S. HRG. 115–341

NOMINATION OF SCOTT GOTTLIEB, M.D., TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE NOMINATION OF SCOTT GOTTLIEB, M.D., TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

APRIL 5, 2017

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C O N T E N T S

STATEMENTS

WEDNESDAY, APRIL 5, 2017

NOMINATION OF SCOTT GOTTLIEB, M.D., TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

WEDNESDAY, APRIL 5, 2017

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

The committee met, pursuant to notice, at 10:02 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, chairman of the committee, presiding.

Present: Senators Alexander, Enzi, Burr, Paul, Cassidy, Young, Hatch, Roberts, Murkowski, Scott, Murray, Sanders, 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.

This morning, we are holding a hearing on the nomination of Dr. Scott Gottlieb to be the next Commissioner of Food and Drugs.

Senator Murray and I will each have an opening statement then we will introduce Dr. Gottlieb. After his testimony, Senators will each have two rounds of 5-minute questions, if they wish to.

Last year, the most important legislation that Congress enacted was the 21st Century Cures law. Those are not my words; they are Majority Leader McConnell's words.

The reason it was such an important bill is that it will drive forward research and the extraordinary medical miracles that are in the works and that have the potential to affect every American family.

Dr. Francis Collins, at the National Institutes of Health, has talked about some of the discoveries that he predicts are possible in the next decade: Non-addictive painkillers; hearts rebuilt from our own stem cells; a universal flu vaccine; an HIV/AIDS vaccine; an artificial pancreas for diabetes patients who have spent decades injecting themselves with insulin.

The key to making these miracles a reality is not just investment in research, but a regulatory process that is efficient and effective enough to bring safe discoveries to patients in a timely way.

The Food and Drug Administration has always been important, but there has never been a more important time to capitalize on the significant funding Congress has given to medical research, and to realize the promise of 21st Century Cures.

Dr. Gottlieb, congratulations to you on your nomination. Welcome to you and to your family members who are here. I hope you will introduce them at the appropriate time. We have enjoyed having the opportunity to visit with you in my office.

If confirmed to lead the Food and Drug Administration as its commissioner, you will be in charge of steering the agency responsible for assuring the safety and effectiveness of our Nation's medical products and protecting our country's food supply. My hope is you will help move the agency forward so that America's patients benefit from the remarkable discoveries our Nation's researchers are working on.

The FDA affects nearly every single American. It regulates a quarter of all consumer spending in the United States, over $4 trillion annually.

It is responsible for prescription drugs for humans and animals, medical devices, biologics, dietary supplements, cosmetics, over the counter medications, food, and tobacco products. It is a vital mission, and we all want to make sure the right person is leading it.

The President has nominated you to do that job, and like every full-time nominee, you have been through an exhaustive process to make sure you do not have conflicts of interest or other problems in your background.

The President announced your nomination on March 10, after an extensive vetting process by the White House and the FBI. Your official nomination was received on March 27 by the Senate. Eight days ago on March 28, this committee received a letter from the Office of Government Ethics, which carefully reviewed your financial information and found that, with several recusals which you have committed to do, you are, "In compliance with applicable laws and regulations governing conflicts of interest."

In accordance with our committee rules, you have submitted your committee paperwork to Senators on March 31, 5 days before this hearing. You have offered to meet with every Senator on this committee. You have met with every Democratic Senator and all but two Republican Senators.

That brings us to today. You come here with impressive qualifications.

You were a practicing physician and a hospitalist for many years receiving your medical degree at Mount Sinai and your residency at the Mount Sinai Hospital.

We will hear more from Senator Murphy about your other credentials, so there is no need for me to repeat them at this time, including those in the Health and Human Services, and your time as a Resident Fellow at the American Enterprise Institute.

You are a prolific writer and speaker, and no stranger to testifying to Congress. You have testified here 18 times on a variety of issues. You are also a cancer survivor. You know firsthand how medical treatments affect patients and their families.

