ORR to ensure the efficient and effective use of HHS funds to support the resettlement of refugees under the authorities provided by Congress.

7. The President’s Fiscal Year (FY) 2018 Budget Request proposed eliminating the Low Income Home Energy Assistance Program (LIHEAP) claiming, “LIHEAP is unable to demonstrate strong performance outcomes.” This claim does not match empirical evidence. In Connecticut alone, the program serves over 100,000 households. Moreover, every year,

the funding availability for the program falls well short of the demand for the program, which serves low-income families, older adults, and persons with disabilities across my state.

Do you accept the FY 2018 Budget Request's claim that "LIHEAP is unable to demonstrate strong performance outcomes?" If confirmed, you will help formulate the President's Budget request for LIHEAP. Do you support maintaining funding for this critical program?

Response: 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.

8. The condition of Puerto Rico's healthcare system is very much personal for Connecticut, which has a higher percentage of Puerto Rican residents than any other U.S. state. As you know, Puerto Rico's Medicaid program is treated differently than that of other states, and absent legislative action, funding for Puerto Rico's Medicaid program will drop dramatically at the beginning of the next calendar year. This so-called "Medicaid cliff" threatens the hundreds of thousands of Puerto Ricans who rely on the program. Moreover, the outmigration of medical professionals that has plagued the island further compounds the problem of the Medicaid cliff. Hurricanes Irma and Maria have accelerated this and other streams of outmigration while making the need for a Medicaid fix more acute.

If confirmed as secretary, what steps will you take to stabilize Puerto Rico's Medicaid program?

Response: I am certainly aware of the unique challenges that the Puerto Rico Medicaid program has faced. Of course, these challenges are compounded following such a serious storm. Much of the Medicaid funding "cliff" can only be addressed by Congress, and, if confirmed, I stand ready to assist Congress.

States and territories must be given the flexibility they need to provide the highest quality healthcare they can to their own unique communities. Removing unnecessary red tape is one way to enable states to provide high quality care while also preparing for the emergencies that are unique to them.

9. Mr. Azar, according to the HHS Assistant Secretary for Planning and Evaluation, prescription drugs account for nearly 17% of medical costs in the U.S. We all know that manufacturers set their own prices for their products, often with no explanation to the consumer or payer, nor any accountability for the performance at the given price.

Would you agree that outcome- or value-based payment models should be encouraged so drug manufacturers are held accountable for the products they produce and the prices they set - whether through improved quality of life, actual lower medical spending for certain conditions, or whether new brand drugs represent a tangible improvement over existing therapies? Under your leadership, what more will the Department do to encourage the development of value-based frameworks and analyze issues surrounding the role of drug pricing in overall health spending?

Response: Yes, the U.S. needs to shift to outcomes and value-based payment models, which would help hold manufacturers accountable for the produced by their products. I believe we also need to look at regulatory barriers in our government price reporting regulations and Anti-Kickback Statute guidance that might prevent or inhibit more significant and pervasive outcomes-based contracting in the private sector. I also look forward to working with Administrator Verma, if confirmed, to explore the opportunities we have to implement value-based payment systems, especially as innovative treatments and cures become available.

10. Last year, I worked with Sen. Isakson and other members of the HELP Committee, to pass legislation to increase surveillance of neurological diseases as part of the 21st Century Cures Act. The goal of this section was to replicate the success of the National Amyotrophic Lateral Sclerosis (ALS) Registry, which is overseen by the Agency for Toxic Substances and Disease Registry within the Centers for Disease Control and Prevention. The ALS registry has connected ALS patients with researchers and helped scientists learn more about incidence and prevalence of the disease.

If confirmed, will you commit to implement this section of 21st Century Cures so that we can increase our understanding of the incidence and prevalence of neurological diseases?

Response: ALS is a tragic disease, and I am committed to efforts to understand it better. If confirmed, I commit to implementing all laws passed by Congress, including the 21st Century Cures Act and its provisions.

Senator Warren

Affordable Care Act

Over the past eleven months, the Trump Administration, including the Department of Health and Human Services (HHS), has carried out a sustained campaign aimed at reducing access to health insurance coverage provided through the Affordable Care Act (ACA) exchanges and reducing the quality and affordability of that coverage. In January 2017, in the critical final week before the end of the annual sign-up period for health insurance, the Administration ordered HHS to end on-line and social media advertisements encouraging enrollment. A subsequent investigation by the HHS Office of Inspector General (OIG), undertaken in response to a letter that Senator Murray and I wrote to the OIG,¹² found that the decision to cancel ACA ads resulted in the waste of \$1.1 million taxpayer dollars. It also appears that the decision to cancel ads was made for primarily political reasons, with little regard for the impact of the cancellations on marketplace enrollment and premiums.¹³

The Department also issued a “market stabilization” rule that dramatically shortened this year’s open enrollment period, from three months to six weeks, and has substantially reduced funding that helps individuals navigate the insurance sign-up process. The Administration cut off payments to insurers that help low-income families afford health care, a move that the Congressional Budget Office has estimated will cost the federal government \$194 billion over the next decade.¹⁴ And Department officials, including former Secretary Tom Price and CMS Administrator Seema Verma, publicly supported proposals by Republicans in Congress to end the Medicaid expansion, take away health insurance from tens of millions of Americans, and end protections for people with pre-existing conditions.

- A. Should you be confirmed as HHS Secretary, what specific steps would you direct HHS to take in order to oversee and stabilize the ACA-established Marketplaces? What criteria would you use to measure your success in doing so?
- B. You have been a vocal opponent of the ACA, yet will be responsible for implementing key portions of it. If confirmed as HHS Secretary, would you commit to assessing the impact on taxpayers of any effort to undermine the law? If a decision to undermine the ACA would result in a loss of taxpayer dollars, would you commit to preventing that decision from taking place?
- C. Should you be confirmed as HHS Secretary, you would likely take office near the end of the open enrollment period for insurance for 2018. Over the course of 2017, the Trump Administration has taken multiple steps to undermine the efficacy of open enrollment,

¹² Letter from Senator Elizabeth Warren and Senator Patty Murray to the HHS Office of Inspector General (January 31, 2017) (online at: [https://www.warren.senate.gov/files/documents/2017-1-](https://www.warren.senate.gov/files/documents/2017-1-31_Letter_to_HHS_re_Obamacare_suspensions.pdf)

[31_Letter_to_HHS_re_Obamacare_suspensions.pdf](https://www.warren.senate.gov/files/documents/2017-1-31_Letter_to_HHS_re_Obamacare_suspensions.pdf)).

¹³ U.S. Department of Health and Human Services, Office of the Inspector General, *Review of The Department of Health and Human Services (HHS) Cancellation of Marketplace Enrollment Outreach Efforts*, OEI-12-17-00290 (October 25, 2017) (online at <https://oig.hhs.gov/oei/reports/oei-12-17-00290.pdf>).

¹⁴ Congressional Budget Office, “The Effects of Terminating Payments for Cost Sharing Reductions” (August 2017) (online at <https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53009-costsharingreductions.pdf>).

including massive cuts to ACA advertising and promotion. These steps threaten to reduce ACA enrollment, ultimately raising premiums and harming enrollees.¹⁵ As HHS Secretary, would you take steps to expand, rather than reduce, awareness of open enrollment?

Response to A-C: Millions of Americans have lost the plans they liked and the doctors they liked under the ACA. A fair analysis of the past five years will conclude that health insurance costs under the ACA have risen substantially year over year – long before President Trump took office. The markets have been failing consumers, choices have been dwindling, and resources have been allocated to programs that simply were not performing. 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 healthcare system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them.

D. What steps would you take to reverse past policies to undercut open enrollment?

Response: I do not agree with the characterization that the Administration or the Department has made an effort to undercut open enrollment.

E. Will you commit to restoring a three-month open enrollment period that allows Americans sufficient time to consider health insurance options and sign up for coverage?

F. If, following the conclusion of this year's open enrollment period, available data indicates that the shorter enrollment period led to lower rates of health insurance coverage, will you commit to returning to a three-month enrollment period?

G. Will you commit to funding advertisement and outreach efforts and restoring funding for groups and organizations that work in local communities to facilitate enrollment?

Response to E-G: Please note that the previous Administration proposed that the open enrollment period be shortened to the current length starting for the 2019 plan year, and that this policy aligns more closely with the one month open enrollment periods we typically see in the employer-sponsored insurance market and the seven week Medicare open enrollment period, the two markets where the vast majority of Americans are successfully enrolled, year after year. If confirmed, I will examine the data and work with the Administrator to make the best, evidence-based decisions, balancing prudent use of resources with faithful execution of the law. As it relates to advertising expenditures, it is my understanding that the current level of spending is consistent with what is spent on promotion for Medicare Advantage and Part D, and that Navigators were funded at levels based partly on their ability to meet their enrollment goals from the year prior so as to

¹⁵ Haeyoun Park, "We're Tracking the Ways Trump is Scaling Back Obamacare. Here are 12." *New York Times* (October 12, 2017) (online at https://www.nytimes.com/interactive/2017/10/12/us/trump-undermine-obamacare.html?_r=0).

inject accountability into that program.

- H. If confirmed as HHS Secretary, will you advise the President to resume payments for the cost-sharing reduction (CSR) subsidies that help low-income families afford health care? If not, why not?

Response: The Administration conducted a legal review and received an opinion from the Attorney General concluding that since the Congress did not appropriate the money for Cost Sharing Reductions, the Administration could no longer legally make the payments.

Medicaid

The Medicaid program covers over 70 million low-income Americans, including 6 million low-income elderly Americans, 40% of all children, 49% of pregnant women, and 30% of all non-elderly, disabled adults.¹⁶ Medicaid also covers a disproportionate share of individuals with individuals with mental illness – 22 percent of adults with mental illness and 26 percent of adults with serious mental illness received Medicaid coverage in 2015.¹⁷

Since taking office, President Trump has supported legislation that would cut Medicaid by more than \$700 billion, converting it to a per capita cap or block grant system.¹⁸ His budget proposal for fiscal year 2018 (FY18) also proposed an additional cut to Medicaid of over \$600 billion.¹⁹ You have also expressed support for block granting the Medicaid program, saying, "I think there's a lot to commend a block grant approach."²⁰ Yet analysts have indicated that Medicaid block grants would "institute deep cuts to federal funding" and "threaten benefits for tens of millions of low-income families, senior citizens, and people with disabilities."²¹ In order to cope

¹⁶ Kaiser Family Foundation, "Medicaid Pocket Primer" (January 3, 2017) (online at <http://kff.org/medicaid/fact-sheet/medicaid-pocket-primer/>); Julia Paradise, Barbara Lyons, and Diane Rowland, "Medicaid at 50: People with Disabilities," Kaiser Family Foundation (May 6, 2015) (online at <http://kff.org/report-section/medicaid-at-50-people-with-disabilities/>); Center on Budget and Policy Priorities, "Policy Basics: Introduction to Medicaid" (August 16, 2016) (online at <http://www.cbpp.org/research/health/policy-basics-introduction-to-medicaid>).

¹⁷ "Facilitating Access to Mental Health Services: A Look at Medicaid, Private Insurance, and the Uninsured," Kaiser Family Foundation (June 8, 2017) (online at: <http://www.kff.org/medicaid/fact-sheet/facilitating-access-to-mental-health-services-a-look-at-medicaid-private-insurance-and-the-uninsured/>)

¹⁸ Philip Bump, "By 2026, Annual Medicaid Cuts under the Senate Health-Care Replacement Plan are Steeper than Under Repeal," *Washington Post* (July 19, 2017) (online at: https://www.washingtonpost.com/news/politics/wp/2017/07/19/by-2026-annual-medicaid-cuts-under-the-senate-health-care-replacement-plan-are-steeper-than-under-repeal/?utm_term=.27c6f093a793); Danielle Kurzleben, "GOP Health Plan Would Leave 23 Million More Uninsured, Budget Office Says," *NPR* (May 24, 2017) (online at: <http://www.npr.org/2017/05/24/529902300/cbo-republicans-ahca-would-leave-23-million-more-uninsured>).

¹⁹ Iris J. Lav, Michael Leachman, "The Trump Budget's Massive Cuts to State and Local Services and Programs," *Center on Budget and Policy Priorities* (June 13, 2017) (online at: <https://www.cbpp.org/research/state-budget-and-tax/the-trump-budgets-massive-cuts-to-state-and-local-services-and>).

²⁰ "Alex Azar: Should Medicaid Be Turned Into a Block Grant Program?" Zetema Project (February 23, 2017) (online at: <https://www.youtube.com/watch?v=ePzgW30qUuc>).

²¹ Edwin Park, "Medicaid Block Grant Would Slash Federal Funding, Shift Costs to States, and Leave Millions More Uninsured," *Center on Budget and Policy Priorities* (November 30, 2016) (online at: <https://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

with their drastically reduced federal funding, "states would likely have no choice but to institute draconian cuts to eligibility, benefits, and provider payments."²²

As HHS Secretary, you will be responsible for addressing the concerns and advancing the interests of America's seniors, people with disabilities, and all Medicaid beneficiaries.

- A. Do you agree that Medicaid plays an essential role in ensuring that seniors and people with disabilities can get access to affordable high-quality services that allow them to live independently at home and in their communities?
- B. Do you agree that hundreds of billions of dollars in cuts to Medicaid would have a negative impact on the ability of seniors and people with disabilities to access health care?
- C. Do you agree that Medicaid plays an essential role in ensuring that individuals with mental health and addiction disorders can access medically necessary treatment?
- D. Do you agree that hundreds of billions of dollars in cuts to Medicaid would have a negative impact on the ability of individuals with mental health and addiction disorders to access health care?
- E. The Center for Medicare and Medicaid Innovation ("CMMI"), a research center under the Centers for Medicare and Medicaid Services ("CMS") has authority to test different approaches of paying for Medicare and Medicaid coverage. You have expressed support for using CMMI's administrative authorities to test Medicaid block grants.²³ Can you reassure Americans that, as HHS Secretary, you will not use your administrative authorities under CMMI or any other HHS program to enact policies that result in reduced benefits or eligibility for Medicaid beneficiaries or increase their out-of-pocket costs?

Response to A-E: 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

²² Edwin Park, "Medicaid Block Grant Would Slash Federal Funding, Shift Costs to States, and Leave Millions More Uninsured," Center on Budget and Policy Priorities (November 30, 2016) (online at: <https://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

²³ "Alex Azar: Should Medicaid Be Turned Into a Block Grant Program?" Zetema Project (February 23, 2017) (online at: <https://www.youtube.com/watch?v=ePzgW30qUuc>).

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.

Protecting vulnerable nursing home residents

There are an estimated 1.4 million nursing home residents in the United States.²⁴ The Medicaid program is the primary payer for this care, paying for the care of 62% of these nursing home residents.²⁵ Providing high-quality care continues to be a challenge for many nursing homes; in fact, earlier this year, the HHS Inspector General found that there were dozens of cases of abuse and neglect in audited nursing homes, and that “CMS has inadequate procedures to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported.”²⁶

Congress has long been concerned about inadequate care in nursing homes, and the Affordable Care Act included a number of provisions designed to address deficiencies, improve staff training, and impose new penalties for nursing homes that violate quality of care requirements. But I have been concerned by recent actions by the Trump Administration to weaken rules put in place by President Obama to implement these new requirements. In June and October 2017, CMS revised policies to make it more difficult to impose civil monetary penalties on nursing homes that repeatedly and/or seriously harm patients.²⁷ And in June, the Trump Administration put out a proposed rule that would allow nursing homes to force patients into arbitration to resolve disputes – allowing Medicaid-funded nursing homes to require patients to give up their legal rights to address poor care.²⁸

- A. Will you commit to strong enforcement of CMS nursing home regulations?
- B. Will you commit to aggressive use of civil monetary penalties in cases where nursing homes have caused repeat and/or serious harm to patients due to deficiencies in care?
- C. What actions will you take to ensure that nursing home residents and their families are not stripped of their legal right to take a nursing home to court if they have suffered abuse or injury as a result of deficiencies in care?
- D. What other actions will you take to address nursing home quality of care problems identified by the HHS Inspector General, by GAO, and by other experts?

²⁴ Kaiser Family Foundation, *Medicaid's Role in Nursing Home Care* (June 2017) (<https://www.kff.org/infographic/medicaids-role-in-nursing-home-care/>).

²⁵ Kaiser Family Foundation, *Medicaid's Role in Nursing Home Care* (June 2017) (<https://www.kff.org/infographic/medicaids-role-in-nursing-home-care/>).

²⁶ HHS OIG, *Early Alert* (August 2017) (<https://oig.hhs.gov/oas/reports/region1/11700504.pdf>).

²⁷ CMS, *Memo to State Survey Directors, 17-36-NH* (June 30, 2017) (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-36.pdf>); CMS, *Memo to State Survey Directors, 18-01-NH* (October 27, 2017) (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-01.pdf>).

²⁸ 81 Fed. Reg 26649 (June 8, 2017).

Response to A-D: My previous experience in the Department suggests that there are two errors that we can make with regard to regulation. The first kind of error is to fail to ensure that adequate protections and surveys are in place for our most vulnerable patients. The second kind of error is to allow regulations to accumulate and grow unchecked over time, loading expensive and unnecessary requirements onto hardworking care providers that increase cost, lead to provider burnout, and ultimately reduce options for patients. Regulations have their place and are important to ensuring quality, integrity, and safety in our healthcare system. But they need to be periodically reviewed to ensure they are furthering the goal of helping patients receive the best possible care without lowering its quality. If I am confirmed, I will work to ensure the safety of all patients in Medicare certified nursing homes while concurrently promoting the patient-physician relationship.

Pandemic flu preparedness

The Department of Health and Human Services would lead the federal government response to a pandemic flu. Before leaving the Centers for Disease Control and Prevention (CDC) in January 2017, the former Director, Dr. Thomas Frieden, stated his concerns about such a pandemic, noting that the greatest public health threat we face is “always for an influenza pandemic,” and that “[I]f the resistant organisms emerge in one part of the world, they will inevitably come to other parts of the world.”²⁹

President Trump’s FY2018 budget proposal included \$1.3 billion in cuts for the CDC and substantial cuts for key public health programs including \$107 million in cuts for the CDC’s Public Health Emergency Preparedness Cooperative Agreements, as well as \$2 billion in State Department global health assistance.³⁰ President Trump’s budget – and legislation attempting to repeal the *Patient Protection and Affordable Care Act* (ACA) would also eliminate the Prevention and Public Health Fund.

A. Do you agree with Dr. Frieden about the risks of a pandemic flu outbreak?

Response: Throughout history, influenza pandemics have led to widespread illness and death. Pandemic influenza is a recurring threat, and we never know when the next pandemic will occur, or how severe it will be. As one of the architects of the pandemic preparedness efforts in the Bush Administration, I have long been an advocate that we need to continue our preparation for public health threats, such as pandemic influenza.

B. What impact could substantial budget cuts have on pandemic flu preparedness?

Response: From my time at HHS previously, I know that a substantial amount of time and work goes into preparing for public health threats, such as pandemic flu. However, I have not recently been privy to the specific work underway or the specific threats we may face. I look forward to continuing this preparedness work, if confirmed, and to ensuring that we use our resources to best prepare for these health threats.

²⁹ Lena H. Sun, “Outgoing CDC Chief Talks about Agency’s Successes – and His Greatest Fear,” *Washington Post* (January 16, 2017) (online at: https://www.washingtonpost.com/news/to-your-health/wp/2017/01/16/outgoing-cdc-chief-talks-about-the-agencys-successes-and-his-greatest-fear/?tid=a_inl&utm_term=.8ca1cfl16944).

³⁰ Lev Facher, “HIV programs, mental health: 8 ways Trump’s new budget might affect public health,” *STAT* (May 24, 2017) (online at: <https://www.statnews.com/2017/05/24/trump-public-health/>)

- C. Specifically, what would be the impact of elimination of the Prevention and Public Health Fund on pandemic flu preparedness?

Response: I am not familiar with CDC's budget or the particulars of how the agency has used the Prevention and Public Health Fund (PPHF) resources. If confirmed, I look forward to ensuring that the Department has the resources to carry out its mission.

- D. What do you believe are the most important steps needed to insure that the nation is prepared for a potential pandemic flu outbreak?

Response: Although it is impossible to predict when the next pandemic will occur, HHS continuously works to ensure that the nation is prepared to respond to the next potential pandemic. Influenza surveillance and monitoring; research, development, and delivery of medical counter measures (MCM) and non-pharmaceutical interventions (NPIs); healthcare system response capacity; vaccine development; and communications are integral to an effective pandemic response. If confirmed, I look forward to continuing this important work.

- E. President Trump has linked vaccines to autism and has embraced vaccine "skeptics." Do you believe that there is any scientific or medical validity to President Trump's concerns about vaccine safety? If so, please indicate which sources lend scientific or medical validity to his concerns. Are you concerned that President Trump's statements may dissuade members of the public from receiving flu or other vaccines?

Response: Vaccines are one of the greatest success stories in public health and are among the most cost-effective ways to prevent disease. If confirmed, I will ensure that HHS will continue to advance the best science and advocate for use of vaccines.

FDA blood donation policies

Ensuring a safe and adequate blood supply is a critical aspect of our public health system. The Food and Drug Administration (FDA) develops blood donation policy for the nation's blood banks – a task that is even more important as we respond to emerging diseases such as the Zika virus that threaten the safety of our blood supply. Evidence indicates that moving to a risk-based referral policy could increase the U.S. blood supply by up to 4 percent, helping to address the nation's blood shortage.³¹ The U.S. Department of Health and Human Services (HHS) has taken steps to develop risk-based blood donation policies, but building on these steps will require leadership from the next HHS Secretary.