I am eager to hear your views today on both the User Fee reauthorizations and 21st Century Cures. Your first order of business will be to work with us on the reauthorization of the User Fee Agreements. We have had over 15 bipartisan briefings on the User Fees going back to late 2015.

Senator Murray and I have held two bipartisan hearings on the reauthorization, our second one yesterday. I support quickly moving the reauthorization recommendations sent to us in January, and I am committed to working with the Administration, and all members of this committee, to authorize the User Fees before August 1.

In addition to drugs and medical devices, you are responsible for protecting our Nation's food supply and working to reduce the number of people who get sick from foodborne illness. Technology is improving and changing the way we improve food safety. It holds the potential to reduce foodborne illnesses and deaths.

FDA is a large and diverse organization that faces management challenges. When I asked Dr. Califf, your predecessor, his top priority while we were working on 21st Century Cures, he said it was to give the FDA the authority to hire and to pay people to do what the agency needs to do. We included that authority in 21st Century Cures.

I am concerned, as are other members of this committee, about the Administration's hiring freeze, and how it will affect the FDA, and how you plan to deal with that, if confirmed.

Thank you for being here. I look forward to hearing your testimony on these important issues.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

SENATOR MURRAY. Thank you very much, Chairman Alexander.

Dr. Gottlieb, I want to welcome you and your family. Thank you for being here and for your willingness to serve.

I do want to start by expressing my disappointment about the limited time we have had to review Dr. Gottlieb's committee paperwork.

We have the full paperwork on Friday, meaning we have had just a handful of days to fully understand the extent of Dr. Gottlieb's unprecedented financial entanglements with the industries he would regulate as FDA Commissioner, find and review the more than 800 publications Dr. Gottlieb has listed, and delve into the wealth of companies and products that raise concerns about potential conflicts of interest.

Chairman Alexander, as you know, I have repeatedly stressed—privately and publicly—the importance of a thorough and complete vetting process for each of President Trump's nominees. Fully vetting the Administration's nominees should not be a priority for Democrats alone. Both parties deserve to make fully informed decisions about the potential leaders of these critical departments and agencies that we oversee.

Unfortunately, the inexplicable rush to advance this nomination falls far short of that basic standard. I will continue to push for a thorough review of Dr. Gottlieb's nomination. Dr. Gottlieb, I hope you will give clear and thorough responses to any followup questions after today as well.

I do appreciate that you responded to my letter requesting additional information on your clients. I hope you are committed to leading an agency that responds to and works with Congress.

I have to say I have been disheartened by the unprecedented lack of responsiveness by this Administration. Throughout several nomination processes, Democrats have requested documents and additional information to assist in our vetting.

Disappointingly, Secretary Price failed to respond to a single one of the questions this committee asked him following his confirmation hearing. We have yet to receive a response to even one of the inquiries we have sent since his confirmation.

Across the Administration, this seems to be the new normal. No responsiveness. No transparency. No accountability. It is really frightening and frustrating. It cannot go on. I hope, given the importance of the work of this agency, that if confirmed, you will not follow that trend.

Our constituents rely on the work of the FDA every single day. They trust the food they buy from the grocery store is safe. That when they go to the emergency room, the drugs and medical devices used in their care have been held to the highest standards of approval, and that the FDA's decisions are based upon science—not politics or ideology—the gold standard.

As you well know, Dr. Gottlieb, I have a long history of holding very firm on that particular point. To me, it is critical the FDA have strong, independent leadership, especially now in light of President Trump's apparent disregard for public health.

Dr. Gottlieb, in the limited time we have had to review your professional history and background, I have grown increasingly concerned about whether you can withstand political pressure pushing you to ignore science by upholding the gold standard, and if you can lead the FDA in an unbiased way, given your unprecedented industry ties. I will ask you to address those concerns here today.