In December 2015, the FDA released final guidance that changed the blood donation policy for men who have sex with men (MSM) from a lifetime deferral to a one-year deferral from last

³¹ Ayako Miyashita and Gary J. Gates, "Update: Effects of Lifting Blood Donation Bans on Men Who Have Sex with Men," The Williams Institute (September 2014) (online at: <http://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Ban-update-Jan-2015.pdf>). See for example: "American Red Cross reports severe winter blood shortage," *WTHITV.com* (January 4, 2017) (online at <http://wthitv.com/2017/01/04/american-red-cross-reports-severe-winter-blood-shortage/>) and "San Antonio in extreme blood shortage," *KHOU.com* (January 10, 2017) (online at <http://www.khou.com/news/local/texas/san-antonio-in-extreme-blood-shortage/384692455>).

sexual contact with another man.³² This one-year deferral policy is still not based on science, nor is it based on an individual donor's risk of carrying a transfusion transmissible infection. It also still prevents many low-risk individuals from donating blood, continues to let higher risk individuals donate. In June 2016, FDA started collecting public input on scientifically sound solutions to risk-based screening, and the information collection period closed in November 2016.³³ If you are confirmed as Secretary –

- A. Are you committed to implementing a risk-based blood donation deferral policy for all donors?
- B. As Secretary of HHS, how would you support the FDA's efforts to move to a risk-based referral policy for all blood donors?
- C. How do you anticipate using public comments received during the comment period for the FDA's recent request for information to implement a risk-based deferral system for all donors? More specifically:
 - a. Will you commit to developing a risk-based on-site questionnaire to be used at blood donation clinics?
 - b. When can we expect FDA to release a draft of a risk-based questionnaire?
 - c. Will you commit to gather stakeholder input on the questionnaire?
 - d. Over what time period will you test the questionnaire and gather input?
 - e. Will you commit to integrating stakeholder input into the questionnaire? How will you perform that integration?
- D. What specific steps will you take to engage with impacted groups, including MSM, to encourage blood donation in line with new policies?

Response to A-D: One of FDA's greatest public health responsibilities is ensuring the safety of our Nation's blood supply. If confirmed, I look forward to working with FDA to ensure that the Agency's regulation of our Nation's blood supply is science-based and fulfills the Agency's mission to protect public health.

Post-market surveillance of medical devices

³² Federal Register Notice 80 FR 79913 "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability" (online at: <https://www.federalregister.gov/documents/2015/12/23/2015-32250/revised-recommendations-for-reducing-the-risk-of-human-immunodeficiency-virus-transmission-by-blood>).

³³ Federal Register notice 81 FR 49673 "Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments" (<https://www.federalregister.gov/documents/2016/07/28/2016-17804/blood-donor-deferral-policy-for-reducing-the-risk-of-human-immunodeficiency-virus-transmission-by>). Accessed Dec. 21, 2016.

In September 2017, the HHS OIG released a report analyzing costs to Medicare associated with a set of seven medical devices that failed prematurely or were recalled.³⁴ The OIG found that Medicare spent \$1.5 billion on medical services incurred in order to replace these poorly performing devices between 2005 and 2014. Medicare beneficiaries whose devices were recalled or failed also paid an additional \$140 million in out-of-pocket costs. In addition to finding that poor performance of medical devices comes at significant cost to the Medicare program and to Medicare beneficiaries, the OIG's analysis concluded that Medicare claim data does not currently support the identification and tracking of recalled or prematurely failed medical devices.

In order to reduce Medicare costs and protect beneficiaries, the OIG recommended that the Centers for Medicare and Medicaid Services (CMS) "continue to work with the Accredited Standards Committee X12 to ensure that the DI is included on the next version of claim forms." The OIG's recommendation echoes the June 2017 assessment of the Medicare Payment Advisory Commission, which stated: "requiring device identifiers on administrative claims for certain devices could improve the information available to conduct post-market surveillance, which is critical to ensure device quality."³⁵ Senator Grassley and I have long supported this recommendation, repeatedly urging stakeholders, including CMS, to support the inclusion of device identifiers on the Medicare claim form.³⁶

However, HHS's position on this issue has been inconsistent. In a July 2016 joint letter to X12, CMS and FDA had asked the standards committee to "support capturing on the claim form the device identifier (DI) portion of the unique device identifier for implantable devices."³⁷ Yet in response to the OIG's recommendation that CMS work with X12 to ensure that device identifier information is collected on the next version of claim forms, CMS Administrator Seema Verma

³⁴ Department of Health and Human Services Office of Inspector General, *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (September 2017) (online at: <https://oig.hhs.gov/oas/reports/region1/11500504.pdf>).

³⁵ Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System (June 2017) (online at: http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf), p. 234.

³⁶ Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services (December 22, 2014); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Daniel Levinson, Inspector General, Department of Health and Human Services (August 12, 2015) (online at: <https://www.grassley.senate.gov/sites/default/files/news/upload/2015.08.06%20UDI%20Letter%20to%20OIG.pdf>); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Sylvia Matthews Burwell, Secretary, Department of Health and Human Services (March 8, 2016) (online at: https://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Gary Beatty, Chair, Accredited Standards Committee X12 (August 29, 2016) (online at: https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf); "Senators Warren and Grassley Comment on HHS Report on Medicare Savings from Inclusion of Medical Device Identifiers on Claim Forms" (October 4, 2016) (online at: https://www.warren.senate.gov/?p=press_release&id=1270).

³⁷ Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascarell.house.gov/sites/pascarell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

has issued a series of conflicting statements.³⁸ Most recently, on October 31st, during testimony before the Senate Committee on Health, Education, Labor, and Pensions, CMS Chief Medical Officer Kate Goodrich responded to a question about whether CMS agreed with the OIG recommendation by saying, “[A]t this time, I don’t have anything else to offer [. . .] because, as is customary for new administrations, we are still reviewing this policy.”³⁹

- A. Do you agree with the HHS OIG and MedPAC that including device identifier information in medical claims could support the evaluation of medical devices after approval?
- B. If confirmed Secretary, will you continue to support the process of adding device identifiers to claims as a critical tool to better understand the performance of these products after approval?
- C. How will you direct CMS and FDA to work together to ensure that device identifiers can be effectively used to monitor threats to Medicare program integrity, as well as to patient health?

Response to A-C: If confirmed, I look forward to learning more about this issue, and working with our CMS and FDA teams as well as other stakeholders to understand the potential benefits and costs. As you mention, there are two significant concerns at stake here: the integrity of the Medicare payment system and ensuring that we do not over-burden hardworking providers who care for Medicare beneficiaries and others. I take both concerns very seriously, and, if confirmed, I will work with CMS and FDA to ensure the Department carefully evaluates this proposal.

Drug prices

Increases in prescription drug costs continue to affect patients, who often struggle financially to afford necessary medications. Nationwide, prescription drug costs grew by 9 percent in 2015. Although this growth rate was lower than the 12 percent growth rate record in 2014, prescription drugs still outpaced the spending growth of all other types of health services.⁴⁰ Government spending on drugs through federal programs, including Medicare, Medicaid, and TRICARE, has also risen, creating costs for patients and taxpayers. A recent *Wall Street Journal* analysis found that the median out-of-pocket cost for a drug purchased by Medicare Part D beneficiaries was

³⁸ Department of Health and Human Services Office of Inspector General, *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (September 2017) (online at: <https://oig.hhs.gov/oas/reports/region1/11500504.pdf>). David Pittman, “ONC Talks up Progress on Goals,” *Politico Morning eHealth* (October 3, 2017) (online at: <http://www.politico.com/tipsheets/morning-ehealth/2017/10/03/onc-talks-up-progress-on-goals-222614>).

Darius Tahir, “Moonshot Launch (and Other Administration Work,” *Politico Morning eHealth* (October 13, 2017) (online at: <http://www.politico.com/tipsheets/morning-ehealth/2017/10/13/moonshot-launch-and-other-administration-work-222793>).

³⁹ “Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology,” Senate Committee on Health, Education, Labor and Pensions (October 31, 2017) (online at: <https://www.help.senate.gov/hearings/implementation-of-the-21st-century-cures-act-achieving-the-promise-of-health-information-technology>).

⁴⁰ Center for Medicare and Medicaid Services, “National Health Expenditures 2015 Highlights” (online at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>).

\$117, up almost 50% from 2011.⁴¹ Prescription drugs accounted for about 14 percent of health care spending in Massachusetts in 2015 – one-third of total health care spending growth that year.⁴²

- A. You have been described as “oppos[ing] government intervention on drug prices,”⁴³ yet the President has also pledged that if confirmed as HHS Secretary, you would be “a star for [. . .] lower drug prices!”⁴⁴ What specific steps will you take as HHS Secretary to lower the out-of-pocket costs paid by individuals using prescription drugs?

Response: As I said at my hearing drug prices, including insulin 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 fix this broken system, and use my knowledge and experience to reduce drug prices for patients.

- B. Do you agree with the President’s recent statement that drug companies are “getting away with murder”?⁴⁵

Response: The President is rightly frustrated with the current system, which clearly needs improving. If confirmed, I look forward to working with the various agencies at HHS to come up with strategies to help make drugs more affordable for patients.

- C. President Trump has expressed support for the government negotiating drug prices under Medicare, and the White House has noted that he is committed to using “his skills as a businessman to drive [prices] down.”⁴⁶ Do you agree with President Trump’s support for allowing the government to negotiate for lower Medicare drug prices? If so, what specific steps would you take to carry out this policy?

⁴¹ Joseph Walker, “High-Price Drugs Raise Costs for Seniors in Medicare Part D,” *The Wall Street Journal* (May 29, 2017) (online at: <https://www.wsj.com/articles/high-priced-drugs-raise-costs-for-seniors-in-medicare-part-d-1496055603>).

⁴² Massachusetts Health Policy Commission, Annual Health Care Cost Trends Report 2016 (February 2017) (online at: <http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/2016-cost-trends-report.pdf>).

⁴³ Anna Edney, Jared S. Hopkins, and Natasha Rausch, “Drug Costs in the Spotlight with Trump’s Pick for Health Secretary,” *Bloomberg* (November 14, 2017) (online at: <https://www.bloomberg.com/news/articles/2017-11-14/trump-health-pick-has-blamed-health-plans-pbms-for-drug-costs>).

⁴⁴ President Donald J. Trump, @realDonaldTrump, “Happy to announce, I am nominating Alex Azar to be the next HHS Secretary. He will be a star for better healthcare and lower drug prices!” *Twitter* (November 13, 2017) (online at <https://twitter.com/realDonaldTrump/status/930087113764327424>).

⁴⁵ Sarah Karlin-Smith, “Trump Renews Attacks on High Drug Prices,” *Politico* (October 16, 2017) (online at: <https://www.politico.com/story/2017/10/16/trump-attacks-high-drug-prices-243836>).

⁴⁶ Alison Kodak, “Medicare Should Leverage Buying Power to Pull Down Drug Prices, White House Says,” NPR (February 7, 2017) (online at: <https://www.npr.org/sections/health-shots/2017/02/07/513945538/white-house-says-medicare-should-leverage-its-buying-power-to-pull-down-drug-pri>).

Response: As I said during my opening statement to the Committee, 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. 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 think about how we can take the lessons from Part D to improve Medicare.

CMS's Center for Medicare and Medicaid Innovation (CMMI) allows policymakers to test and evaluate pioneering payment and delivery system models that can enhance quality and lower costs. In March 2016, CMMI proposed a Medicare Part B drug payment demonstration designed to help move Medicare Part B from a volume-based system to a system that structured reimbursements around quality and innovation.⁴⁷ I commended CMS's efforts to develop the Medicare Part B demonstration, which I believe had the potential to advance the conversation about how Medicare can incentivize value and outcomes, not simply volume.⁴⁸ However, in November 2016, CMS stated that it would not be finalizing rulemaking for the Demonstration during the Obama Administration.⁴⁹ During our conversation in my office prior to your confirmation hearing, you indicated that you believed there were opportunities to harness competition to lower drug prices in Medicare Part B. If you are confirmed Secretary –

- A. Are you committed to continuing to test innovative solutions to lowering drug prices for Medicare, and for Medicare Part B in particular?
- B. What specific efforts will you pursue to ensure that the Medicare Part B drug payment program ensures access to necessary medications, builds on existing payment reform models, enhances private sector payment innovations, and promotes value?
- C. Which Congressional proposals dealing with Medicare drug prices do you believe would be most effective at incentivizing value and positive outcomes?

Response to A-C: If I am confirmed as Secretary, one of the critical areas I plan to focus my efforts on is to lower drug prices for Medicare. I believe through my experiences in both the public and private sectors I can start working immediately at the Department of

⁴⁷ 81 FR 13229, "Medicare program; Part B drug payment model" (March 11, 2016) (online at: <https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model>).

⁴⁸ Letter to HHS Secretary Sylvia Burwell, CMS Acting Administrator Andy Slavitt, and CMMI Acting Principal Deputy Administrator Patrick Conway (May 16, 2016).

⁴⁹ Zachary Brennan, "CMS drops Medicare Part B drug payment pilot," *Regulatory Affairs Professional Society* (Dec. 16, 2016) (online at: <http://raps.org/Regulatory-Focus/News/2016/12/16/26388/CMS-Drops-Medicare-Part-B-Drug-Payment-Pilot/>).

Health and Human Services to identify solutions to the drug pricing issue. I look forward to working with you on innovative value-based methods to lowering drug prices in Medicare.

Lab-developed tests

Once relatively straightforward and familiar pathology tests used for diagnostic purposes, lab-developed tests (LDTs) have become more advanced and are increasingly integrated into clinical decision-making. They are often now used to diagnose diseases that are both common and carry high risks for patients. Advancements in genetic science and how specific genes are related to disease has spurred the development of increasingly sophisticated medical diagnostic technology. LDTs are essential tools for diagnostic decision-making. However, because of their increasing prevalence in the clinic, it is imperative that they perform reliably and accurately. Inaccurate or incorrect results could mean that patients defer or do not seek out needed care, or could pursue ineffective or unneeded therapies.⁵⁰ FDA, which has authority under the Food, Drug and Cosmetic Act to regulate LDTs, released draft guidance in October 2014 after years of delay.⁵¹ However, in November 2016, FDA stated that it would not release final guidance during the Obama Administration. If you are confirmed Secretary –

- A. What role do you believe that FDA and CMS should play in ensuring that LDTs provide clinically relevant information to the physicians and patients who rely on them for making decisions impacting patient health and well being?
- B. Do you agree that high-risk lab-developed tests that inform clinical diagnoses should be clinically validated?
- C. How will you ensure patient safety by implementing risk-based oversight and regulation of LDTs?
- D. How will you direct FDA and CMS to ensure reliability of LDTs, particularly those that are moderate- or high-risk?
- E. What steps should CMS and FDA take to improve reporting by clinicians and patients of faulty or unreliable LDTs? What steps should be taken when such LDTs are identified?

Response to A-E: LDTs play a critical role in patient care, and it is important for both patients and their healthcare providers to have confidence in these tests. If confirmed, I will work closely with Administrator Verma and Commissioner Gottlieb to ensure we have a risk-based regulatory approach that supports patient access to reliable tests and advancing innovations in this area on behalf of patients.

⁵⁰ FDA, “The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies” (November 16, 2015) (online at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf>).

⁵¹ FDA, “Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories” (October 3, 2014) (online at: <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf>).

Opioid epidemic and national emergency

The opioid epidemic is devastating communities across the country and requires an all-hands-on-deck approach. Opioids caused more than 33,000 deaths in 2015, an average of 91 deaths every day.⁵² In Massachusetts, more than 2,000 individuals died from opioid overdoses in 2016.⁵³ The epidemic continues to grow, with deadly consequences. In just three years, across the country overdose deaths related to synthetic opioids such as fentanyl, which is 50 to 100 times more powerful than morphine, grew by 264%.⁵⁴ The Department of Health and Human Services oversees eleven agencies that play a role in addressing the opioid epidemic. The Secretary must collaborate across federal agencies, and with state and local governments, the private sector, and international partners - key partners in tackling the opioid crisis.⁵⁵

On October 26, 2017, more than two months after initially saying he would declare the opioid crisis a national emergency, President Trump declared the opioid epidemic a national public health emergency under the Public Health Service Act (PHSA).⁵⁶ Under the PHSA, the Secretary of HHS's determination of a public health emergency expands their powers, to "take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder."⁵⁷ As HHS Secretary, you will be empowered to deliver on President Trump's promises, which have not yet included any commitment for the increased federal funds that experts on the front lines of this crisis have suggested we need.

Additionally, on November 1, the Commission on Combating Drug Addiction and the Opioid Crisis released a series of recommendations for the federal government and Congress to address this crisis. The majority of the 56 recommendations in the report will require the involvement and leadership of the HHS Secretary, including recommendations to "design and implement a wide-reaching, national multi-platform media campaign," to "remove reimbursement and policy barriers" to substance use disorder treatment, to "provide additional resources to the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and National

⁵² "Opioid Overdose," *Centers for Disease Control and Prevention (CDC)*, (online at: <https://www.cdc.gov/drugoverdose/index.html>) (Accessed November 2, 2017); "Understanding the Epidemic," *CDC* (online at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>) (Accessed November 2, 2017).

⁵³ Martha Bebinger, "Opioid Overdose Deaths In Mass. Reach Grim Milestone," *WBUR* (May 10, 2017) (online at: <http://www.wbur.org/commonhealth/2017/05/10/opioid-overdose-deaths-top-2000>)

⁵⁴ "Prescription Behavior Surveillance System (PBSS) Issue Brief," *CDC National Center for Injury Prevention and Control* (July 2017) (online at: <https://www.cdc.gov/drugoverdose/pdf/pbss/PBSS-Report-072017.pdf>).

⁵⁵ HHS Agencies & Offices (online at: <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>); U.S. Department of Health and Human Services Strategic Plan: Introduction (online at: <https://www.hhs.gov/about/strategic-plan/introduction/index.html>) (Accessed November 2, 2017).

⁵⁶ Julie Hirschfeld Davis, "Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds," *The New York Times* (October 26, 2017) (online at: <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>); "Presidential Memorandum for the Heads of Executive Departments and Agencies," *White House Office of the Press Secretary* (October 26, 2017) (online at: <https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies>).

⁵⁷ 42 U.S.C. Sec. 247d, Public health emergencies (online at: <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchap11-partB-sec247d.pdf>); Public Health Emergency Declaration (online at: <https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>) (Accessed November 2, 2017).

Institute on Alcohol and Alcoholism (NIAAA),” and to “negotiate reduced pricing for all governmental units.”⁵⁸

- A. Will you commit to treating the opioid epidemic as a real emergency, including by working to secure increased funds for states and communities already on the front lines of this emergency?

Response: If confirmed, I am committed to ensuring that HHS is bringing everything it has to bear in fighting this epidemic. I would look forward to working with Congress as it determines what additional funding to appropriate for this crisis.

- B. Will you urge the President and other cabinet members to publicly call for a significant increase in federal funding to address this epidemic?

Response: If confirmed, I will ensure that HHS continues its work to manage and monitor its current resources to ensure the most evidence-based prevention, treatment, and recovery support services are provided. HHS will continue this work with any funds agreed upon by the Administration and Congress.

- C. What specific actions will you take as HHS Secretary to fulfill the President’s declaration of a national public health emergency on opioids?

Response: I know that HHS is committed to bringing all that the Department has to bear to fulfill the President’s declaration of a national public health emergency. HHS has a five point opioid strategy that it is using to guide its efforts to both address the opioid epidemic and the President’s declaration. The five points include, 1) strengthening public health surveillance, 2) advancing the practice of pain management, 3) improving access to treatment and recovery support services, 4) targeting availability and distribution of overdose-reversing drugs, and 5) supporting cutting-edge research. In addition to efforts already underway, I will continue to look for avenues that the declaration of a public health emergency may provide to further address this crisis, such as the possible expansion of telemedicine.

- D. What steps will you take to update and work with members of Congress on this emergency, and to ensure that HHS has the resources it needs to stem this epidemic?

Response: If confirmed, I will ensure that HHS is providing updates to and working with members of Congress on this public health emergency. I would look forward to working with Congress as it determines what additional funding to appropriate for this crisis.

- E. How will you work with states like Massachusetts that have previously declared the opioid epidemic an emergency to learn about their efforts and share these lessons with other states?

⁵⁸ Recommendations of The President’s Commission on Combating Drug Addiction and the Opioid Crisis (November 1, 2017) (online at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf).

Response: If confirmed, I would be eager to coordinate with and learn from others who have worked to address the opioid epidemic. I would be pleased to work with states, including Massachusetts, to understand what is working on the ground and could potentially be used as a model for other states.

Partial fill and the opioid epidemic

At the core of the opioid epidemic has been the overprescribing and misuse of addictive and dangerous prescription painkillers. CMS reported that generic Vicodin was prescribed to more Medicare beneficiaries than any other drug in 2013 – more than blood pressure medication, more than cholesterol medication, more than acid reflux medication.⁵⁹ The National Institute on Drug Abuse has estimated that over 70% of individuals who misuse prescription opioids get the medication from friends or relative, so reducing the amount of unused medications in the home is a powerful new tool to tackle prescription drug abuse.⁶⁰

The *Comprehensive Addiction and Recovery Act*, passed in July 2016, included a bipartisan provision that I worked on with Senator Capito, which empowers patients to talk to their physicians and pharmacists about partially filling their prescription medications in order to reduce the amount of unused opioids in circulation.⁶¹ This provision amended the *Controlled Substances Act* to allow partial filling of any Schedule II prescription, including painkillers such as OxyContin and Vicodin. For example, this means that when a patient goes to the pharmacy to pick up their opioid prescription, they can request that their pharmacist only fill enough of the prescription for a few days supply – and then, return to the pharmacy if pain persists to pick up the remainder of their prescription.

- A. Do you believe that reducing the number of unused medications in the home is an important tool in tackling the misuse of prescription medications?

Response: Yes, reducing the number of unused opioid medications in the home is one important factor in tackling the misuse of prescription medications.

- B. Would you commit to working with the Drug Enforcement Administration to address the overprescribing and misuse of addictive prescription medications, while still ensuring that patients who need pain medication can receive it?

Response: As I mentioned during my hearing, the opioid crisis is one of the most pressing issues facing our country. I know the Department already has a robust strategy in place, and I believe work across the agencies is critical to our success. I look forward to working with other agencies, such as the DEA, to address the opioid crisis, if confirmed.

⁵⁹ “CMS Releases Prescriber-Level Medicare Data for First Time,” *Centers for Medicare & Medicaid Services* (April 30, 2016) (online at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>).

⁶⁰ National Institute on Drug Abuse fact sheet (online at: <https://www.drugabuse.gov/sites/default/files/poppingpills-nida.pdf>).

⁶¹ See S. 524: Comprehensive Addiction and Recovery Act of 2016 (online at <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>).

- C. How would you work with states, physicians, pharmacists, and patient groups to increase awareness about partial fill policies?

Response: If confirmed, I look forward to learning more about the effectiveness of partial fill policies on opioid misuse, abuse, and overdose. It will be important for HHS to be involved in increasing awareness about policies that can help curb the opioid epidemic, including recommendations contained within the CDC Guideline for Prescribing Opioids for Chronic Pain that clinicians provide no greater quantity than needed for the expected duration of pain severe enough to require opioids.

Fentanyl

In Massachusetts, there has been a clear shift from overdose deaths connected to prescription drugs and heroin to the increased use of the harmful synthetic opioid fentanyl. This has further contributed to this public health crisis and has created a significant challenge for our public health and safety officials. Recently, the CDC collaborated with the Massachusetts Department of Public Health and the Office of the Chief Medical Examiner to study fentanyl overdoses. The original study released in 2016 found that for opioid-related fatalities in the state in which it was possible to conduct a toxicology screen, 74% of individuals tested positive for fentanyl.⁶² As of November 2017, that percentage had increased to 81%. That study also noted, “the rate of heroin or likely heroin present in opioid-related deaths has been decreasing while the presence of fentanyl is still trending upward.”⁶³

- A. What would you do to build on HHS’s efforts to address this specific component of the opioid epidemic?

Response: The increased use of synthetic opioid fentanyl is of serious concern and presents new challenges as we seek to stem the tide of the opioid crisis. CDC has an important role to play in tracking the patterns and use of fentanyl. This information can be helpful to understanding how to target the response in particular communities where fentanyl use is high. In addition, FDA has inspectors at international mail facilities who can interdict fentanyl and its analogues. It will be critical for HHS to coordinate with DOJ, DEA, and DHS on this issue to ensure that the full force of the federal government is brought to bear on the increase of fentanyl use. If confirmed, I look forward to learning more about other efforts underway at HHS to address the use of fentanyl and ensuring that these efforts continue.

- B. How would you work with other federal agencies to improve surveillance and support the work of states dealing with significantly high rates of opioid overdoses due to illicitly produced fentanyl?

⁶² Massachusetts Department of Public Health, “Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents” (November 2016) (online at <http://www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-nov-2016-ma-residents.pdf>).

⁶³ Massachusetts Department of Public Health, “Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents (November 2017) (online at: <https://www.mass.gov/files/documents/2017/11/13/sec1-od%20deaths%20mass%20residents%20Nov-17.pdf>).

Response: Surveillance is critically important as we work to address the opioid crisis. Wherever interagency collaboration could enhance our efforts, I would seek to partner with those other agencies, if confirmed.

C. What steps would you take to address emerging trends in this crisis, such as the increased use of carfentanil?

Response: HHS can provide technical assistance to help states better understand the nature of the epidemic and how best to respond. The Department's work is critical to arming state and community officials with the information needed to develop programs and strategies tailored to best address their specific needs. Specifically, CDC's surveillance data can be used to educate on these trends to ensure that dollars spent are targeted towards the greatest need.

Syringe exchange programs, supervised injection facilities, and infectious diseases

Syringe exchange programs, also known as syringe services programs (SSPs), are locations where individuals can go to get sterile needles and syringes and safely dispose of used items, as well as get education on safer practices and treatment for other medical, social, or mental health needs. The public health benefits of such programs, including reduced risks for HIV and Hepatitis C, are clearly acknowledged by the NIH, CDC, and other scientific bodies.⁶⁴ In 2015, then-Governor Mike Pence responded to an HIV and HCV outbreak in Indiana by signing a law that allowed counties in Indiana to establish Syringe Service Programs.⁶⁵ Massachusetts has fourteen successful syringe exchange programs, with the goal of getting people into treatment for addiction and other health issues.⁶⁶

The opioid epidemic has spurred increases in Hepatitis B and Hepatitis C infections.⁶⁷ In 2015, the CDC released data showing a nationwide increase in reported cases of Hepatitis C (HCV) – increases that indicate “a geographic intersection among opioid abuse, drug injecting, and HCV infection.”⁶⁸ And in 2016, the CDC announced the number of Americans infected with Hepatitis B (HCB) had significantly increased in the geographic areas most affected by the opioid epidemic.⁶⁹

⁶⁴ “Syringe-Exchange Programs Are Part of Effective HIV Prevention,” National Institute on Drug Abuse, National Institutes of Health (December 1, 2016) (online at: <https://www.drugabuse.gov/about-nida/noras-blog/2016/12/syringe-exchange-programs-are-part-effective-hiv-prevention>). Syringe Services Programs, Centers for Disease Control and Prevention (online at: <https://www.cdc.gov/hiv/risk/ssps.html>) (last updated September 28, 2017).

⁶⁵ Megan Twohey, “Mike Pence’s Response to H.I.V. Outbreak: Prayer, Then a Change of Heart,” *New York Times* (August 7, 2016) (online at https://www.nytimes.com/2016/08/08/us/politics/mike-pence-needle-exchanges-indiana.html?_r=0).

⁶⁶ Jamie Ducharme, “DPH Seeks Money for More Mass. Needle Exchanges,” *Boston Magazine* (March 24, 2017) (online at: <http://www.bostonmagazine.com/health/2017/03/24/massachusetts-needle-exchanges/>).

⁶⁷ HEP, “The Intersection of the Opioid and Heroin Epidemic and Hepatitis” (May 17, 2016) (online at <https://www.hepmag.com/blog/intersection-opioid-heroin-epidemic-hepatitis>).

⁶⁸ Centers for Disease Control and Prevention, “Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012” (May 8, 2015) (online at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm>).

⁶⁹ Centers for Disease Control and Prevention, “Increases in Acute Hepatitis B Virus Infections—Kentucky, Tennessee, and West Virginia, 2006–2013” (January 29, 2016) (online at <https://www.cdc.gov/mmwr/volumes/65/wr/mm6503a2.htm>).

Research has also shown the benefits of Supervised Injection Facilities (SIFs), where people can use their own drugs, under medical supervision. Research indicates that SIFs can help reduce HIV and hepatitis transmission risks, prevent overdose deaths, and increase the number of people seeking out addiction treatment.⁷⁰

- A. As HHS Secretary, would you commit to continued support for syringe exchange programs/syringe services programs?

Response: I know that the Department and the Administration are committed to bringing everything we have to bear to address the opioid crisis. 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.

- B. HHS has developed guidance for health departments on how to request permission to use federal funds to support SSPs. Will you commit to retaining this guidance? Would you continue to share this guidance with states and work with states as they navigate this process?

Response: As mentioned above, if Congress should decide to continue funding for support of SSPs, I would ensure that these programs are fully implemented, consistent with such laws.

- C. Given the devastating effects of the opioid epidemic, including increased risks for Hepatitis transmission, would you commit to increasing your agencies support for syringe services programs to provide outreach and linkage-to-care to those most at risk and in need of HIV, Hepatitis, overdose, and addiction treatment services?

Response: If confirmed, I will ensure that HHS implements the law as directed, uses federal funds as appropriated, and I would be happy to work with Congress on this issue.

- D. Would you commit to advocating for studying safe injection facilities as a tool in the fight against the opioid epidemic?

Response: Safe injection facilities are relatively new concepts, and the U.S. has limited experience with implementation. As with any issue, I will commit to reviewing the evidence, if confirmed.

Expanded access to naloxone

Access to naloxone, a prescription drug meant to reverse an opioid overdose, saves lives. However, more could be done to expand access to naloxone. In August 2016, the FDA outlined the steps it was taking to ensure greater access to naloxone, including “helping manufacturers pursue approval of an OTC naloxone product, including helping to develop the package label

⁷⁰ Frakt, Austin, “JAMA Forum: Safe Injection Facilities Reduce Individual and Societal Harms,” JAMA (April 5, 2017) (online at: <https://newsatjama.jama.com/2017/04/05/jama-forum-safe-injection-facilities-reduce-individual-and-societal-harms/>)

that would be required for such a product.”⁷¹ The FDA indicated that it had created a model Drug Facts Label and accompanying pictogram that could provide consumers with necessary information about how to use naloxone safely, and was engaged in label comprehension testing of this model label.

For naloxone to be accessible, it also needs to be affordable – but naloxone prices have surged in recent years, with one formulation, the two-dose Evzio package, increasing in price by about 500% in only two years.⁷² The opioid epidemic continues to make its way into new communities, and we’re finding a steep increase in deaths associated with higher concentration opioids, such as fentanyl.⁷³ When someone overdoses on fentanyl, it often takes multiple doses of naloxone to reverse the overdose.

A. As HHS Secretary, what steps would you take to work with your agencies, other federal departments, manufacturers, and other partners to expand access to naloxone?

Response: HHS has developed a five-point strategy to address the opioid epidemic. One of the points includes increasing access to overdose reversing drugs, including naloxone. If confirmed, I look forward to working with agencies, such as the Substance Abuse and Mental Health Administration, to see what we can do to increase access to naloxone. 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 FDA to help bolster this effort, and I look forward to working with him to ensure that increased competition for drugs, such as naloxone, leads to lower list prices.

B. Would you commit to supporting the FDA’s ongoing work to develop and test a package label for an OTC naloxone product?

Response: Yes.

C. What specific actions would you take to address price increases in overdose reversal medications?

Response: As I said during my opening statement to the Committee, drug prices are too high. 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,

⁷¹ Karen Mahoney, “FDA Supports Greater Access to Naloxone to Help Reduce Opioid Overdose Deaths,” FDA Voice (August 10, 2016) (online at: <https://blogs.fda.gov/fdavoices/index.php/2016/08/fda-supports-greater-access-to-naloxone-to-help-reduce-opioid-overdose-deaths/>).

⁷² Gupta, Ravi, “The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths,” *The New England Journal of Medicine* (Dec. 8, 2016) (online at: <http://www.nejm.org/doi/full/10.1056/NEJMp1609578#t=article>).

⁷³ Katz, Josh, “The First Count of Fentanyl Deaths in 2016,” *The New York Times* (Sept. 2, 2017) (online at: <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>).

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, such as naloxone, leads to lower list prices.

Safe drug disposal

Safe drug disposal options are an important tool to help limit the volume of unused medications in circulation. Twice a year, the U.S. Drug Enforcement Agency holds National Prescription Drug Take Back Days, meant to help individuals dispose of unused medicines. 450 tons of drugs were disposed of in the last national take-back day in May.⁷⁴ In September 2014, the DEA released the final rule on “Disposal of Controlled Substances,”⁷⁵ aimed at making it easier to for individuals to dispose of unused medicines and allow for more continuous collection opportunities. Over a year ago, Massachusetts announced its “first statewide safe medication disposal program with Walgreens to fight substance misuse,”⁷⁶ and today in Massachusetts, in addition to semi-annual national take-back days, there are a number of permanent kiosks where individuals can go to dispose of unused medications.⁷⁷

A. As HHS Secretary, would you direct your agencies to raise awareness about these safe drug disposal opportunities?

Response: Reducing the number of unused opioid medications in the home is one important factor in tackling the misuse of prescription medications. However, an effective way to decrease the amount of unused opioids is to more effectively prescribe in the first place so that no more than is needed for the expected duration of pain is prescribed. Safe storage and disposal can also help.

B. Would you support research by the NIH on safe drug disposal technologies?

Response: I cannot speak to specific research that should be supported as each study must be reviewed for its scientific merit, but I do believe the development of safe drug disposal technologies is an important element to addressing the opioid crisis.

Marijuana research

As more states pass laws providing for the use of marijuana for medical purposes, or “medical

⁷⁴ “DEA Brings in Record Amount of Unused Prescription Drugs on National Prescription Take Back Day,” *U.S. Drug Enforcement Administration* (May 8, 2017) (online at: <https://www.dea.gov/divisions/hq/2017/hq050817a.shtml>).

⁷⁵ Federal Register, Vol. 79, No. 174 (September 9, 2014) (Online at: https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf).

⁷⁶ “Baker-Polito Administration Announces First Statewide Safe Medication Disposal Program with Walgreens to Fight Substance Misuse,” *The Official Website of the Governor of Massachusetts* (September 7, 2017) (online at: <http://www.mass.gov/governor/press-office/press-releases/fy2017/statewide-safe-medication-disposal-program-launched.html>).

⁷⁷ “Safely Dispose of Prescription Drugs,” *Mass.gov* (online at: <https://www.mass.gov/safely-dispose-of-prescription-drugs>) (accessed October 25, 2017).

marijuana,” and for recreational adult-use, it is critical that the federal government reduce barriers to research on the drug. HHS in particular must work with other federal agencies to facilitate scientific and population-based research, as the agency has a unique role in understanding the potential health effects of medical marijuana, including its therapeutic benefits.

I have sent numerous letters to HHS, the Office of National Drug Control Policy, and the Drug Enforcement Administration to express my concerns regarding barriers to research that have persisted⁷⁸, and appreciate HHS’ willingness to respond and work with my office on these important issues. I also have been pleased to see the growing interagency dialogue regarding marijuana research, and while there is still significant work to be done to support patients, doctors, researchers, and states I look forward to working with a new HHS Secretary to build on these efforts.

- A. If confirmed as HHS Secretary, will you commit to prioritizing efforts to facilitate research on the potential health benefits of marijuana when used for medical purposes?

Response: I will be committed to working with Congress and our federal partners to facilitate more research on both the harms, and therapeutic potential, of marijuana and cannabinoids.

- B. What specific actions will you take to encourage qualified research applications on the potential health benefits of marijuana and its components?

Response: I believe that more research is needed on both the harms associated with marijuana use and the therapeutic potential of marijuana and its components. HHS through NIH welcomes investigator-initiated research proposals for pre-clinical and clinical research evaluating marijuana and its constituent cannabinoids for treating disease.

- C. As you know, marijuana is currently classified as a Schedule I substance under the Controlled Substances Act (CSA), defined as having “no currently accepted medical use.” However, millions of Americans are eligible to use marijuana for the treatment in accordance with state laws, such as for chronic pain, multiple sclerosis, post-traumatic stress disorder, epilepsy, and terminal illness. Last year, the Drug Enforcement Administration rejected petitions to reschedule marijuana, citing scientific analysis and recommendations from HHS and the FDA.⁷⁹ If confirmed as HHS Secretary, will you commit to facilitating further research on the therapeutic benefits on marijuana in an effort to provide an evidence-based scheduling recommendation to the DEA? Furthermore, will you commit to ensuring a transparent review, in coordination with the DEA and in accordance with the CSA, which facilitates public comments on the

⁷⁸ Letter from U.S. Senator Elizabeth Warren, et al. to the Department of Health and Human Services, the Office of National Drug Control Policy, and the Drug Enforcement Administration (July 9, 2015, December 21, 2015, and June 23, 2016)

⁷⁹ Drug Enforcement Administration, “DEA Announces Actions Related to Marijuana and Industrial Hemp,” (August 11 2016) (online at: <https://www.dea.gov/divisions/hq/2016/hq081116.shtml>).

therapeutic benefits of marijuana and its components?

Response: Yes, I believe scheduling recommendations should be based on the most current scientific understanding.

- D. In an April 2016 letter,⁸⁰ HHS and other federal agencies indicated that the “DEA, FDA, and NIDA have been working together to address the issues relating to cannabidiol (CBD), including scheduling considerations.” This letter also stated that FDA and NIDA are working to generate additional data on the abuse potential of CBD. If confirmed, will you commit to updating Congress on the status of this review, including any resources needed to complete it? Will you ensure an expedited scientific analysis and scheduling recommendation for CBD?

Response: Yes, if confirmed, I will look into this matter further.

- E. HHS must lead the federal effort to facilitate surveillance and epidemiological studies to assess how medical marijuana is being used and to better understand health and safety outcomes. If confirmed as HHS Secretary, how will you work with the CDC, NIDA, and other federal agencies to improve current systems to collect data on the total number of medical marijuana patients in the United States, the nature of their ailments, modes of use, and patient reported outcomes?

Response: Because of the diverse nature of state medical marijuana laws and relevant state/local level surveillance systems, agencies can be supported to work closely with states to collect better data on medical marijuana use.

- F. What specific actions will you take to work with state public health departments so that epidemiological data can be compared between states and inform scientific research efforts? What steps will you take to provide guidance to states in an effort to limit the broad variations between state data collection?

Response: HHS, through CDC, collaborates with state public health departments to share state-based data. CDC provides support in developing public health information systems and managing public health surveillance programs. This health related data is critical to help states monitor, control and prevent the occurrence and spread of diseases and adverse health infections. HHS and CDC have made a concerted effort to standardize data collection and will continue to further develop these efforts.

- G. Will you commit to working closely with other federal agencies, as well as state and local entities, to ensure continued interagency collaboration that leads to evidence-based policies?

Response: Yes.

⁸⁰ Letter from Department of Health and Human Services, the Office of National Drug Control Policy, and the Drug Enforcement Administration to U.S. Senator Elizabeth Warren, et al. (April 4, 2016)

Medical marijuana has the potential to mitigate the effects of the opioid crisis. A 2017 *American Journal of Public Health* study, for example, studied Colorado's legalization of adult-use recreational marijuana and found that it resulted in almost one fewer opioid overdose death each month and determined that the "legalization of cannabis in Colorado was associated with short-term reductions in opioid-related deaths."⁸¹ This is consistent with other data from states that have developed laws for medical or recreational marijuana use.

H. As HHS Secretary, what would you do to further study this potential alternative to opioids?

Response: There are many open questions related to evolving marijuana laws that research can help to address, including how policy changes will affect the use of marijuana and related health outcomes, including mental illness, and health outcomes—positive and negative—related to State-level initiatives to permit the medical use of marijuana. More research is needed in this area and, if confirmed, I commit to ensuring NIH continues to support this research.

I. Are you committed to implementing evidence-based policies regarding its use?

Response: I am committed to following the best scientific evidence and the relevant laws enacted by Congress in this area.

J. What specific actions will you take to utilize every tool available to study marijuana's impact on opioid overdose deaths?

Response: If confirmed, I first need to meet with HHS's experts and fully assess this aspect of the opioid epidemic before I decide on specific actions; however, please be assured that NIH will continue to support such research.

K. Will you commit to making any research available to states so that they can make evidence-based marijuana policies in an effort to address the opioid epidemic?

Response: Yes. One of the core missions of NIH is to disseminate research findings, and they will continue to do so.

L. Will you commit to including any research on marijuana's potential as an alternative pain treatment to addictive and dangerous prescription medications as part of any scientific analysis and recommendation to reschedule marijuana in accordance with the CSA?

Response: NIH will continue working closely with the ONDCP, DEA, and FDA to explore ways to streamline these processes to facilitate research.

⁸¹ Livingston, Barnett, Delcher, Wagenaar, "Recreational Cannabis Legalization and Opioid Related Deaths in Colorado, 2000-2015," *American Journal of Public Health* (October 11, 2017) (online at: <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304059?journalCode=ajph&>).

Over-the-counter hearing aids

Approximately 30 million Americans experience age-related hearing loss, including over half of adults between the ages 70-79.⁸² Yet only a small share of Americans with hearing loss – around 14 percent – use assistive hearing technologies, primarily because they cannot afford to buy costly hearing aids.⁸³ Hearing aids are not covered by Medicare or most private insurance plans, and out-of-pocket costs for a single hearing aid average \$2,400 – far out of reach for many consumers.⁸⁴ Bipartisan legislation that I sponsored with Senators Grassley, Hassan, and Isakson, and which passed as part of the FDA Reauthorization Act of 2017, requires the FDA to establish a category of over-the-counter hearing aids and will allow individuals with perceived mild to moderate hearing impairment to obtain these devices without the intervention of a licensed hearing health professional.