I am very interested in how you would ensure independent, science-based decisionmaking at the FDA if you are confirmed.

During your time at the FDA under the Bush administration, then-Senator Clinton and I fought long and hard to ensure that emergency contraception, known as Plan B, would be sold over the counter to all age groups, consistent with expert recommendations.

The Administration then ignored the science and made a decision based on purely ideological grounds, a choice that a GAO report later called unprecedented.

Dr. Gottlieb, you defended the Administration's ideological position on behind the counter options for Plan B, allowing politics to interfere directly with women's access to the health services they need.

Given the Trump administration's clear willingness to skirt ethics' rules and pressure Federal employees to jam their policies through, not to mention their commitment to undermining women's access to birth control and other health services, I find that aspect of your professional history especially troubling.

As I mentioned, I am also very concerned about your unprecedented financial entanglements, especially given this Administration's record on this issue from President Trump on down.

One example of my concerns is in 2012, you were quoted in the "*Washington Post*" stating,

> "If consumers can track their blood sugar levels using pen and paper, why should the Government have to clear an application that does the same thing more reliably?"

You are an investor in Glytec, a medical technology company that developed software that allows patients and doctors to manage and adjust insulin therapy using smart phones and devices, and received an FDA approval for that software in 2012. Not surprisingly, you have also served on Glytec's board since 2013.

Another example, FDA and Congress have both been engaged in an ongoing debate about the regulation of medical tests. In a column related to embattled lab company Theranos, you argued the regulation of these tests is best left outside of FDA's jurisdiction, all the while serving on the board of two medical lab companies that would be directly impacted by your preferred regulatory scheme.

Dr. Gottlieb, it does trouble me greatly that you appear to be investing in and advising a company, and then using your public platform to promote policies that actually benefit that company in the future.

Meanwhile, reports continue to surface about Secretary Price's questionable actions on behalf of companies in which he invested. In fact, this committee should know that just last Friday, a ProPublica story indicated Secretary Price had lobbied the Department of Health and Human Services on behalf of companies on the very same day his broker invested in them on his behalf.

When the Trump administration released its financial disclosures just a few days ago, we learned of more financial entanglements in the health sector.

President Trump's top economic advisor, Gary Cohn, has millions of dollars in financial investments in a number of medical technology, drug, and tobacco companies.

President Trump's pick to lead the Justice Department's Anti-Trust Division—which decides whether to approve the proposed $54 billion Anthem-Cigna merger—received hundreds of thousands of dollars as a lobbyist on behalf of Anthem.

You can see there is a concerning pattern here, and we do not need more of it. I know that, if confirmed, you have agreed to recuse yourself for 1 year from decisions involving some companies in which you have invested. I do struggle to see how this will make sure your views and decisions will not be shaped by your investments. I will ask for your response on that today.

Our HELP committee research shows that companies that you invested in have more than 60 drugs that could come before the FDA for approval, and companies you worked for have interests in over 120 drugs that are currently being tested, and that is unprecedented.

Finally, Dr. Gottlieb, the vast majority of your professional work is focused on drugs and medical devices, and I have some concerns with your published positions on a number of important issues.

On marketing and communications by drug companies for off-label or unapproved uses of their products, you were quoted in 2006 saying,

"Efforts to limit prescription and scientific exchange to indications only specified on a label could slow the most important advances in 21st century medicine."

I would argue that over the last 11 years we have seen incredible advances in medicine, while also ensuring that only truthful and non-misleading information is given to doctors and patients.

I am concerned about what you describe as regulatory overreach by FDA, including your opposition to the regulation of medical applications, and your rejection of Risk Evaluation and Mitigation Strategies, or REMS, meant to protect patients: FDA's central mission.

I am also eager to hear how you will implement recent legislation passed by this committee, including 21st Century Cures and the Drug Quality and Security Act, passed to regulate compounding pharmacies and build a modern supply chain.