During testimony before the House Energy and Commerce Committee, Dr. Jeff Shuren, Director of the FDA’s Center for Devices and Radiological Health, confirmed that there was “absolutely no medical reason or rationale to consider limiting the intended use of over-the-counter hearing aids to only those individuals with a mild hearing loss” and stated that “limiting [over-the-counter hearing aids] to just patients with mild hearing loss may deny access to other patients who could benefit from hearing aids who otherwise won’t be getting it.”⁸⁵ Section 709 of the FDA Reauthorization Act of 2017 states that over-the-counter hearing aids are “intended to compensate for perceived mild to moderate hearing impairment.”

- A. If confirmed as Secretary, do you commit to ensuring that Section 709 of the FDA Reauthorization Act of 2017 is fully implemented by the FDA, within the timeframes specified in the law?

Response: Yes.

Value-based payment models for quality health care

⁸² Frank R. Lin, John K. Niparko, and Luigi Ferrucci. 2011. “Hearing Loss Prevalence in the United States,” *Archives of Internal Medicine* 171: 1851-1853 (online at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/>).

⁸³ National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at: <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 183.

⁸⁴ President’s Council of Advisors on Science and Technology, *Aging America and Hearing Loss: Imperative of Improved Hearing Technologies* (October 2015) (online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_lette_report_final.pdf), p.1.

National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at: <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 21-22.

Sergei Kochkin. 2007. “MarkeTrak VII: Obstacles to Adult Non-User Adoption of Hearing Aids,” *The Hearing Journal* 60: 24-50 (online at: <http://www.betterhearing.org/sites/default/files/hearingpediaresources/MarkeTrak%20VII%20obstacles%20to%20adult%20nonuser%20adoption%20of%20hearing%20aids.pdf>).

Karl E. Strom. 2014. “HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers,” *The Hearing Review* 21 (4): 22-28 (online at: <http://www.hearingreview.com/2014/04/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-boxretailers-comparison-present-past-key-business-indicators-dispensing-offices/>).

⁸⁵ Dr. Jeffrey Shuren, Testimony before the Subcommittee on Health, Energy and Commerce Committee, U.S. House of Representatives, “Examining Improvements to the Regulation of Medical Technologies” (May 2, 2017) (online at: <https://www.youtube.com/watch?v=fhdFyZZzTuw>).

The Affordable Care Act gave CMS the authority to develop alternative payment models (APMs) and other innovative methods to lower health care costs. One type of APM, episode-based or “bundled” payments, incentivizes health care providers to better coordinate and streamline care for things like heart attacks, bypass surgery, or joint replacements.⁸⁶ Bundled payments also create incentives for providers to eliminate unnecessary services and reduce costs.⁸⁷ For example, according to the second annual evaluation of Models 2-4 of CMS’ Bundled Payments for Care Improvement Initiative, “Orthopedic surgery under Model 2 hospitals showed statistically significant savings of \$864 per episode while showing improved quality as indicated by beneficiary surveys.”⁸⁸ A recent analysis of the bundled payments for joint replacements in the Baptist Health System (BHS) found that “bundled payment for procedures at BHS was associated with substantial hospital savings and reduced Medicare payments.”⁸⁹

Under former Secretary Price, HHS abandoned its commitment to value-based payment systems. In August 2017, CMS released a proposed rule to cancel or significantly roll back mandatory bundled payment models, including the Cardiac Rehabilitation Initiative, the Comprehensive Care for Joint Replacement Model, and the Episode Payment Models.⁹⁰ On November 30, 2017, CMS announced that it had finalized this proposed rule.⁹¹ In your testimony provided to the HELP Committee for your confirmation hearing, you stated that “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.”

- A. Do you believe that value-based payment systems, including bundled payments, can improve quality of care at reduced costs for patients and taxpayers?
- B. Successful development of APMs, such as bundled payments, requires running large demonstrations, involving dozens – if not hundreds – of health care providers in a variety of settings, geographic locations, and health care ecosystems. If confirmed Secretary –

⁸⁶ Amanda Cassidy, “Bundled Payments for Care Improvement Initiative. The Centers for Medicare and Medicaid Services is testing how to pay providers for episodes of care instead of for individual services” *Health Affairs* (November 23, 2015) (online at: http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_148.pdf). Accessed Jan. 8, 2017.

⁸⁷ See, for example, John Bertko and Rachel Effros, “Increase the Use of “Bundled” Payment Approaches” *Rand Corporation* (2010) (online at: http://www.rand.org/pubs/technical_reports/TR562z20/analysis-of-bundled-payment.html). Accessed Jan. 8, 2017.

⁸⁸ Acting Principal Deputy Administrator Patrick Conway, “Delivering coordinated, high quality care for patients” *The CMS Blog* (September 19, 2016) (online at: <https://blog.cms.gov/2016/09/19/delivering-coordinated-high-quality-care-for-patients/>). Accessed Jan. 8, 2017.

⁸⁹ Amol S. Navathe, Andrea B. Troxel, Joshua M. Liao, Nan Nan, Jingsan Zhu, Wenjun Zhong, Ezekiel J. Emanuel, “Cost of joint replacement using bundled payment models” (2017), *JAMA Internal Medicine*. Published online at: <http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2594805>.

⁹⁰ Centers for Medicare and Medicaid Services, “CMS Proposes Changes to the Comprehensive Care for Joint Replacement Model, Cancellation of the Mandatory Episode Payment Models and Cardiac Rehabilitation Incentive Payment Model,” (August 15, 2017) (online at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-08-15.html>).

⁹¹ Laura Dydra, “CMS Cancels Hip Fracture, Cardiac Bundles and Finalizes CJR Model: 5 Things to Know,” *Becker’s ASC Review* (November 30, 2017) (online at: <https://www.beckersasc.com/asc-coding-billing-and-collections/cms-cancels-hip-fracture-cardiac-bundles-and-finalizes-cjr-model-5-things-to-know.html>).

- a. Will you commit to support the Center for Medicare and Medicaid Innovation (CMMI)'s efforts to develop and implement payment models based on value, not volume?
- b. How would you propose building upon CMS's progress in lowering health care costs while improving patient outcomes?
- c. How would you propose incentivizing increased coordination and streamlining of care, including reducing unnecessary procedures and tests?

Response to A & B, a-c: As I made clear in my opening statement, 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 healthcare 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 the details or deliberative process behind the most recent actions cited in this question, but if confirmed, I look forward to coordinating with CMS and CMMI as they work toward their goal of fostering an affordable, accessible healthcare system that puts patients first. It is my understanding that 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.

A top priority would be harnessing 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.

- C. Congress provided the HHS Secretary with the rulemaking authority to expand the scope and duration of models – including the authority to test these models on a nationwide basis. However, in order for the Secretary to exercise this authority, Congress specified that a model must meet certain criteria. The model must either reduce spending without reducing the quality of care provided or must improve the quality of care without increasing spending. Models must also not deny or limit coverage or the provision of benefits. Determinations of whether models meet these criteria are made through evaluations and analyses carried out by CMS and the CMS's chief actuary.
 - a. Do you agree that reducing spending without reducing the quality of care should be used as criteria for evaluating health care policies?
 - b. Do you agree that improving the quality of care without increasing spending should be used as criteria for evaluating health care policies?

- c. Do you agree that ensuring that coverage and benefits are not limited or denied should be used as criteria for evaluating health care policies?
- d. Will you commit carrying through mandatory expansions of models that meet these criteria, based on independent analysis by HHS civil service staff and the chief actuary?

Response to C, a-d: CMMI provides a significant opportunity for testing new payment and service delivery models. If confirmed as HHS Secretary, I plan to work closely with CMS to ensure that CMMI -- after appropriate consultation with Congress, the States, healthcare stakeholders, and CMMI staff -- tests innovative models to reduce expenditures and improve quality for Medicare, Medicaid, and CHIP beneficiaries.

It is my understanding that 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 reviewing the comments received and working on the new direction for CMMI.

Biomedical research funding

Research funded by the National Institutes of Health (NIH) is critical to supporting the next generation of biomedical innovation. The NIH needs predictable, robust funding in order to conduct the research, development, and review of tomorrow's new discoveries and medical breakthroughs. The Commonwealth of Massachusetts relies on NIH funding to continue to pioneer scientific innovations: in FY2016 alone, the 190 NIH-funded institutions in the state received a total of 5,029 NIH grants.⁹² The HHS Secretary is responsible for developing policy proposals and budgets that will provide support for current and future biomedical scientists, scientific innovations, and breakthroughs. In May 2017, President Trump released a draft budget that would have cut the NIH's budget by \$5.8 billion.⁹³ The President's budget met bipartisan opposition, and Congress ultimately rejected these dramatic cuts to biomedical research funding.⁹⁴

- A. Do you agree that research funded by the NIH is critical to fueling advances in biomedical innovation?

⁹² Federation of American Societies for Experimental Biology, "Massachusetts: National Institutes of Health State Funding Facts for FY2016" (online at <http://www.faseb.org/viewer.aspx?type=statefactsheet&id=209&nocache=636467849453183003&Name=Value-of-NIH-Funding-in-Massachusetts.pdf>).

⁹³ Joel Achenbach and Lena H. Sun, "Trump budget seeks huge cuts to science and medical research, disease prevention," *Washington Post* (May 23, 2017) (online at https://www.washingtonpost.com/news/to-your-health/wp/2017/05/22/trump-budget-seeks-huge-cuts-to-disease-prevention-and-medical-research-departments/?utm_term=.dde0f407d1f8); Ellen v. Sigal, "Trump's proposed budget would cripple the NIH and FDA," *STAT* (May 24, 2017) (online at <https://www.statnews.com/2017/05/24/trump-budget-nih-fda/>).

⁹⁴ Robert Pair, "Congress Rejects Trump Proposals to Cut Health Research Funds," *New York Times* (September 11, 2017) (online at <https://www.nytimes.com/2017/09/11/us/politics/national-institutes-of-health-budget-trump.html>).

Response: Yes. Foundational insight gained from NIH supported science can be seen in nearly every treatment on the market.

- B. Over the past 15 years, growth in the NIH budget has failed to keep pace with inflation and funding has declined in real terms. As HHS Secretary, what specific steps would you take to restore investments in the NIH?

Response: I commit to working with the administration and Congress to invest in NIH.

- C. As HHS Secretary, would you commit to proposing NIH budgets that provide meaningful and sustainable funding for biomedical research?

Response: Yes. The Administration budget process is designed to evaluate all programs at HHS. As part of that process, meaningful and sustainable investments will be a priority for me in all areas of HHS responsibility.

Combatting Antibiotic Resistance

The 2014 *National Strategy for Combatting Antibiotic-Resistant Bacteria* brought together the Secretaries of Health and Human Services, Agriculture, and Defense to declare that, “the misuse and over-use of antibiotics in health care and food production continue to hasten the development of bacterial drug resistance, leading to the loss of efficacy of existing antibiotics.”⁹⁵ Through this initiative, we’ve made some significant progress establishing policies that better protect lifesaving antibiotics.

There is strong and growing evidence that antibiotic use in food animals can lead to antibiotic resistance in humans, yet the use of medically important drugs in food animals continues to grow. According to the FDA, “Domestic sales and distribution of medically important antimicrobials approved for use in food producing animals increased by 26% from 2009 through 2015.”⁹⁶ Last March, the GAO released a report, “Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals,” which included a series of recommendations that would increase HHS’s oversight of the use of medically important drugs in food animals.⁹⁷

- A. Do you agree that curbing the misuse and over-use of antibiotics in health care and food production should be a public health priority?

Response: Yes.

- B. Would you direct the FDA to implement GAO’s recommendations:

⁹⁵ “National Strategy for Combating Antibiotic-Resistant Bacteria,” The White House (September 2014) (online at: https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf), p.4.

⁹⁶ Food and Drug Administration, “2015 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals” (December 2016) (online at: <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM534243.pdf>).

⁹⁷ U.S. Government Accountability Office, “Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals” (March 2017) (online at: <http://www.gao.gov/assets/690/683130.pdf>).

- a. To create parameters for the usage of medically important antibiotics in foods?

Response: Yes.

- b. To increase veterinary oversight?

Response: Yes.

- c. To create “performance measures and targets for actions to manage the use of antibiotics”?

Response: If confirmed, I would work with FDA to assess and implement, as appropriate, GAO’s recommendations.

- C. If you are confirmed Secretary, what specific steps will HHS take to prevent the development of bacterial drug resistance?

Response: One of our largest public health threats is antibiotic drug resistance. 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 working with stakeholders, such as physicians and nurses, to ensure strong antibiotic stewardship programs are in place and implemented.

- D. In March, the FDA’s comment period closed “regarding the establishment of appropriately targeted durations of use of antimicrobial drugs of importance to human medicine when they are administered in the feed or water of food-producing animals for therapeutic purposes.”⁹⁸ Would you commit to urging the FDA to set these parameters?

Response: Yes. If confirmed, I will work with FDA to set these parameters.

Child care assistance

Extensive research shows that federal investment in child care and early childhood education pays off, resulting in increased earnings for families, higher levels of parental employment, and improved health development of children.⁹⁹ The Child Care and Development Fund is the primary source of federal funding dedicated to helping low-income families afford child care. Yet national figures show that five out of six children who are eligible for help and who need that help aren’t receiving a subsidy. According to a GAO report released in December 2016, many states manage demand by setting their eligibility limits very low, preventing many families from being able to participate.¹⁰⁰

⁹⁸ A Notice by the Food and Drug Administration, 81 FR 63187 (online at: <https://www.federalregister.gov/documents/2016/09/14/2016-21972/the-judicious-use-of-medically-important-antimicrobial-drugs-in-food-producing-animals-establishing>).

⁹⁹ CLASP, “Child Care Assistance: A Vital Support for Working Families” (June 2015) (<http://www.clasp.org/resources-and-publications/publication-1/CCDBG-Advocacy-Fact-Sheet.pdf>)

¹⁰⁰ U.S. Government Accountability Office, “Report to Congressional Committees: Child Care: Access to Subsidies and Strategies to Manage Demand Vary Across States” (December 2016) (<http://gao.gov/assets/690/681652.pdf>)

On the campaign trail, President-elect Trump spoke about the importance of child care, saying that “we need working mothers to be fairly compensated for their work, and to have access to affordable, quality child care for their kids,” acknowledging that “for many families in our country, childcare is now the single largest expense.”¹⁰¹ But while the President may understand the value of child care for many families, his proposals on the campaign trail would have primarily benefited high-income families.

- A. If confirmed Secretary, will you commit to requesting increased funding for CCDF and similar programs, to ensure that all families who are eligible for these funds can receive them?

Response: Child care is important to helping parents find and maintain employment, and the Administration supports federal, state, and private investments that can help more families access child care. At the Federal level, the President’s Fiscal Year 2018 Budget Request includes nearly \$15 billion total in funding for Child Care and Head Start, the two largest federal early care and education programs.

- B. Will you commit to working to increase the number of low- and middle-income families who receive assistance paying for child care?

Response: If confirmed, I will work with states to maximize flexibility to more efficiently use all available resources to provide access to child care for the working families who need it.

- C. What strategies would you suggest for improving the accessibility and affordability of child care programs for low- and middle-income families?

Response: Improving the accessibility and affordability of child care programs for low- and middle-income families requires looking across the early care and education system and employing localized options, such as subsidies and tax credits, and funding sources, such as untapped public funds and public-private partnerships. The Early Head Start-Child Care Partnerships are an example of leveraging multiple funding sources to increase access to and quality of child care, while enhancing alignment within the complex early childhood system in states.

- D. Evidence shows that investing in child care leads to beneficial economic outcomes, including employment and stability for parents.¹⁰² Do you agree that we should continue to invest in child care programs, like the CCDF, that have proven economic benefits?

Response: If confirmed, I am committed to helping people work and to funding evidence-based programs that have a high return on investment. Child care both enables parental employment and promotes healthy child development.

¹⁰¹ Video of Donald Trump unveiling child care policy in Aston, PA (Sept. 13, 2016) (<https://www.youtube.com/watch?v=gNjevVSXmus>)

¹⁰² CLASP, “Child Care Assistance: A Vital Support for Working Families” (June 2015) (<http://www.clasp.org/resources-and-publications/publication-1/CCDBG-Advocacy-Fact-Sheet.pdf>)

- E. One issue that is critical to producing a good return on our investments in kids is improving the quality of the child care they receive, which means improving the skills and education of child care workers. But training and credentials cost money, and about half of students who get an associate's degree have to borrow money to complete their programs. Bureau of Labor Statistics data show that child care workers rank in the bottom 3% of average annual earnings.¹⁰³ In 2014, I worked hard to get language added to the reauthorization of the Child Care Development Block Grant program to allow states to use funds to connect child care workers with financial aid. Do you agree that the skills and education of a child care worker is of high importance?

Response: As in any field, it is important for child care workers to have the skills, training, and temperament necessary to do their jobs well and support the families and children they serve.

- F. Will you commit to supporting continued or increased funding to connect child care workers with financial aid through CCDBG?

Response: States have flexibility in how they allocate their CCDBG funds and are free to use a portion of these awards to provide supports to child care workers to improve their skills and the quality of care they provide. If confirmed, I will support ACF's work to provide technical assistance to states that choose to invest in these activities.

- G. Will you commit to coordinating the work of the Administration of Children and Families to provide technical assistance to states in order to increase their use of successful strategies to connect child care workers with financial aid?

Response: If confirmed, I will work with ACF leadership to provide technical assistance to states as they implement strategies to support child care workers and connect them with training.

Head Start

Academic research shows that participating in Head Start makes a major, positive impact on the lives of disadvantaged children. Not only does Head Start have a strong, positive impact on children's readiness for school, but it has the biggest impacts for the most disadvantaged children.¹⁰⁴ Evidence of the high returns on investment in early childhood education programs have generated a long history of bipartisan support for these programs. The most recent reauthorization of the Head Start program passed with broad bipartisan support,¹⁰⁵ and the

¹⁰³ Marcy Whitebook, Deborah Phillips, and Carollee Howes, *Worthy Work, STILL Unlivable Wages: The Early Childhood Workforce 25 Years after the National Child Care Staffing Study*, Center for the Study of Child Care Employment (2014) (online at: <http://cscce.berkeley.edu/files/2014/ReportFINAL.pdf>).

¹⁰⁴ Avi Feller, Todd Grindal, Luke W. Miratrix, and Lindsay Page, "Compared to What? Variation in the Impacts of Early Childhood Education by Alternative Care Type" (January 11, 2016) (online at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2534811). Marianne P. Bitler, Hilary W. Hoynes, and Thurston Domina, "Experimental Evidence on Distributional Effects of Head Start," NBER Working Paper No. 20434 (August 2014) (online at: <http://www.nber.org/papers/w20434>).

¹⁰⁵ H.R. 1429 passed the House by a vote of 365-48 and passed the Senate with an amendment by Unanimous Consent

bipartisan FY16 omnibus bill included an increase of \$570 million for Head Start and Early Head Start programs.¹⁰⁶

A. Do you believe that early childhood education is a worthwhile investment?

Response: I believe that when early childhood education programs are implemented effectively they can have a positive impact on children and their families.

B. Will you make investments to support and strengthen Head Start to ensure that low-income students under the age of five are ready to be successful in school and life?

Response: I share your support for and commitment to the Head Start program. If confirmed, I will work to ensure that HHS appropriately implements the Head Start statute in an effective and efficient manner so that the children we serve are better prepared for success in school and life.

C. Last year, a final rule was released bringing the Head Start Program Performance Standards up to date and in accordance with the 2007 Head Start Act, in order to incentivize continuous quality improvement and data driven decision making. As Secretary of HHS, will you support redesign of the Head Start monitoring system to meet these new Standards, while ensuring that current access to the program is not limited by such changes?

Response: If confirmed, I look forward to working with leadership at the Administration for Children and Families to identify ways we can improve not just our Head Start monitoring system, but also the efficiency and effectiveness of any system within the program.

D. If confirmed Secretary, what actions would you recommend that HHS take to strengthen the educator workforce, specifically for early childhood educators and caregivers?

Response: The Head Start Program Performance Standards went into effect in the fall of 2016. If confirmed, I look forward to working with ACF leadership to understand how the workforce-related standards for early childhood education have been received and are operating. It is in our best interest to take actions that have a positive impact on our workforce while considering the potential of creating any burdens that may negatively impact existing programs and grantees.

Electronic health records

Correct patient matching is necessary for sharing patient information between providers, ensuring efficient use of health care resources, and improving the quality of health care. Patient misidentification can lead to inadequate, inappropriate, and costly care and, in the worst cases, patient harm or death. A 2012 survey conducted by The Council of Health Information Management Executives found that one in five physicians encountered mismatched information that led to inadvertent illness or injury at least once over the previous year.¹⁰⁷ A 2016 report of

¹⁰⁶ National Head Start Association, "National Head Start Association Statement on Fy'16 Omnibus Appropriations Bill" (December 16, 2015) (<https://www.nhsa.org/pr-update/statement-fy16-omnibus-appropriations-bill>).

¹⁰⁷ "Summary of CHIME Survey on Patient Data-Matching," CHIME (May 16, 2012) (online at: https://chimecentral.org/wp-content/uploads/2014/11/Summary_of_CHIME_Survey_on_Patient_Data.pdf).

nurses, physicians, and information technology (IT) practitioners found that the total estimated value of denied claims resulting from patient misidentification at the average hospital was \$1.2 million annually.¹⁰⁸

In 1996, when the Health Insurance Portability and Accountability Act was signed into law, it required the creation of patient identifiers and other uniform standards for electronic data transmission to improve reliability of health information. However, Congress later banned the Department of Health and Human Services from expending funds to develop a unique patient identifier system. This has resulted in the development of patient identifiers that are often proprietary and unique to specific health systems, instead of one identifier that travels with a patient from provider to provider.¹⁰⁹ Given this Congressional ban, HHS's ability to lead the development of solutions to patient matching is limited.¹¹⁰

- A. As Secretary, how would you seek to improve how patients are linked to their data across the care continuum?
- B. Would you support the Office of the National Coordinator (ONC) to study to the application of a national patient matching strategy?
- C. Would you support the removal of the ban on the use of federal funding to adopt a national standard for patient identification?

Response to A-C: I believe that modern technology will continue to lead to significant advancements in patient matching, and we are encouraged by the ongoing work in the private sector. The Cures Act tasks the GAO with developing a report on improving patient matching. If confirmed, I look forward to working across the department to implement the health IT provisions of 21st Century Cures.

Behavioral health coverage

According to 2015 data from the Substance Abuse and Mental Health Services Administration, over 18 percent of adults in the U.S. have some type of mental illness, yet less than half of these individuals receive mental health services.¹¹¹ Lack of insurance coverage and funding for mental health services are key causes of this gap in treatment. Mental health parity laws require that insurance coverage for behavioral health care services is equivalent to the coverage that insurers provide for physical health care services. However, surveys of beneficiaries and reports from patients tell a very different story. A 2015 survey from the National Alliance on Mental Illness

¹⁰⁸ "2016 National Patient Misidentification Report," Ponemon Institute (Dec. 2016) (online at: https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf)

¹⁰⁹ Gliklich, Dreyer, and Leavy, "Registries for Evaluating Patient Outcomes," Ch. 17, *Managing Patient Identity Across Data Sources*, Agency for Healthcare Research and Quality (April 2014) (Online at: <https://www.ncbi.nlm.nih.gov/books/NBK208618/>)

¹¹⁰ "Electronic Health Records: Nonfederal Efforts to Help Achieve Health Information Interoperability," United States Government Accountability Office (September 2015), p.18 (online at: <http://www.gao.gov/assets/680/672585.pdf>)

¹¹¹ Center for Behavioral Health Statistics and Quality, SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health" (September 2017) (online at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm>).

(NAMI) found that over twice as many respondents had been denied coverage for mental health services as for general medical care.¹¹²

Patients often find it difficult to navigate the process of appealing coverage denials and reporting problems. The lack of robust data regarding denial rates, reasons for denials, and insurance plan design further complicates enforcement of mental health parity. Last year, in response to a recommendation of President Obama's Mental Health Parity and Substance Use Disorder Parity Task Force, the Department of Health and Human Services, working with the Departments of Labor and Treasury, released a parity portal website, to "help consumers navigate parity." However, the "Mental Health and Addiction Insurance Help" website merely directs individuals to the various federal or state agencies who handle their claim and provides minimal information on parity laws. The Parity Task force said the original portal, "creates a starting point for future efforts to build out additional functionality such as complaint tracking."¹¹³

- A. Given the importance of mental health parity laws in improving access to mental health and addiction treatment, do you commit to work with the Secretaries of Labor and the Treasury to increase enforcement of mental health parity laws?

Response: Yes.

- B. Would you advocate for increased audits of health plans to ensure they are complying with mental health parity laws?

Response: If confirmed, I would work with my counterparts at the Departments of Labor and Treasury to ensure we are implementing and enforcing the laws that Congress has put in place on parity.

- C. Would you commit to work with the Secretaries of Labor and the Treasury to make the parity portal website more easily accessible to health care consumers seeking assistance with parity questions or complaints?

Response: If confirmed, I look forward to reviewing the current parity portal and working with the Departments of Labor and Treasury to determine what updates might be needed.

- D. Will you commit to work with the Secretaries of Labor and the Treasury to expand the capacity of the parity portal (i.e. by adding functions such as complaint resolution and complaint tracking)?

¹¹² National Alliance on Mental Illness (NAMI), "A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care" (April 2015) (online at: <https://www.nami.org/About-NAMI/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-A-LongRoadAhead.pdf>).

¹¹³ Mental Health and Substance Use Disorder Parity Task Force, *Final Report* (October 2016) (online at: <https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.pdf>); Department of Health and Human Services, "Mental Health and Addiction Insurance Help" (online at: <https://www.hhs.gov/mental-health-and-addiction-insurance-help>).

Response: If confirmed, I look forward to exploring ways in which the parity portal can be promoted and more widely utilized by individuals needing assistance with their behavioral health insurance benefits.

E. What criteria will you use to measure your success in enforcing and improving compliance with mental health parity laws?

Response: If confirmed, I would work with my counterparts at the Departments of Labor and Treasury to ensure we are implementing and enforcing the laws that Congress has put in place on parity. If confirmed, I would make sure that HHS works within the regulatory authority it has in order to best implement the requirements of mental health parity laws. I would work with my counterparts at the Departments of Labor and Treasury to ensure we are implementing and enforcing the laws that Congress has put in place on parity. I would ensure that HHS continues its efforts in working with states, communities, providers, insurers, and consumers to identify best practices and create state and federal partnerships of value.

HHS and fact-based women’s health policy

The expertise of medical experts, along with fact- and evidence-based programs, are critical to the successful implementation of health policy at HHS. Over the course of this year, I have been deeply disturbed by the caliber of some of President Trump’s appointees at the Department—some of whom are unable to discern between fact and fiction in the realm of women’s health policy.

The head of OPA, for example, has publicly stated that “contraception doesn’t work” and that “[t]here...is no evidence to support” the claim that contraceptive use “reduce[s] the incidence of abortion.”¹¹⁴ There is, in fact, a plethora of scientific evidence confirming that contraception prevents pregnancy¹¹⁵ and reduces the incidence of abortion.¹¹⁶ Dr. Charmaine Yoest, the Department’s Assistant Secretary for Public Affairs believes that abortion procedures cause breast cancer—which the National Cancer Institute, the American Congress of Obstetricians and Gynecologists, and the American Cancer Society have “rejected, based on an abundance of research.”¹¹⁷ E. Scott Lloyd, head of the Department’s Office of Refugee Resettlement, insists that “contraceptives are the cause of abortion,”¹¹⁸ which, again, is objectively false. Even former HHS Secretary Price asserted that “there’s not one” woman in the country who struggled to

¹¹⁴ Hannah Levintova, “Trump Just Picked a Contraception Skeptic to Head Federal Family Planning Efforts,” *Mother Jones* (May 1, 2017) (online at <http://www.motherjones.com/politics/2017/05/donald-trump-hhs-teresa-manning-contraception-abortion/#>).

¹¹⁵ See U.S. Food and Drug Administration, “Birth Control Guide” (online at <https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf>).

¹¹⁶ Joerg Dreweke, New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines,” *Guttmacher Institute* (March 18, 2016) (online at <https://www.guttmacher.org/gpr/2016/03/new-clarity-us-abortion-debate-steep-drop-unintended-pregnancy-driving-recent-abortion>).

¹¹⁷ Emily Bazelon, “New Soldiers for Trump’s Anti-Abortion Army,” *New York Times* (May 2, 2017) (online at <https://www.nytimes.com/2017/05/02/opinion/abortion-charmaine-yoest-teresa-manning.html>).

¹¹⁸ Rachel Siegel, “The Trump official who tried to stop a detained immigrant from getting an abortion,” *Washington Post* (October 26, 2017) (online at https://www.washingtonpost.com/news/post-nation/wp/2017/10/26/the-trump-official-who-tried-to-stop-a-detained-immigrant-from-getting-an-abortion/?utm_term=.64921229598f).

purchase birth control prior to the passage of the Affordable Care Act—contrary to the experience of millions of women.¹¹⁹

As the head of HHS, it is critical that you understand, respect, and build policies based on scientific consensus—not fringe pseudoscience.

- A. Do you agree that all FDA-approved contraception methods—including but not limited to sterilization, the IUD, the implant, the shot, the pill, the patch, the vaginal ring, and the male and female condom—prevent pregnancy when used correctly?
- B. Do you agree that contraceptive use is associated with a decline in abortion rates?
- C. Do you agree that contraceptive devices—including the IUD—are not abortifacients?
- D. Do you agree that all reproductive-health-related policies (including policies relating to contraception and abortion) should be based on the fact- and evidence-based conclusions of the medical and scientific communities?
- E. As HHS Secretary, what would you do to ensure that existing employees of HHS—particularly those in leadership positions—who hold fringe beliefs about reproductive health do not allow their unsubstantiated views to affect HHS policies?
- F. Should you find that Administration policies on reproductive health directly conflict with science, what steps will you take to ensure that the American people are not harmed by these policies?

Response to A-F: The Department is the world's leader in the public sector scientific enterprise. I am committed to ensuring that all the Department's programs and activities follow the science and evidence where it leads us, and I will hold Department employees to the same standard.

Contraception and the Affordable Care Act

Prior to the ACA, one in five women reported that they “put off or postponed preventive services” due to cost.¹²⁰ Section 2713 of the Affordable Care Act requires qualified health plans to cover “preventive services” for women as an essential health benefit with no cost-sharing. The Secretary of HHS has the authority to define these preventive services for women, based on the evidence-based recommendations of the Health Resources and Services Administration (HRSA). Current HRSA recommendations include contraception as a preventive service. However, in October 2017, HHS issued two interim final rules that allow employers to refrain

¹¹⁹ Olag Khazan, “Tom Price: ‘Not One’ Woman Struggled to Afford Birth Control,” *The Atlantic* (November 29, 2016) (online at <https://www.theatlantic.com/health/archive/2016/11/tom-price-not-one-woman-cant-afford-birth-control/509003/>).

¹²⁰ Kaiser Family Foundation, “Preventive Services for Women Covered by Private Health Plans under the Affordable Care Act” (December 20, 2016) (online at <http://files.kff.org/attachment/Fact-Sheet-Preventive-Services-for-Women-Covered-by-Private-Health-Plans-under-the-Affordable-Care-Act>).

from offering birth control coverage to their employees, should they have a religious or moral objection to doing so.¹²¹

- A. Do you believe that HRSA should continue to define “preventive services” for women to include all FDA-approved forms of contraception?

Response: HHS should continue to implement the laws as passed by Congress.

- B. The interim final rules went into effect immediately, yet are open for public comment until December 5, 2017. A cursory scan of already-submitted comments to HHS, Treasury, and the Department of Labor reveals that thousands of Americans oppose the new rules. As HHS Secretary, what steps would you take to address the commenters’ concerns?

Response: As with any rulemaking process, I believe the Department should follow the Administrative Procedure Act.

- C. What steps would you take to expand access to birth control? What steps would you take to ensure that women impacted by the new interim rules can access contraception in spite of their employers’ opposition?

Response: Patients should have access to the healthcare that they need, and employers should be able to make decisions such that their moral and religious beliefs are respected.

Teen Pregnancy Prevention Program

Since the implementation of Title X in 2010, teen childbearing has declined by 35% nationwide, suggesting that the program is “highly effective.”¹²² However, in July 2017, the Office of Adolescent Health announced that it would cut short funds for all TPP grants.¹²³ OAH provided no rationale for its decision. Earlier this month, OAH announced a “new research and evaluation collaboration” under the auspices of TPP designed to “improve teen pregnancy prevention and

¹²¹ U.S. Department of Health and Human Services, “Trump Administration Issues Rules Protecting the Conscience Rights of All Americans” (October 6, 2017) (online at <https://www.hhs.gov/about/news/2017/10/06/trump-administration-issues-rules-protecting-the-conscience-rights-of-all-americans.html>).

¹²² Christine Dehlendorf, “Successful teen pregnancy prevention program threatened by funding cuts,” *STAT News* (April 20, 2017) (online at <https://www.statnews.com/2017/04/20/successful-teen-pregnancy-prevention-program-threatened-funding-cuts/>).

¹²³ Christine Dehlendorf, “Successful teen pregnancy prevention program threatened by funding cuts,” *STAT News* (April 20, 2017) (online at <https://www.statnews.com/2017/04/20/successful-teen-pregnancy-prevention-program-threatened-funding-cuts/>).

sexual risk avoidance.”¹²⁴ “Sexual risk avoidance” is a euphemism for “abstinence-only”¹²⁵—an ineffective form of sex education that does not reduce the rates of teen pregnancy.¹²⁶

- A. As HHS Secretary, would you direct the Department to implement evidence-based, effective pregnancy prevention programs that are proven to reduce teen pregnancy rates? Would you take steps to restore the Title X grants that OAH recently cut short?
- B. The scientific consensus on “sexual risk avoidance,” or abstinence-only, programs, is that they are ineffective. Do you agree with this consensus?
- C. Do you believe American taxpayers should fund ineffective health programs?
- D. As HHS Secretary, what steps would you take to ensure that other pregnancy prevention programs within the Department, such as the Personal Responsibility Education Program (“PREP”), are not co-opted by “sexual risk avoidance” programs at the expense of evidence-based pregnancy prevention?

Response to A-D: If confirmed, I am committed to faithfully implementing the law. Any grant programs will be operated in accordance with any statutory requirements and the grant making rules and procedures of the Department. 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.

The role of the Director of the Office of Refugee Resettlement (ORR)

The Office of Refugee Resettlement, housed within the Administration for Children & Families at HHS, is responsible for providing “care and placement for unaccompanied children who enter the United States from other countries without an adult guardian.”¹²⁷ The current director of ORR is Scott Lloyd.¹²⁸

Mr. Lloyd has made concerning statements suggesting that is unaware of the legal boundaries of his role as ORR Director. He is a zealous anti-abortion advocate, and has used his role as

¹²⁴ U.S. Department of Health and Human Services, Office of Adolescent Health, “HHS Announces New Efforts to Improve Teen Pregnancy Prevention & Sexual Risk Avoidance Programs” (November 6, 2017) (online at <https://www.hhs.gov/ash/oah/news/news-releases/new-sexual-risk-avoidance-programs/index.html>).

¹²⁵ Mark Peters, “Euphemism: sexual risk avoidance,” *Boston Globe* (June 23, 2017) (online at <https://www.bostonglobe.com/ideas/2017/06/23/euphemism-sexual-risk-avoidance/cowYJFTOeIS7hmD0wtm64O/story.html>).

¹²⁶ John Santelli, “Abstinence-only education doesn’t work. We’re still funding it.” *Washington Post* (August 21, 2017) (online at https://www.washingtonpost.com/news/posteverything/wp/2017/08/21/abstinence-only-education-doesnt-work-were-still-funding-it/?utm_term=.6d87ac444f17).

¹²⁷ Office of Refugee Resettlement, “What We Do” (online at <https://www.acf.hhs.gov/orr/about/what-we-do>).

¹²⁸ Administration for Children and Families, “Scott Lloyd” (online at <https://www.acf.hhs.gov/about/leadership/scott-lloyd>).

Director to personally influence young women’s decisions regarding unplanned pregnancy.¹²⁹ An HHS spokesman has described Mr. Lloyd as having “custody of these children, and just like a foster parent, he know that that’s a lot of responsibility and he is going to make choices that he thinks are best for both the mother and the child.”¹³⁰

Nothing in statute defines the Director of ORR as a “foster parent.”¹³¹ The young women under the custody of ORR are not Mr. Lloyd’s children, and he has no legal right to make decisions for them—or their fetuses—as a father-figure.

- A. As HHS Secretary, would you commit to ensuring that the Office of Refugee Resettlement is run in accordance with federal statute—not based on the whims of a Director who appears to misunderstand the autonomy of the young women in ORR’s custody?

Response: 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.

- B. As HHS Secretary, would you commit to providing all individuals within the custody of ORR with medically accurate health information, including medically accurate information on abortion and contraceptive services?

Response: If confirmed as HHS Secretary, I will ensure that unaccompanied children in ORR’s custody receive medically accurate health information, as required by the interim final rule on “Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children,” which requires that unaccompanied alien children who suffer abuse in an ORR care facility and become pregnant receive timely and comprehensive information about all lawful pregnancy-related medical services. For youth who suffer abuse outside of ORR custody or become pregnant through consensual sex, ORR follows its 2008 policy on “Medical Services Requiring Heightened ORR Involvement.”

Title X Family Planning Program

The Title X Family Planning Program funds basic reproductive health services—including cancer screenings, STI testing, and contraception—for over 4 million low-income Americans every year.¹³² Title X does not provide funds for abortion services.

¹²⁹ Rachel Siegel, “The Trump official who tried to stop a detained immigrant from getting an abortion,” *Washington Post* (October 26, 2017) (online at https://www.washingtonpost.com/news/post-nation/wp/2017/10/26/the-trump-official-who-tried-to-stop-a-detained-immigrant-from-getting-an-abortion/?utm_term=.fc5b29800a4).

¹³⁰ *Ibid.*

¹³¹ 8 USC 1522; 6 USC 279.

¹³² Planned Parenthood Action Fund, “Title X: America’s Family Planning Program” (online at <https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x>).

Though it was originally established with bipartisan support, Title X has faced increased attacks from Republicans in recent years. Some states have attempted to exclude reproductive health centers that also provide abortion services from receiving Title X funds—a process that the Trump Administration made easier this year¹³³ when it nullified an HHS rule clarifying that Title X recipients cannot be barred from receiving funds “on bases unrelated to their ability to provide Title X services effectively.”¹³⁴ In addition, a policy memo from the White House’s Domestic Policy Council reveals that the Trump Administration would like to “cut [the budget of Title X] in half at least” in order to fund “childcare programs, or new fertility awareness programs for adolescents.”¹³⁵

- A. Do you believe that states should be able to deny Title X funding to health providers that meet program criteria for providing reproductive health services?
- B. As HHS Secretary, would you restore Department policies ensuring that states do not deny Title X funding to health providers for reasons other than their ability to provide reproductive health services?

Response to A & B: If confirmed as Secretary, I will faithfully implement laws written by Congress. Any grant programs will be operated in accordance with any statutory requirements and the grant making rules and procedures of the Department. To the extent that states receive Title X funding, I believe they are best equipped to determine and meet the family planning needs of their citizens, within the legal parameters of the program.

- C. An analysis of Title X in the *American Journal of Public Health* found that the program would require “approximately \$737 million...to provide family planning services to all uninsured low-income women of reproductive age in the United States.”¹³⁶ In FY 2017, Title X received just \$286.5 million, or roughly 40% of the budget necessary to meet the need for Title X services.¹³⁷
 - a. Do you agree with the Trump Administration that the Title X budget should be “cut in half”?
 - b. As HHS Secretary, would you advocate for increased funding for Title X?

¹³³ Colin Dwyer, “Trump Signs Law Giving States Option to Deny Funding for Planned Parenthood,” *NPR* (April 13, 2017) (online at <http://www.npr.org/sections/thetwo-way/2017/04/13/523795052/trump-signs-law-giving-states-option-to-deny-funding-for-planned-parenthood>).

¹³⁴ Health and Human Services Department, *Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients* (December 19, 2016) (online at <https://www.federalregister.gov/documents/2016/12/19/2016-30276/compliance-with-title-x-requirements-by-project-recipients-in-selecting-subrecipients>).

¹³⁵ Brian Beutler, “Leaked Memo Reveals White House Wish List,” *Crooked* (October 19, 2017) (online at <https://crooked.com/article/leaked-memo-reveals-white-house-wish-list/>).

¹³⁶ National Family Planning & Reproductive Health Association, “Title X: Budget and Appropriations” (online at https://www.nationalfamilyplanning.org/title-x_budget-appropriations); Euna M. August et al., “Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act,” *American Journal of Public Health* (February 2016) (online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985850/>).

¹³⁷ National Family Planning & Reproductive Health Association, “Title X: Budget and Appropriations” (online at https://www.nationalfamilyplanning.org/title-x_budget-appropriations).

Response: Although the President submits a budget request to Congress, the Title X program's funding level is ultimately determined by Congress. If confirmed, I will faithfully implement laws written by Congress.

- D. According to a Domestic Policy Council memo, the Trump Administration hopes to prioritize “fertility awareness programs” in lieu of the existing Title X program. Fertility awareness is a behavioral contraceptive method in which a woman tracks her menstruation, cervical mucus, and/or basal body temperature to determine when she is most fertile, allowing her to avoid sexual intercourse during her peak fertility. The fertility awareness method, without dual use of a barrier contraceptive, does not protect against sexual transmitted infections (STIs).¹³⁸ The fertility awareness method is more complicated and time consuming than other forms of birth control, such as the pill and the IUD, and is also less effective: for every 100 women relying on the fertility awareness method each year, 12-24 women will become pregnant—compared to 9 pill users and 1 IUD user.¹³⁹
- a. Do you believe that HHS should devote significant time and resources to promoting the fertility awareness method, at the expense of more effective contraceptives?
 - b. Do you believe that women who access reproductive health services through government programs should have access to the full range of contraceptive devices and methods, with the freedom to choose which method works best for them?

Response to a & b: The statutory language governing the Title X program requires Title X projects to offer a broad range of acceptable and effective family planning methods and services, and expressly includes natural family planning methods, and services for adolescents. Women should have access to the health care and services they need.

Health care for pregnant women, new mothers, and newborns

The Medicaid program currently finances almost half of all births in the United States and provides pre-natal care to 46% of our nation's pregnant women.¹⁴⁰ You have advocated for policies that would gut the Medicaid program—jeopardizing the health care of these pregnant women and their fetuses. The Strong Start For Mothers and Newborns Initiative, meanwhile, is an HHS program that “aims to reduce preterm births and improve outcomes for newborns and

¹³⁸ American Congress of Obstetricians and Gynecologists, “Fertility Awareness-Based Methods of Family Planning” (online at <https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning#what>).

¹³⁹ American Congress of Obstetricians and Gynecologists, “Fertility Awareness-Based Methods of Family Planning” (online at <https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning#what>); U.S. Food and Drug Administration, “Birth Control Guide” (online at <https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf>).

¹⁴⁰ Julia Paradise, Barbara Lyons, and Diane Rowland, “Low-Income Pregnant Women, Children and Families, and Childless Adults,” *Henry J. Kaiser Family Foundation* (May 9, 2015) (online at <http://kff.org/report-section/medicaid-at-50-low-income-pregnant-women-children-and-families-and-childless-adults/>).

pregnant women.”¹⁴¹ The Initiative, however, is funded by the Affordable Care Act—which you have advocated repealing.¹⁴²

- A. As HHS Secretary, would you commit to preserving existing programs that promote the health and well-being of pregnant women, new mothers and newborns?
- B. As HHS Secretary, what would you do to expand pregnant women’s access to prenatal and post-natal healthcare services that improve health?
- C. According to the American Academy of Pediatrics, breastfeeding is associated with a variety of health benefits for infants, including a 36% reduction in sudden infant death syndrome.¹⁴³ The ACA guarantees women access to a variety of free preventive services—including breastfeeding counseling and supplies. This ACA mandate has increased the number of breastfeeding infants by 47,000, compared to 2014 levels.¹⁴⁴ As HHS Secretary, what specific actions would you take to ensure that women’s gains in breastfeeding support and coverage are retained?

Response to A-C: Medicaid is more than a safety net; it’s a lifeline that needs to be preserved and improved for those who truly need it. I believe HHS has an obligation to help those who need it most, and we need to ensure that we are building a Medicaid program that is sound and solvent and helps all beneficiaries reach their highest potential. I also believe that it is critical that women, children and infants have access to high quality prenatal and postnatal care. If confirmed, I look forward to working with Congress to promote a healthcare system that will provide access to high quality care while ensuring patients are able to make decisions that work best for them.

Health care for LGBTQ individuals

As HHS Secretary, you would be responsible for “enhance[ing] and protect[ing] the health and well-being of all Americans”—including LGBTQ citizens. Over the course of 2017, I have grown increasingly concerned with the Department’s commitment to promoting LGBTQ health. President Trump has appointed a number of high-level Department employees who are outspokenly opposed to LGBTQ individuals. The HHS Assistant Secretary of Public Affairs, for example, has claimed that LGBTQ individuals are “wrestling with a disorder,” and has been connected to statements describing transgender individuals as “crazy” “creatures” who “take a meat cleaver to [their] manhood.”¹⁴⁵

¹⁴¹ Centers for Medicare & Medicaid Services, “Strong Start for Mothers and Newborns Initiative: General Information” (online at <https://innovation.cms.gov/initiatives/strong-start/>).

¹⁴² Adelle Simmons, Katherine Warren, and Kellyann McClain, “The Affordable Care Act: Advancing the Health of Women and Children,” *ASPE Issue Brief* (January 9, 2015) (online at https://aspe.hhs.gov/sites/default/files/pdf/77191/ib_mch.pdf).

¹⁴³ American Academy of Pediatrics, “Policy Statement: Breastfeeding and the Use of Human Milk” (March 2012) (online at <http://pediatrics.aappublications.org/content/pediatrics/129/3/e827.full.pdf>).

¹⁴⁴ Kandice A. Kapinos, Lindsey Bullinger, and Tami Gurley-Calvez, “Lactation Support Services and Breastfeeding Initiation,” *Health Services Research* (November 10, 2016) (online at <http://onlinelibrary.wiley.com/doi/10.1111/1475-6773.12598/abstract>).

¹⁴⁵ Transgender Legal Defense and Education Fund, “Transgender Legal Defense Debates Family Research Council” (November 13, 2006) (online at <https://www.youtube.com/watch?v=REZ4NuLmm-k>).

Each year, HHS is required to develop and solicit public comment on a “strategic plan” for the agency. In September 2017, HHS released its Draft Strategic Plan for 2018-2022.¹⁴⁶ The Draft Strategic Plan included a series of concerning omissions—in particular, it failed to reference Section 1557 of the ACA, the “first federal civil rights law to prohibit sex discrimination in health care,” and LGBTQ individuals as a priority population for the Department.¹⁴⁷ This omission comes in the wake of HHS’ decision, earlier this year, to remove language from its Office of Civil Rights website clarifying that discrimination based on gender identity and sex stereotyping constitutes discrimination on the basis of sex.¹⁴⁸ In addition, HHS has taken multiple steps to limit data collection on LGBTQ individuals.

- A. Do you believe that LGBTQ individuals deserve the same rights and access to health care as other American citizens, regardless of their sexual orientation or gender identity?

Response: Americans have equal rights under the law, without distinction, and the government cannot deny any individual access to healthcare for illegally arbitrary reasons. If confirmed I will ensure HHS will faithfully implement the anti-discrimination protections contained in the laws passed by Congress.

- B. As HHS Secretary, what steps would you take to prevent individual employees’ opposition to LGBTQ rights from harming the health and wellbeing of LGBTQ citizens?

Response: If confirmed, no person under my management will be authorized to harm the health and wellbeing of any citizens. HHS employees and programs will be dealt with appropriately, if they violate that directive.

- C. As HHS Secretary, would you make the healthcare of LGBTQ individuals a priority, including but not limited to placing LGBTQ individuals’ needs into the Department’s Strategic Plan?

Response: HHS has historically responded to pressing healthcare issues with thoughtful and vigorous action including most recently the opioid crisis, but also issues such as diabetes, cancer, and HIV/AIDS. If confirmed, I am committed to maintaining this legacy to respond appropriately to the healthcare needs of all of our fellow Americans.

- D. As HHS Secretary, would you commit to protecting LGBTQ individuals from sex discrimination, including through aggressive enforcement of Section 1557 of the ACA?

Response: If confirmed, I am committed to making sure all Americans are free from unlawful discrimination in health and human services, including under Section 1557 and

¹⁴⁶ U.S. Department of Health and Human Services, “HHS Invites Public Comment on Draft 2018-2022 Strategic Plan” (October 19, 2017) (online at <https://www.hhs.gov/hepatitis/blog/2017/10/19/hhs-invites-public-comment-draft-2018-2022-strategic-plan.html>).

¹⁴⁷ Steve Lee, “Civil rights and health advocates express strong concerns about HHS’s draft strategic plan,” *LGBT Weekly* (November 15, 2017) (online at <http://lgbtweekly.com/2017/11/15/civil-rights-and-health-advocates-express-strong-concerns-about-hhss-draft-strategic-plan/>).

¹⁴⁸ See Letter from Senate Democrats to Secretary Tom Price (August 15, 2017) (online at https://www.help.senate.gov/imo/media/doc/20170815_August%201557%20Letter.pdf).

other civil rights laws, consistent with court orders and I will ensure HHS will faithfully implement anti-discrimination protections contained in the laws passed by Congress.

- E. What additional steps would you take, as HHS Secretary, to prioritize the health of LGBTQ Americans?

Response: HHS has historically responded to pressing healthcare issues with thoughtful and vigorous action including most recently the opioid crisis, but also issues such as diabetes, cancer, and HIV/AIDS. If I am confirmed, I am committed to maintaining this legacy to respond appropriately to all medical needs facing our nation so all have the opportunity for improved health and wellness.

HIV/AIDS programs

As HHS Secretary, you would be responsible for managing life-saving HIV/AIDS programs, including the Centers for Disease Control and Prevention (CDC).

- A. As HHS Secretary, will you commit to maintaining existing levels of funding for HHS programs that combat HIV/AIDS?

Response: It is a top public health priority that we continue making progress in the fight against HIV/AIDS. I intend to maintain this commitment to addressing HIV/AIDS.

- B. As HHS Secretary, will you commit to ensuring that all Americans maintain access to existing levels of care for HIV/AIDS and related conditions? Will you commit to expanding access to care for HIV/AIDS patients?

Response: It is a top public health priority that we continue making progress in the fight against HIV/AIDS. I intend to maintain this commitment to addressing HIV/AIDS. I defer to Congress on how best to ensure access to care and commit to fully implementing the laws passed by Congress.

Medicare Part D cost estimates and response to congressional requests

The Medicare Part D drug benefit was signed into law by President Bush in December 2003, with lawmakers at the time relying heavily on cost estimates provided by the Congressional Budget Office. However, several months after passage of the law, Richard Foster, the former HHS Actuary, revealed that estimates prepared at HHS “as early as ... spring” of 2003 showed that the legislation would cost far more than estimated by CBO.¹⁴⁹ Mr. Foster disclosed that he was prevented from disclosing these estimates, revealing that he was told by Tom Scully, then the Medicare Administrator, “that he would be dismissed if he replied directly to legislative requests for information about prescription drug bills pending in Congress.”¹⁵⁰ You were the HHS General Counsel in 2003 and 2004, when the Medicare Part B bill was debated, passed, and signed into law.

¹⁴⁹ Washington Post, Foster: White House Had Role in Withholding Medicare Data (Mar. 19, 2004) (https://www.washingtonpost.com/archive/politics/2004/03/19/foster-white-house-had-role-in-withholding-medicare-data/af6d062c-4d4b-43f8-902f-72332abf7610/?utm_term=.a8926649051b).

¹⁵⁰ *Id.*

- A. Were you aware at any time prior to passage of the bill and President Bush signing it into law that internal HHS estimates of the bill's cost were higher than estimates by CBO?
- B. If so, when did you become aware of this information, and what did you do when you became aware of it?

Response to A & B: I do not believe I was aware of this issue until it became a matter of public controversy after passage of the statute.

- C. Did you ever indicate to the HHS actuary or any other HHS official that they should not publicly release these internal cost estimates?
- D. Did you ever indicate to the HHS actuary or any other HHS official that they should not release these internal cost estimates to any member of Congress?

Response to C & D: As noted above, I do not believe I was aware of this issue until it became a matter of public controversy after passage of the statute.

- E. Were you aware that Secretary Thompson had told Mr. Foster not to respond to Congressional requests for cost estimates?

Response: I do not recall such allegations being made regarding Secretary Thompson.

- F. Were you aware of Secretary Thompson's threats to dismiss Mr. Foster if he did so?

Response: I do not recall such allegations being made regarding Secretary Thompson.

- G. If so, when did you become aware of this, and what did you do about it?

Response: As noted above, I do not believe I was aware of this issue until it became a matter of public controversy after passage of the statute.

- H. Do you believe that this situation was handled appropriately?
- I. If confirmed, will you commit to allowing the HHS Actuary to respond openly and completely, without interference, to all requests by members of Congress?

Response to H & I: I believe it is important for Executive agencies and Congress to work together to fulfill requests for information in a timely manner.

Puerto Rico and the U.S. Virgin Islands

Puerto Rico and the U.S. Virgin Islands are territories of the United States, and their residents are U.S. citizens. As HHS Secretary, you will head a department whose work will have a significant impact on these U.S. citizens' lives. In the wake of Hurricanes Irma and Maria, which have devastated both territories, public health concerns have multiplied.

- A. In Puerto Rico, the official fatality count due to Hurricane Maria currently stands at 58, but multiple reports indicate that the true death toll might be much higher,¹⁵¹ and a recent

¹⁵¹ Nidhi Prakash, "Puerto Rico's Government Just Admitted 911 People Died After The Hurricane—Of 'Natural Causes,'" *Buzzfeed* (October 27, 2017) (online at https://www.buzzfeed.com/nidhiprakash/puerto-rico-natural-causes?utm_term=.ao9rqEJ9OB#.ctBP4eo3Nb); Frances Robles, "Puerto Rico Deaths Spike, but Few Are

study suggests that “the actual death count may be closer to 1,085” deaths, which “exceeds the government’s official figure by a factor of 20.”¹⁵² So far, the Department of Homeland Security has shown an unwillingness to verify that the methodology for calculating fatalities in Puerto Rico accords with best practices and does not undercount, and to ensure that the fatality count is accurate. Federal Emergency Management Agency (FEMA) Administrator Brock Long recently wrote that neither FEMA nor HHS “has a role in the cause and manner of death determination.” Do you agree? Do you believe that HHS should take no steps to ensure the accuracy of the fatality count even when there are numerous credible reports that this count is inaccurate?

Response: Under the current national response framework, federal assets are deployed, usually in response to requests, to meet the needs of states, commonwealths, and territories during a disaster response. HHS has assets from medical care to mortuary services to meet those needs. With regard to causes of death, from the public information I have seen, my understanding is that this is a decision made by local officials.

B. Do you agree with the Department of Defense’s decision to withdraw the Navy hospital ship the USNS Comfort from Puerto Rico on November 17? Why or why not?

Response: During my time at HHS, the USNS Comfort was deployed on numerous occasions and met the needs of those it was deployed to serve. With regard to the deployment of the USNS Comfort during Hurricane Maria, I do not possess information to have an informed view.

C. Experts believe that water- and vector-borne diseases, such as leptospirosis and Zika, pose an ongoing threat to the people of Puerto Rico and the U.S. Virgin Islands. Will you pledge to ensure that the Centers for Disease Control and Prevention, and the local territorial agencies, have all the resources they need to combat water- and vector-borne diseases in both territories?

Response: CDC’s mission is to protect the U.S. and U.S. territories against public health threats, including water- and vector-borne diseases. I know CDC has been instrumental in supporting the response to Hurricanes Irma and Maria and will continue to work with U.S. territories and other federal agencies to re-establish important public health infrastructure such as disease surveillance and laboratory diagnostics.

Attributed to Hurricane,” *New York Times* (November 8, 2017) (online at https://www.nytimes.com/2017/11/08/us/puerto-rico-deaths-fema.html?_r=0).

¹⁵² Eliza Barclay and Alexia Fernández Campbell, “New data shows hurricane deaths in Puerto Rico could be 20 times higher than the government claims,” *Vox* (November 29, 2017) (online at <https://www.vox.com/policy-and-politics/2017/11/29/16623926/puerto-rico-death-toll-hurricane-maria-count>).

Senator Whitehouse

1. The United States spends over 17 percent of gross domestic product (GDP) on health care. We far outspend the most expensive, universal coverage health care systems in the world, and don't get better results. The next-highest-spending country, as a percentage of GDP, is Switzerland at 12.4 percent. Our life expectancy is comparable to Turkey and the Czech Republic, and over 250,000 Americans die due to medical errors every year.

Simply moving from the highest spending to the second-highest spender would realize significant savings in our health care system. We could achieve that savings while improving care and outcomes for patients by aggressively pursuing changes to the way we pay for and deliver care.

- a. Do you agree that payment and delivery system reforms can reduce health care spending and improve patient care?
- b. Will you commit to maxing out our pursuit of payment and delivery system reforms before pursuing cuts to benefits and eligibility in Medicare and Medicaid or restructuring those programs into voucher programs or block grants?

Response to a & b: If we start from the principle of empowering patients and putting their needs first, healthcare payment and delivery system reforms can help reduce healthcare spending and improve patient care. If confirmed, I will strive to work with staff across HHS to make healthcare 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. Under the status quo, premiums and deductibles 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.

2. Congress created the Center for Medicare and Medicaid Innovation in CMS to test innovative payment and delivery models to reduce costs while preserving or enhancing the quality of care.

Under Secretary Price, work at the Innovation Center has slowed, and in some cases stopped altogether. CMS first delayed implementation, now finalized the cancellation of several bundled payment models and an incentive payment program for cardiac rehabilitation services. The agency also scaled back a payment model to improve the quality and efficiency of care related to joint replacements.

In 2009, you were quoted by the *Indianapolis Star* saying:

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 . . . We need to pay for episodes of care, rather than separately reimbursing each procedure

and provider who touches the patient. We need incentives for prevention, and better and smarter primary care so all Medicare patients have a medical home.

- a. Do you continue to support value-based payment and alternative payment models? What is your vision for the future of these programs?
- b. Do you think the actions taken by CMS this year to scale back and cancel new payment models will improve quality and lower costs to Medicare?
- c. How do you envision refining episodic care models if there isn't a way to engage in broad-scale testing?

Response to a-c: As I made clear in my opening statement, 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 healthcare 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 the details or deliberative process behind the most recent actions cited in this question, but if confirmed, I look forward to coordinating with CMS and CMMI as they work toward their goal of fostering an affordable, accessible healthcare system that puts patients first. I believe we need to review the work of CMMI periodically to identify what's working and what is not, as provided in the statute, and I look forward to working with CMS to ensure we are carefully evaluating the CMMI models and applying those lessons learned in new models. In addition, it is my understanding that 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. As I said during my opening statement to the Committee, we must make healthcare more affordable, more available, and more tailored to what individuals want and need in their care.

3. In January 2015, Secretary Burwell announced goals of tying 30 percent of Medicare fee-for-service payments to quality or value through alternative payment models by the end of 2016 and 50 percent by 2018. The Obama Administration announced it achieved its 2016 goal ahead of schedule, and stated that they are on track to achieve the goal of linking 50 percent of Medicare payments to alternative payment models by the end of 2018.
 - a. If you are confirmed as Secretary of Health and Human Services, will you direct the agency to continue to work to achieve these payment reform goals?
 - b. If not, what are your payment reform targets? How will you encourage private health care stakeholders to sustain momentum in the transition away from fee-for-service?
4. Do you think it is important that our health care system has measurable, accountable targets to work toward? If so, what goals do you think are important?

Response to questions 3 & 4: As I made clear in my opening statement and in my written responses to you, one of my top priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our healthcare 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. I look forward to coordinating with CMS, CMMI and others in the Department as they work toward fostering an affordable, accessible healthcare system that puts patients first. I believe we need to review the work of CMMI periodically to identify what's working and what is not, as provided in the statute, and I look forward to working with CMS to ensure we are carefully evaluating the CMMI models and applying those lessons learned in new models.

5. CMS recently released a Request for Information (RFI) that describes a "new direction" for the Center for Medicare and Medicaid Innovation. The RFI seeks feedback on concepts and models that appear to define patient-centeredness in a manner that simply means shifting costs to seniors.

Through the Innovation Center, Congress granted CMS considerable flexibility to test and expand new payment and delivery models. That authority does not allow the agency to unravel the Medicare guarantee or to circumvent beneficiary protections established by Congress.

- a. Do you believe CMS should use its authority under the Innovation Center to implement a premium support or voucher program in Medicare?
- b. Do you believe CMS should use its authority under the Innovation Center to require seniors to negotiate their out-of-pocket health care costs directly with their doctors?

Response: If confirmed, I will work to ensure that any new models and concepts are geared first and foremost to the patient and his or her needs and that any new ideas or models are consistent with the statute. It would be premature for me to declare the contours of the "new direction" for CMMI without first reviewing the submitted ideas and concepts with Department staff. I look forward to reviewing your ideas and proposals as they relate to this RFI.

A top priority would be harnessing 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.

6. The opioid epidemic is devastating communities across the country, but it is hitting particularly hard in my home state of Rhode Island. The Trump administration recently declared the opioid crisis a Public Health Emergency. While this declaration may help raise awareness of the crisis and give HHS the opportunity to waive some regulations, it fails to commit much-needed additional resources to combatting this crisis. In 2016, Congress passed the Comprehensive Addiction and Recovery Act (CARA), bipartisan legislation that I co-authored that treats addiction as a disease and aims to increase access to prevention, treatment, and recovery programs.

- a. Do you support the goals of CARA?

Response: Yes, I fully support the goals of CARA.

- b. As HHS Secretary, will you support committing significant additional funding to combatting the opioid crisis, including for the programs authorized by CARA?

Response: As mentioned above, I am supportive of the goals of CARA. It is within Congress's purview to determine the amount of funding appropriated for the programs created under CARA.

- c. Will you commit to advocating for robust funding for SAMHSA to combat the opioid epidemic?

Response: If confirmed, I am committed to working with the Administration and Congress to combat the opioid crisis.

7. One of the most effective ways to reduce the illicit use of opioids and overdose fatalities is medication-assisted treatment, which is the combined use of medication with counseling and behavioral therapies to treat substance use disorders. Secretary Price said in May, "If we're just substituting one opioid for another, we're not moving the dial much." I think that view is shortsighted. Studies show that medication, combined with behavioral therapy, is moving the dial, and we could move it more if we expanded access. In fact, the final report of the President's own Opioid Commission supports the expansion of medication-assisted treatment.

Will you support efforts to expand access to medication-assisted treatment through the allocation of federal resources, as well as through other ways to increase the availability of treatment, like giving incentives to prescribers or making it easier for prescribers to obtain the requisite training?

Response: 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.

8. One of the ways that the Comprehensive Addiction and Recovery Act (CARA) aimed to expand access to medication-assisted treatment was by extending the prescribing authority for buprenorphine to nurse practitioners and physicians assistants. CARA also required that HHS provide a mechanism for providers, nurse practitioners and physicians assistants included, to have their prescribing caps increased from 30 to 100. Earlier this year, HHS withdrew a notice of proposed rulemaking on this topic.
 - a. Do you agree that we should expand the prescribing authority of nurse practitioners and physicians assistants in order to improve access to medication-assisted treatment?
 - b. Will you commit to ensuring this expansion goes into effect without delay?

Response to a & b: Nurse Practitioners (NPs) and Physician Assistants (PAs) play an important role in expanding access to medication-assisted treatment, and I am in complete support of ensuring that NPs and PAs are able to obtain waivers and expand their prescribing authority when requirements have been met.

9. I understand you played an important role in HHS's response to 9/11, the subsequent anthrax attacks, and preparing for influenza outbreaks during the Bush administration. It is my opinion that the United States is not adequately prepared to respond to biological threats, including both the natural spread of infectious diseases and deliberate attacks on our country.
- a. Do you believe the United States is prepared to respond to a deliberate biological attack or a severe infectious disease outbreak?

Response: From the public information I have seen, I think significant progress has been made to address many of the threats; however, the threats are ever expanding and more work is needed to make America truly prepared.

- b. Will you commit to prioritizing improving our country's preparedness, including through requesting adequate funding for such activities, as HHS Secretary? What are your top priorities in this area?

Response: Numerous studies have shown that investment in preparedness and community resilience result in significant cost savings when a disaster strikes. If confirmed, I look forward to gaining access to additional information to better inform my top priorities in this area, but I think that they would include developing additional medical countermeasures, addressing issues with distribution of stockpiled products, and partnering with state and local governments to further our mutual preparedness and ability to withstand and respond to a public health emergency.

- c. The HELP Committee is due to reauthorize the Pandemic and All-Hazards Preparedness Act next year. Will you commit to working with our committee to ensure HHS has both the funding and the authorities it needs to improve our preparedness?

Response: If confirmed, I look forward to working with the committee on the reauthorization of the Pandemic and All-Hazards Preparedness Act, alongside the HHS Assistant Secretary for Preparedness and Response who assisted in drafting the original legislation, as did I during my previous tenure at HHS. The threats facing America evolve daily, and I look forward to working with the committee as we identify areas of the law that may need to evolve to meet those threats.

10. A number of well-respected groups, including the American Academy of Pediatrics, the American Lung Association, the American College of Physicians, and the American Public Health Association have gone on record with a consensus statement about the dangers of the health effects of climate change. In June, these groups and others signed the latest version of a declaration saying the health effects of climate change "demand immediate action."
- a. Do you believe climate change is a threat to public health?

- b. Will you commit to supporting funding for HHS programs that help health departments deal with the health effects of climate change, like the CDC's Climate and Health Program?

Response to a & b: Within HHS, CDC and ASPR work with state and city health departments to plan for responses to the health impacts of extreme weather-related hospitalizations and disease outbreaks. For instance, we saw HHS' response this summer to three major hurricanes. States and cities benefit by being able to establish infrastructure to address these situations, and if confirmed, I will continue to build on the work already ongoing to ensure Americans are prepared to respond to threats of this nature.

11. CMS Administrator Seema Verma has publicly stated this Administration will make a significant policy shift in the Medicaid program by allowing states to introduce work requirements into their Medicaid programs.

Many of these work-requirement proposals would require "able-bodied adults" otherwise eligible for Medicaid to demonstrate that they are working, searching for work, or in an education or training program to qualify for coverage. The Kaiser Family Foundation reported that at least 57 percent of the Medicaid expansion population are working full or part-time. Of those who are not working, 29 percent were taking care of home or family; 20 percent were looking for work; 18 percent were in school; 17 percent had an illness or disability that interfered with work; and 10 percent were retired.

- a. What is your definition for the term "able-bodied"?
- b. Do you believe the term "able-bodied" includes people who have addiction, mental health, or behavioral health issues?
- c. Should individuals lose their health insurance because they are taking care of family members or are retired?
- d. Will you commit to opposing the imposition of work requirements for Medicaid recipients in these circumstances?

Response to a-d: 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 was not privy to the policy development at CMS regarding their January 11 SMD letter, 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 healthcare.

12. There have long been disparities in the way Medicare reimburses hospitals in different regions under the wage-index formula. While the formula may accurately reflect costs in many parts of the country, for years my colleagues in the Rhode Island delegation and I have raised concerns with the Department of Health and Human Services about how this formula is implemented in Rhode Island.

In FY2013 and each subsequent fiscal year, the Centers for Medicaid and Medicare Services has addressed Rhode Island concerns about how the wage index affects Rhode Island hospitals by proposing and finalizing an alternative methodology for calculating the imputed wage index floor (“imputed floor”) in its annual Inpatient Prospective Payment System Rule (IPPS). The alternative methodology better reflects Rhode Island’s proximity to expensive health care markets, like Boston, as well as the size of the state. This fix is important to Rhode Island hospitals and the overall fiscal condition of Rhode Island’s health care system as it generates approximately \$29 million for 10 hospitals each year.

Will you commit to continuing the alternative methodology for calculating the imputed floor for Rhode Island in forthcoming IPPS rules?

Response: I am not yet familiar with CMS’s methodology for calculating the imputed wage index floor in its annual Inpatient Prospective Payment System Rule, but I know that each state has unique needs. If confirmed, I will work with you and your office as well as other members of Congress to make sure the Department develops and implements sound payment policies in accordance with the law.

13. As you know, the adoption and use of electronic health record technology (EHRT) by health care providers has been a priority for both the Bush and Obama Administrations. While there’s been tremendous growth in adoption of EHRT in the past 10 years, too often incompatibilities between the systems inhibit the movement of data from one system to another.

Rhode Island has been able to address challenges related to EHRT through its statewide Health Information Exchange. Rhode Island’s CurrentCare is central point of connectivity in the state. In that position, CurrentCare is able to aggregate patients’ health information, which allows for the creation of a complete, longitudinal record that has tremendous value to patients and providers.

CurrentCare received federal funding under the American Recovery and Reinvestment Act of 2009, but there hasn’t been sustained federal funding to support the operations of Health Information Exchanges. Funding for Health Information Exchanges has been nowhere near the over \$37 billion that has poured through the Electronic Health Record Incentive Programs offset providers’ costs of purchasing EHRT.

If confirmed Secretary of Health and Human Services, how will you support the work of Health Information Exchanges, like CurrentCare?

Response: I support the goal of nationwide interoperability. To achieve this goal, all Health Information Exchanges and Networks should be able to provide connectivity to the stakeholders they support. Current Health Information Exchanges will be a critical asset to achieve this goal. If confirmed, I would look forward to learning more about the work of CurrentCare.

14. What roles do you see Health Information Exchanges and data-sharing networks playing in our health care system?

Response: Health Information Exchanges, data-sharing networks, and innovative health IT companies are partners that can provide new, valuable data services as the Department works to make health information flow more easily between organizations. Interoperable health information technology is one of the key potential enablers of improving cost, quality, and value in our healthcare system.

15. The opioid crisis – highlighted by President Trump’s recent public health emergency declaration – points to the need to expand the clinical capacity of mental health and addiction treatment providers. I introduced the Improving Access to Behavioral Health Information Technology Act (S. 1732) with Senator Portman, which would authorize the Center for Medicare and Medicaid Innovation to conduct demonstrations that include financial incentives to support the adoption of health IT by mental health and addiction providers. We believe that mental health and addiction providers are the medical home for patients with mental health and substance use disorders, and as such these providers need tools help with clinical management of the whole patient.

As Secretary, in what ways will you encourage relevant agencies, like SAMHSA, CMS, and ONC, to promote and support the use of health IT among behavioral health providers?

Response: Treatment for individuals with mental health and substance use disorders is critical. I support leveraging use of health IT where this can provide additional and needed support for patients. If confirmed, I commit to reviewing current programs at SAMHSA, CMS, and ONC to see how we can better provide treatment through the use of health IT.

16. I have observed a recurring bias within the Department of Health and Human Services for taking care of the middle of the pack on major health initiatives. This type of policymaking makes political sense, because that is where most health care providers are. But it fails to drive and reward the health care providers who take financial and reputational risks by engaging early in new payment and delivery models and investing in the tools and personnel needed to improve the quality of care while reducing costs.

In what ways would you use the office of the Secretary to direct the agencies and offices of the Department of Health and Human Services to support the health care providers that are at the forefront of payment and delivery system reform?

Response: Innovation in the private sector is essential to making available life-improving therapies and in harnessing the power of big data and predictive analytics to make us more efficient and more capable of serving our fellow Americans. If confirmed, I look forward to working with agencies and offices across the Department to encourage innovation across the healthcare system, including among providers. I agree with you that we do need to ensure that our programs do not penalize or create any disincentives for those providers who are at the forefront of leading us toward the desired future state of our healthcare system.

17. In 2014, Congress reauthorized the Children’s Hospitals Graduate Medical Education (CHGME) Payment program with overwhelming bipartisan support. The CHGME program supports training for half of our nation’s pediatric workforce and has successfully increased

the supply of pediatricians and pediatric specialists. The current authorization of this program extends through the end of FY2018.

- a. Do you believe the CHGME program provides needed resources to ensure adequate training of our pediatric workforce?

Response: If confirmed, I will support policies that ensure the pediatric workforce has needed training, particularly in underserved communities.

- b. If confirmed as Secretary of Health and Human Services, will you commit to seeking full funding for the CHGME program through the President's budget?

Response: If confirmed, I will work within the Department and with the Office of Management and Budget (OMB) to support programs that directly increase the number of health care professionals working in communities facing shortages.

- 18. The Recalcitrant Cancer Research Act, legislation I sponsored, was signed into law in January 2013. The law directs the National Cancer Institute (NCI) to develop scientific frameworks that will provide a strategic direction to help make advancements toward preventing and curing some of the deadliest types of cancer. Since the law's enactment, NCI has released frameworks for pancreatic ductal adenocarcinoma and small cell lung cancer. The frameworks guide National Institutes of Health (NIH) research priorities for these cancers, and ensure that promising areas of research are identified and pursued. As Secretary of Health and Human Services, you would oversee the majority of our federal investment in medical research.

Do you commit to fulfilling the requirement of the Recalcitrant Cancer Research Act to update the scientific frameworks five years after their initial development?

Response: Yes, I commit to carrying out all laws passed by Congress.

- 19. While carrying out the objectives of the Beau Biden Cancer Moonshot, will you consult the National Institutes of Health's scientific frameworks required by the Recalcitrant Cancer Research Act to inform your decisions about research priorities?

Response: The NIH and NCI are responsible for developing the scientific frameworks. I do not have specific information on how their research priorities are set, but I commit to reviewing this, if confirmed.

- 20. The Centers for Disease Control and Prevention estimate that antibiotic-resistant infections cost the United States economy between \$20 and \$35 billion each year in excess health care costs and contribute to the death of up to 23,000 people each year. While these resistant infections largely have their impact in our hospitals, resistant bacteria emerge in communities globally. Preventing these infections and preserving the ability of antibiotics to fight infections will require a global approach.

Do you believe the Department of Health and Human Services should work with

international health organizations, like the World Health Organization, to address the global emergence and spread of antibiotic-resistant microbes?

Response: With the expansion of international travel, antibiotic resistant infections can spread quickly between countries, including the United States, requiring all countries to take steps to stop this spread. If we continue to act aggressively, we can slow transmission of AR infections. If confirmed, I look forward to working with HHS's Office of Global Affairs and CDC to ensure that we are doing all we can to partner with other countries to stop the spread of drug-resistant bacteria.

21. Do you believe Department of Health and Human Services (HHS) has a role addressing antibiotic-resistant infections? What additional steps do you think HHS should take to address growing resistance to antibiotics?

Response: HHS is the lead implementing agency for actions to combat antibiotic resistance. Therefore, HHS will need to continue to have a comprehensive approach to combatting AR by improving the drug development pipeline and by investing in detection, response, prevention, and improving antibiotic use activities to preserve the efficacy of the antibiotics we have and to ensure the efficacy of future antibiotics.

22. Do you support continued U.S. participation in the Transatlantic Taskforce on Antimicrobial Resistance?

Response: Yes.

23. Do you support continued U.S. participation in the Global Health Security Agenda Steering Group?

Response: Yes. In order to effectively advance U.S. policy priorities related to global health security, the U.S. should continue to participate in the Global Health Security Agenda Steering Group.

24. The Centers for Disease Control and Prevention estimate that two million people develop antibiotic-resistant infections each year in the United States. One strategy to minimize the growth of antibiotic resistance is to implement antibiotic stewardship programs to improve appropriate prescribing of antibiotics. Professional medical societies such as the Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, and American Academy of Pediatrics recommend that antibiotic stewardship programs are implemented in all hospitals.

Last year, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule to update its Conditions of Participation with requirements for acute care and critical access hospitals to implement antibiotic stewardship programs. Based on publicly published comment letters on the proposed rule, the proposed Conditions of Participation received a wide range of support from stakeholders, including the American Hospital Association and Federation of American Hospitals.

- a. If you are confirmed, will you instruct CMS to finalize the proposed Conditions of Participations concerning antibiotic stewardship programs?
- b. If this rule is finalized, will you commit to enforcing the new antibiotic stewardship requirements?

Response to a & b: I share your concern regarding the need to take seriously the public health threat posed by antibiotic resistance. I appreciate the important role HHS can play in combatting this public health threat, from identifying resistance and educating the American people about it, to helping to advance innovative, new therapies to treat emerging infections.

I have not had a chance to review the details of the proposed rule concerning incorporating antibiotic stewardship programs into CMS's Conditions of Participation, but if confirmed, I look forward to working with Department and CMS staff to examine ways we can address this critical issue without introducing excessive provider burdens.

25. Reporting from the President's Council of Economic Advisors shows that the Affordable Care Act's payment and delivery system reforms are improving quality, reducing patient harm, and lowering spending.

One example is the Hospital-Acquired Conditions Reduction Program, which holds hospitals accountable for a variety of harmful conditions – many of which are preventable – that patients may experience while receiving care at a hospital, like infections and medical errors that lead to complications. Since the Affordable Care Act was passed in 2010, there's been a 21 percent decline in the rate of hospital-acquired conditions. Due to that reduction, the Agency for Healthcare Research and Quality estimates approximately 125,000 deaths have been avoided and \$28 billion in health care costs saved from 2010 to 2015.

Do you believe the Department of Health and Human Services should continue to have the authority to reduce hospital payments for hospital-acquired conditions as it currently does under the ACA?

26. If a patient is exposed to a preventable infection or medical error during the course of his or her hospital stay, should taxpayer-funded Medicare dollars be used to fully reimburse hospitals for the care provided during that patient's hospital stay?

Response to Questions 25 & 26: In August 2017, CMS updated existing policies regarding the Hospital-Acquired Conditions Reduction Program in its Medicare hospital inpatient prospective payment systems final rule.¹⁵³ In addition, under Medicare, for certain types of conditions that are Hospital-Acquired Conditions, hospitals do not currently receive additional payment for certain cases if that selected condition occurred and was not present on admission.

In combination with other efforts across HHS, the Hospital-Acquired Conditions Reduction Program and the payment provisions for hospital-acquired conditions

¹⁵³ <https://www.federalregister.gov/documents/2017/08/14/2017-16434/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

encourage hospitals to improve healthcare quality and value while giving patients and providers tools and information to make decisions. If confirmed, I will work to move these programs forward in the least burdensome manner possible while continuing to promote improvement in the quality of care provided to patients. While we should hold providers accountable for achieving outcomes, we must ensure that providers are not beset by unnecessary administrative burdens that could impede progress on achieving this goal.

27. Last year, the Centers for Medicare and Medicaid Services finalized through rulemaking a new Accountable Care Organization (ACO) model under the Medicare Shared Savings Program called the “Medicare ACO Track 1+ Model.” This new payment model provides an opportunity for provider practices that want to move toward performance-based risk, but find level of downside financial risk required in Tracks 2 or 3 of the Medicare Shared Savings Program prohibitive. Do you commit to maintaining the Medicare ACO Track 1+ Model?

Response: While I have not reviewed the specific details of this model in full, I do believe firmly in value-based purchasing models and their potential to incentivize higher quality care and lower costs. 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.

28. Rhode Island was one of 14 regions selected to participate in the Comprehensive Primary Care Plus Model, a multi-payer payment model designed to improve and enhance the capacity of primary care practices, among other goals. Do you commit to maintaining the Comprehensive Primary Care Plus Model?

Response: CMMI’s Comprehensive Primary Care Plus Model began in 2017, and will include additional regions in 2018. This model is a national advanced primary care medical home model that aims to strengthen primary care through regionally-based multi-payer payment reform and care delivery transformation. While I have not reviewed the specific details of this model in full, I do believe firmly in value-based purchasing models and their potential to incentivize higher quality care and lower costs. 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.

29. The Centers for Medicare and Medicaid Innovation (CMMI) was authorized under the Affordable Care Act to test, evaluate, and expand – under certain circumstances -- innovative health care payment and delivery models. This work is key to changing how health care is paid for and provided, and is integral to the success of physician payment reform under Medicare Access and CHIP Reauthorization Act. Many states, like Rhode Island, participate in a number of CMMI initiatives.

Will you allow CMMI to continue implementing the demonstration projects currently underway? If not, which demonstration projects would you plan to terminate?

30. Do you support continuing the work of the Centers for Medicare and Medicaid Innovation to identify alternative payment models that achieve savings and improve quality of care?

31. How do you expect to use the Centers for Medicare and Medicaid Innovation's authority if confirmed as HHS Secretary?

Response to Questions 29-31: A top priority would be harnessing 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.

32. Former HHS Secretary Tom Price opposed the Center for Medicare and Medicaid Innovation (CMMI) using its authority to conduct mandatory demonstrations of new payment models. The Congressional Budget Office's (CBO) estimate that CMMI will save \$34 billion through 2026 rests in part on the Center's ability to mandate participation in demonstrations. CBO noted that this authority is an "important tool" because it "general results in a stronger research design for evaluating the effects of the demonstration."

Response: CMMI should work in a way that is open, transparent, and collaborative. There are many cases where voluntary models can be effective. However, there may also be instances where mandatory approaches are needed to ensure a robust evidence base to test any payment model reforms. CMMI provides a significant opportunity for testing new payment and service delivery models. If confirmed as HHS Secretary, I plan to work closely with CMS to ensure that CMMI -- after appropriate consultation with Congress, the States, healthcare stakeholders, and CMMI staff -- tests innovative models to reduce expenditures and improve quality for Medicare, Medicaid, and CHIP beneficiaries.

It is my understanding that 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. 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 healthcare to their patients. If confirmed, I look forward to reviewing the comments received and working on the new direction for CMMI.

33. As Secretary of Health and Human Service, if you direct CMMI not to use its authority to mandate participation in payment and delivery models, what steps will you take to ensure the research design for evaluating voluntary demonstrations is robust and delivers clear evidence of the effects of those demonstrations?
34. Accountable Care Organizations (ACOs) are now widespread in the Medicare program, including in my home state of Rhode Island. Over 9 million Medicare beneficiaries received care through more than 480 Medicare ACOs under the Medicare Shared Savings Program (MSSP). In 2016, MSSP ACOs saved \$652 million and resulted in improvements across key quality measures. There is evidence to believe that gross savings generated by ACOs

will grow over time, as they gain experience. Do you commit to maintaining the Medicare Shared Savings Program?

Response to 33 & 34: Accountable Care Organizations are a tool in the toolbox to help ensure high quality, low cost healthcare 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 healthcare system.

35. Do you support the goals of the Physician Payment Sunshine Act, which was signed into law as Section 6002 of the Affordable Care Act? Do you commit to maintaining public reporting of payments and transfers of value made to physicians or teaching hospitals, including payments related to continuing medical education?

Response: My previous employer and I were supporters of the creation and passage of the Sunshine Act, and if confirmed, I will continue to support this transparency.

36. The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 was the first step toward guaranteeing health insurance plans cannot impose less favorable benefit limitations on mental health and substance use disorder services than they do on medical/surgical benefits. Since its passage, Congress has acted twice to strengthen the law, through the passage of the Affordable Care Act and with the passage of the 21st Century Cures Act last year.

Part of the focus of the 21st Century Cures Act is improving compliance with the parity law. It directs HHS to produce an action plan for improving federal and state enforcement of mental health parity and requires the Secretaries of HHS, Labor, and Treasury to audit health plans that have been found to violate existing mental health parity laws five times.

a. Will you commit to fulfilling the requirements the 21st Century Cures Act places on the Department of Health and Human Services?

Response: Yes.

b. As Secretary, what other steps will you take to improve the enforcement of mental health parity requirements?

Response: If confirmed, I plan to review the laws in place on mental health parity and ensure they are carried out as Congress intended. This will involve coordination between HHS and the Departments of Labor and Treasury. I will work with these departments to ensure that the mental health parity requirements are adequately implemented.

37. In March 2016, CMS finalized a rule extending mental health parity protections to Medicaid and CHIP plans. The rule extended mental health parity protections to more than 23 million

Americans. If confirmed, will you commit to working with states and federal partners to strongly enforce this rule?

Response: Yes.

38. According to the Association of American Medical Colleges, the current medical school curriculum has had to evolve in response to the opioid crisis. Many medical schools are working to integrate lessons about addiction, recovery, and pain management into their required and elective courses. As death rates from this epidemic continue to rise, it is more important than ever that all of our health care providers are working to prevent and treat addiction.

- a. If you are confirmed as Secretary of Health and Human Services, how will you support medical schools' efforts to increase the amount of information medical students receive on addiction, recovery, and pain management?

Response: The Department plays an important role in education efforts. Given the scientific expertise at the agency, it is important that the Department disseminates the information developed through research and scientific development. If confirmed, I would ensure that HHS not only continues this important work but seeks to disseminate the information so that it can be used as a resource.

- b. How will you ensure this information is consistent with the best available science on these issues?

Response: Information should always be developed according to the best available science. If confirmed, I plan to ensure that the agency continues to do so.

39. Naloxone is an effective drug for reversing overdose from both prescription opioids and heroin, and in states like Rhode Island, access to naloxone is an integral part of fighting the opioid epidemic. Doctors at Butler Hospital, a psychiatric hospital in Rhode Island, try to prescribe naloxone to every patient they think is at risk of overdosing. Rhode Island also has a collaborative practice agreement that allows any Rhode Islander to obtain naloxone from a local pharmacy. And Rhode Island has a state law that requires all schools educating students in grades six through twelve to have naloxone or other opioid antagonists available on school premises. Do you support co-prescribing of naloxone to patients at high risk of overdose?

Response: If confirmed, combatting the opioid epidemic will be one of my highest priorities as Secretary. I believe this public health crisis requires us to seriously consider all of our options to stem the tide of this epidemic and the staggering public health toll it is taking on families across our country, and I look forward to being briefed by senior Agency leaders on what options we might consider, such as co-prescribing.

40. Do you support improving naloxone access through comprehensive practice agreements or standing order prescriptions?

Response: I understand that many States have helped to improve access to naloxone through flexible arrangements under state pharmacy law and otherwise. HHS does not have a direct role in shaping such state-law policies, but I support the goal of improving access to appropriate medications and treatments that can help to reduce the impact of the opioid epidemic.

41. Do you support training law enforcement and other community members in the proper administration of naloxone?

Response: Yes, I support training of law enforcement and other community members in the proper administration of naloxone.

42. Do you support the expansion of federal programs, like the Prescription Drug Opioid Overdose Prevention Grants, to assist states in purchasing naloxone?

Response: As we fight this opioid epidemic, I believe it is important for states to purchase naloxone. I support efforts to assist the states in these purchases and, if confirmed, will review the current efforts underway to support the states in this area.

43. According to the American Academy of Child and Adolescent Psychiatry, only 8,300 practicing child and adolescent psychiatrists (CAPs) have been fully trained to treat the over 15 million children and adolescents who need their services. In my home state of Rhode Island, there are only 65, or about 30 CAPs for every 100,000 children. Unsurprisingly, the majority of them are located in the state's capitol, Providence, leaving the more remote areas of the state even more underserved.

a. Do you believe the federal government should invest in mental health workforce training?

Response: 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.

b. Do you commit to advocating for funding for mental health workforce training in the President's budget at no less than current funding levels?

Response: 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.

44. Families of children with behavioral health conditions who lack health insurance often find it very difficult to access treatment for the child, even if they live in a community that isn't facing a shortage of child and adolescent psychiatrists. If the Affordable Care Act is repealed, how will you ensure that children and adolescents have access to the specialized mental health care that they need?

Response: I am committed to ensuring that all individuals have access to the necessary mental healthcare 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.

45. Our prescription drug market relies on competition to keep costs down for consumers. Generic competitors help give patients more options and drive down drug prices across the board. However, some brand name drug manufacturers have engaged in behavior that makes it more difficult for potential generic competitors to get samples of their drugs – samples they need to be able to prove substantial equivalence and get approval from the FDA. Or these companies are refusing to agree on a shared safety protocol for the drug, another FDA requirement. I am a cosponsor of the CREATES Act, which would allow a generic company facing one of these delay tactics to bring action in federal court to obtain the sample it needs, or enter into court-supervised negotiations for a shared safety protocol.

Will you support efforts to remove the incentives for companies to engage in these delay tactics and improve opportunities to create generic competition?

Response: I have made clear my concerns with gamesmanship and evergreening of patents and exclusivities by branded companies under Hatch-Waxman and other provisions of the Food, Drug, and Cosmetics Act. If confirmed, I will ask the FDA to review its regulatory authorities to see which abuses can be tackled with existing authority, which require coordinated action by other parts of the government, and which would require legislative changes. As we discussed in the hearing, I am particularly concerned about the issues of branded companies using REMS programs to prevent the study of and approval of generics, branded companies limiting supplies of reference product on which to conduct needed studies, and branded companies securing patented modifications to the underlying product and withdrawing the previously approved product from the market, thus disabling entry of a generic competitor to that earlier version of the product. 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. I will support the work of Commissioner Gottlieb and the FDA to eliminate barriers which are standing in the way of drug manufacturers getting access to the samples they need to create lower-cost generic alternatives.

46. This year, we've heard testimony in the HELP Committee about patients who rely on off-patent drugs and their unique vulnerability to drug price increases. I am interested in ways that we could draw a distinction between drug companies that are creating new drugs, and hedge funds that exploiting de facto monopolies by purchasing an old, off-patent drugs and raising their prices. How can we best discourage hedge funds from buying these drugs and raising their prices? What additional authority does the federal government need in order to prevent these drugs from becoming unaffordable for the patients who rely on them?

Response: As you rightly point out, several financial companies have engaged in a form of regulatory arbitrage in order to artificially inflate prices while other suitable replacement therapies go through the FDA's regulatory process. I share your concern and support the

FDA's efforts to make the regulatory system less prone to such abuse. Under Commissioner Gottlieb's stellar leadership, FDA has taken steps to encourage generic drug development; for the first time in agency history, FDA is actively identifying those branded drugs that have no unexpired patents or exclusivities and for which the agency has yet to approve a generic drug application. The agency is also expediting the review of any generic drug application for a reference product on this list to ensure that they come to market as expeditiously as possible. And the FDA expediting the review of generic drug applications until there are three approved generics for a given reference drug product. If confirmed, I look forward to working with Agency leadership – and with other components of the Executive Branch - to continue addressing this issue and taking steps to ensure consumers can benefit from choice and competition when it comes to their medicines.

47. Earlier this year it was reported that President-elect Trump, who has publicly questioned the safety of vaccines and perpetuated the myth that vaccines cause autism, planned to convene a Commission on Vaccine Safety. The scientific community has overwhelmingly concluded vaccines are safe and have saved countless lives. Though plans for a Commission on Vaccine Safety appear to have stalled, as Secretary of Health and Human Services under President Trump, you may be charged with implementing an anti-vaccine agenda.
- a. Do you commit to protecting access to life-saving vaccinations?
 - b. Do you commit to ensuring that information about vaccine safety and efficacy that is disseminated by the Trump administration reflects the best available scientific evidence?

Response to a & b: Vaccines are one of the greatest success stories in public health and are among the most cost-effective ways to prevent disease. If confirmed, HHS will continue to advance the best science and advocate for use of vaccines.

48. Bankruptcies resulting from unpaid medical bills were the leading cause of such filings in the years leading up to the implementation of the Affordable Care Act (ACA). In fact, they outpaced bankruptcies due to credit-card bills or unpaid mortgages. The National Center for Health Statistics recently reported that the percentage of persons under age 65 who were in families having problems paying medical bills decreased from 21.3 percent in 2011 to 16.2 percent in early 2016.

You have expressed support for efforts to repeal the ACA, which has provided insurance coverage to 20 million Americans and limits out-of-pocket costs for individuals and families on plans offered on the ACA's health insurance marketplaces.

If the Trump Administration and Republican Members of Congress are successful in repealing the ACA, as Secretary, how will you protect millions of Americans that benefit from the ACA's out-of-pocket cost protections from going bankrupt because of their medical bills?

Response: The ACA has failed to live up to the promises made at the time of its passage, and the status quo is not working for millions of Americans – whether for those who are in the insurance market or for 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 healthcare system where they can choose the type of insurance coverage that works best for them.

49. Earlier this year, the FDA announced it would delay the compliance date for changes to the Nutrition Facts label for packaged foods that were finalized in 2016. These changes are part of an effort to make it easier for consumers to understand and make informed food choices. One significant change is that the label will now include “added sugars,” including the grams of sugar and the percentage of a “Daily Value” that is included in a product. Evidence shows that while the sugars found in fruits and other natural foods can be part of a healthy diet, consuming large amounts of added sugar can make it difficult to meet your body’s nutritional needs.

Will you ensure that the Nutrition Facts label update, including the “added sugar” line, is implemented without any further delay?

Response: 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.

50. According to the Centers for Disease Control and Prevention, tobacco use is the leading cause of preventable death in the United States, responsible for 1,300 deaths every day. I think tobacco use needs more regulation, which is why I am a cosponsor of the Tobacco to 21 Act, which would raise the minimum legal age for the sale of tobacco from 18 to 21. A number of states and localities across the country have already recognized the benefits of this policy and taken action to raise the age to 21.

As Secretary of Health and Human Services (HHS), you would be charged with working to enhance the health and wellbeing of Americans, and there is clear evidence that access to tobacco products does nothing but detract from it.

a. Do you believe HHS has a role in regulating tobacco products?

Response: The Family Smoking Prevention and Tobacco Control Act of 2009 clearly charged FDA with the authority to regulate tobacco products. If confirmed, I look forward to working closely with Commissioner Gottlieb as he implements a comprehensive approach to nicotine and tobacco regulation.

b. As Secretary, will you support efforts to restrict the sale of tobacco products to young Americans?

Response: Yes.

51. Will you support the ongoing efforts of the Center for Tobacco Products to monitor retailer, manufacturer, importer, and distributor regulatory compliance, as well as educate the public about the health effects of tobacco use?

Response: Yes.

52. Early this year I stood on the Senate floor and voted against a budget resolution to repeal the Affordable Care Act on behalf of Charlie, a 14 year-old from Woonsocket, RI who was born with an inherited genetic condition called neurofibromatosis (NF). NF, which causes tumors on the skin and throughout the body, hearing loss, and spinal deformities, is an expensive disease.

Before the ACA, families of children with NF would quickly hit the lifetime cap on health benefits imposed by many insurance companies. The ACA eliminated those caps, so families like Charlie's don't go bankrupt because their insurance runs out. President Trump and Congressional Republicans support legislation that would repeal the ban on lifetime limits for health insurance coverage.

- a. Do you think that someone with a chronic condition should be denied coverage for care by an insurer because a policy limit has been reached?
- b. Will you commit to supporting the Affordable Care Act's ban on lifetime limits?

Response to a & b: The mission of the U.S. Department of Health and Human Services (HHS) is to protect the health and well-being of all Americans. I believe that everyone should have access to quality, affordable healthcare and insurance coverage that works for them and that meets their needs. If confirmed I will work to support that goal for all Americans. Everyone ought to be treated fairly and with compassion – particularly when it comes to their healthcare needs. HHS must follow Congress's lead in defining and enforcing nondiscrimination laws, and HHS will comply with all statutory requirements in doing so.

53. The Affordable Care Act has achieved significant expansion of behavioral health services by expanding access to Medicaid coverage, strengthening the mental health parity and addiction equity law, and requiring coverage of behavioral health services as essential health benefits.

Do you think individuals with mental health and/or substance use disorders will be better off if the Affordable Care Act is repealed?

Response: If confirmed, I would ensure that HHS is fully committed to implementing the laws and regulations that guide our nation's healthcare system. Insurance you can't afford to buy or you can't afford to use if you do buy it helps nobody. 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. Under the status quo, premiums and deductibles 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. I look

forward to working with Congress on the best way to achieve the goal of ensuring that all individuals have access to healthcare, including mental healthcare.

54. In Rhode Island, 93 percent of voters believe it is important for women to have access to all of the reproductive health care options available to them. One such Rhode Islander is Natalie, a college student from Jamestown, Rhode Island, who wrote to me to explain how important Planned Parenthood has been to maintaining her health. Far from home and with limited resources, Natalie said she depends on Planned Parenthood for essential health care, including preventive screenings and birth control.

You have expressed support for proposals to repeal the Affordable Care Act. Those proposals would have eliminated several protections for women's health and defunded Planned Parenthood.

- a. Do you support defunding Planned Parenthood, even though no federal funding goes to abortion services?
- b. Are you concerned that eliminating preventive services for women would cause an increase in abortions?

Response: In deference to the rights of conscience of American taxpayers, Congress has instructed that tax monies may not be used to pay for certain procedures. I defer to Congress on issues related to funding of specific providers, and if confirmed, look forward to implementing the laws as passed by Congress. I believe that all women should have access to quality, affordable healthcare and to services they choose that work for them and that meet their needs.

55. The Office of Population Affairs within HHS administers the Title X family planning program and provides guidance on a range of reproductive health topics. The current leader of this office is someone who has called contraception "medically irresponsible," despite the fact that she has no medical training. She has also said that the birth control pill doesn't work, despite overwhelming evidence to the contrary.

- a. In your professional opinion, are the statements above about contraception true?
- b. Do you believe statements like these should be used to inform policies of the Department of Health and Human Services?
- c. What will you do as HHS Secretary to ensure the Department's policies on women's health are guided by science rather than ideology?

Response to a-c: I have not spoken to the current director of the Office of Population Affairs (OPA) and cannot comment directly on her opinions or past statements. With regard to women's health—as with the health of all Americans—if confirmed, I am fully committed to following the science and evidence where it leads us and to implementing evidence-based and evidence-informed policies.

56. Do you support limiting the right of a person to have a civil jury decide a medical malpractice case?

57. Do you believe civil juries are able to appropriately assess damages in a medical malpractice case?

Response to 56 & 57: The right of a person to a trial before a jury of her peers is one of the bedrock principles of the U.S. Constitution – and it is important that such right is appropriately maintained. At the same time, it is important to recognize that, sometimes, civil juries can get things wrong and can be unduly influenced by sympathy for an injured plaintiff, especially in medical malpractice cases.

58. You have expressed support for block granting federal Medicaid funding, saying “I think there’s a lot to commend [about] a block grant approach . . .”. Rhode Islanders are very concerned the possibility that Medicaid funding could be turned into a block grant. One Rhode Island advocate told me that a Medicaid block grant would “wreak havoc” on the state budget and “pit babies and families against grandparents and people with disabilities for funding of vital services.”

- a. If you succeed in block granting the Medicaid program, how do you expect states will cope with such drastic funding shortfalls? Do you think states should cut Medicaid benefits for seniors needing long-term care services and supports? Or should they cut Medicaid benefits for individuals with disabilities? Or should they cut Medicaid benefits for children?

Response: 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 healthcare 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.

59. Many Republicans, including President Trump, advocate for selling insurance plans across state lines to improve the number of options available to consumers. Do you think a policy to allow insurance companies to sell products across state lines without regard to the regulations of the state they are selling in would strengthen or weaken states’ ability to protect consumers in their marketplaces?

Response: Millions of consumers in too many state marketplaces have already lost the plans they liked and the doctors they liked under the Affordable Care Act. 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.

60. President Trump's budget cuts almost \$80 million from disability programs within the Administration on Community Living. The President himself has publicly mocked a disabled person.
- a. Do you believe these budget cuts will lead to better outcomes for people with disabilities?
 - b. Please list three things you will do if confirmed to support disabled Americans and the federal programs that serve them.

Response to a & b: I believe strongly in the value that people with disabilities provide to their communities, and I strongly support the goal of delivery services that help to achieve optimal independence, productivity, integration, self-determination, and inclusion in the community while eliminating silos that make it harder for people to access the services they need. If confirmed, I will work with Congress, in coordination with the Office of Management and Budget, to ensure all HHS programs are funded in the most responsible way; HHS will continue to work to develop policies to help disabled Americans; and we will take a hard look at ways HHS regulations and other policies that may serve as obstacles for people with disabilities could be removed or improved.

61. As part of the 21st Century Cures Act, I worked with Senator Cassidy to include new authorities for the Office of the National Coordinator for Health Information Technology and the Office of the Inspector General at HHS to address information blocking. As you may know, information blocking includes practices by health IT developers, health care providers, and data networks that interfere with or prevent the access, exchange, or use of electronic health information. The Office of the National Coordinator recently announced it plans to release a proposed rule on information blocking in the spring of 2018.
- a. Will you encourage the Office of the National Coordinator to stick to its timeline for issuing a proposed rule on information blocking?
 - b. In the forthcoming President's budget, will you commit to advocating for the inclusion of full funding -- \$10 million -- for the Office of Inspector General to investigate claims of information blocking?

Response to a & b: I support the goals of the 21st Century Cures Act in respect to health information technology. I agree that preventing information blocking should be a top priority. It is a crucial to achieving interoperability of health information technology, which is a key enabler of improving cost, quality, and value in our healthcare system. If confirmed, I look forward to working with Congress to make sure this important provision is implemented.

Senator Kaine

1. The Affordable Care Act has for the first time ensured a national standard of coverage with the ten Essential Health Benefits and protecting Americans with pre-existing conditions. Do you support a national standard of essential health benefits that guarantee protections like mental health parity, coverage equity for women and preventive care? Do you support the concept that people should be able to purchase health insurance regardless of pre-existing conditions? Do you support the concept that people should be able to purchase health insurance regardless of pre-existing conditions?

Response: We must make healthcare 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.

2. As Secretary, can you commit to making sure that all lawful provisions of the ACA, even ones you may not personally agree with, are carried out?

Response: If confirmed, I will faithfully implement laws written by Congress and the regulations issued by the Department.

3. The Administration has also gone out of its way to keep Americans from getting insured, by shortening open enrollment, cutting funding for navigators, and reducing ad buys. Will you commit to making sure these programs are funded going forward and to a transparent process to evaluate their impact?

Response: I do not agree with the characterization that the Administration or the Department has made an effort to destabilize the market. Prior to President Trump taking office, millions of Americans had already lost the plans they liked and the doctors they liked. If confirmed, I will examine the data and work with the Administrator to make the best, evidence-based decisions, balancing prudent use of resources with faithful execution of the law.

4. You have strongly criticized the movement towards high deductible health care plans on the individual marketplace. I share your concern about the growth of these plans. However, you have strongly supported bills – such as the House ACA repeal bill – that would lead to higher deductibles and patients paying more for care. The President has also encouraged the creation of more of these high deductible “bare-bones” plans with his health care executive order signed on October 12th. Do you support these efforts to make high deductible plans more common? Do you think these high deductible plans offer meaningful coverage and financial protection for middle class families?

Response: I have not criticized the availability of high deductible health care plans for those who wish to have them. In particular, I have long been a supporter of high deductible plans with an associated and funded Health Savings Account. What I have been critical of

is the impact of the rise of high deductible plans on patients' out-of-pocket spending on prescription drugs. I have not blamed insurers for these plans, but rather have said that the pricing system for drugs is broken in light of the rise of these plans and needs to be fixed. 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, 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 healthcare 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.

5. I am gravely concerned about the survival of safety net and rural hospitals. Will you revisit cuts to the 340B program finalized earlier this month?

Response: I understand that the 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. 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, this payment change does not apply to critical access hospitals since they are not paid by the Outpatient Prospective Payment System.

6. I am also concerned about a delayed rule that would have prevented pharmaceutical companies from overcharging 340B hospitals. Will you commit to ensuring that rule's timely implementation?

Response: If confirmed, I will work with the Department and with Office of Management and Budget (OMB), to follow the rulemaking policy in the most responsible and timely manner.

7. A question I have asked both NIH Director and Surgeon General is: can the government set a big goal like being addiction free in ten years? If not addiction-free, have a goal for addiction to no longer face stigmatization and that all people who need services who are able to access them?

Response: Goals such as this give us something to strive toward. Meeting such a goal will require a coordinated effort across federal and state agencies as well as other partners. Not only do we need to find non-addictive alternatives to treat pain, but we need to change prescribing patterns and re-educate physicians on how to treat pain. In addition, we need to remove the stigma of addiction so that it can be treated as a medical condition or disease.

8. My state has an 1115 waiver to offer more substance abuse treatments to Medicaid and Medicare beneficiaries. However, my state's behavioral health department says without Medicaid expansion means these programs are not reaching everyone they could be helping. Do you agree that access to coverage through Medicaid is an important tool to fighting the opioid epidemic?

Response: It is critical that all Americans suffering from mental health and substance abuse disorders have access to the care they need. While significant changes to the Medicaid program would come from Congress, I am committed to using Department resources to helping to fight the opioid crisis consistent with the President's direction in this area.

9. Health disparities are a threat to minority groups who experience higher rates of conditions like diabetes, many types of cancer and hepatitis. These groups also face social and economic barriers to care, such as housing and being uninsured. The HHS Office of the Minority Health is the government's lead agency for addressing health disparities, through strategic coordination and effective grant programs. How do you envision the role of the Office of Minority Health in your plan for the department? How do you view the role of language access and cultural knowledge in the provision of health care?

Response: If confirmed, I will work to enhance and protect the health and wellbeing of all Americans. This includes working together with the statutorily established Office of Minority Health, which works to improve minority health and the quality of health care minorities receive and to eliminate racial and ethnic disparities. Language access and cultural knowledge are certainly factors that can impact health outcomes, and I look forward to working with you to address these issues.

Senator Hassan

1. During your HELP Committee hearing, when asked whether you believe that all women should have access to the health care their doctor recommends for them, you said, "I do believe we have to balance, of course, woman's choice of insurance that she would -- that she would want with the conscience of employers."
But what will you do to ensure that employers do not interfere with their female employees' exercise of their faith or conscience as they seek the health care their doctors recommend for them, as many women have an obligation under their faith and/or conscience, for example, to avoid and unintended pregnancy and/or protect their own health?
2. Should you be confirmed, what is your specific plan for ensuring women have access to the full range of sexual and reproductive health care while ensuring that they are not charged more for health insurance or basic preventative services than men are?

Response to 1&2: If confirmed, I will faithfully implement laws written by Congress, which has not enacted the definition of preventive services in the Affordable Care Act statute. If the law requires certain coverage, that coverage will be offered. As I mentioned during the hearing, there should be flexibility for Americans to choose the type of insurance package they need.