Your plans to encourage a more robust market for generics and biosimilars to help reduce the astronomically high cost of prescription drugs.

The FDA also does far more than drugs and devices. I hope in this hearing you will directly address priorities like keeping tobacco out of the hands of children, ensuring a safe and nutritious food supply, and other efforts to protect public health. These are all core responsibilities at the FDA, and I would be very concerned if you simply aligned with President Trump's extreme vision and take orders from his Administration. I will ask about those today.

Again, I really appreciate you and your family who are doing really well behind you right now, joining us today. I look forward to hearing from you about whether and how you will provide strong, independent, and science-based leadership that families in my State and across the country expect from this agency.

Thank you very much.

THE CHAIRMAN. Thank you, Senator Murray.

We will now welcome the nominee Dr. Scott Gottlieb. We welcome your wife and your daughters, your parents, your sisters-in-law, as well as your other guests whom you should feel free to introduce.

Dr. Gottlieb will be introduced by a member of this committee, Senator Murphy. I will turn it over to him and then to Dr. Gottlieb for his opening statement.

STATEMENT OF SENATOR MURPHY

SENATOR MURPHY. Thank you very much, Chairman Alexander, for the opportunity to introduce Dr. Scott Gottlieb to this committee.

I am indeed eager to hear from him today. I have disclosed to Dr. Gottlieb that I have not made up my mind as to his nomination as will be clear. We have some serious policy disagreements between us, but I am very eager to take the opportunity to welcome an important Connecticut resident to the HELP committee.

While Dr. Gottlieb was born in New Jersey, he does have long ties to my State of Connecticut. He has lived in Westport since 2010. Dr. Gottlieb is joined today by his family including his wife

Allison and their three daughters; I will let Dr. Gottlieb do the formal introductions.

I would note that Dr. Gottlieb's twin daughters' first grade class in Westport will be watching part of today's hearing to learn about our work in Washington. As the father of an 8-year-old and a 5-year-old, I know that first graders really want nothing more than to hear about the FDA and watch the HELP committee in action.

SENATOR MURPHY. I am really glad that they are here with us today.

Dr. Gottlieb and Allison are active members in their town and their surrounding community, especially through their synagogue Temple Israel. Dr. Gottlieb serves on the board of directors at the temple and Allison helps run a local homeless shelter in Westport and volunteers in the Bridgeport school system.

Dr. Gottlieb's connection to our State started when he attended Wesleyan University in Middletown. He was the editor of the school newspaper there and a student member of the board of trustees.

After graduating from Wesleyan with a bachelor's degree in economics, he went on to receive his medical degree from Mount Sinai School of Medicine in New York. After completing his residency at Mount Sinai Medical Center, Dr. Gottlieb then practiced medicine for 6 years at Stanford Hospital, again in Connecticut.

If confirmed, Dr. Gottlieb will be returning to the FDA for the third time. He first served as senior advisor to Commissioner Mark McClellan for medical technology and then as director of the medical policy development. During this time, he would travel back to Connecticut to work at Stanford Hospital on the weekends.

Dr. Gottlieb also brings a unique perspective to this committee because he has both been a practitioner and a patient. He is a survivor of Hodgkin's lymphoma and has served as a policy board member with the Leukemia and Lymphoma Society from 2012 to 2014.

Since leaving the FDA, Dr. Gottlieb has primarily worked as a consultant and advisor to a number of companies including as a venture partner at New Enterprise Associates. NEA is one of the largest venture capital firms in the country. It has investments in many firms in the broader healthcare space. He also has his own consulting firm. He has been a managing director of T.R. Winston, a merchant corporate investment banking firm which has a focus in healthcare.

He has come before various committees in Congress over the years to offer his opinions as a resident fellow at the American Enterprise Institute. She is no stranger to the U.S. Congress. We are proud of him in Connecticut and his commitment to Stanford Hospital and his community in Westport, and I look forward to his testimony, and I welcome him to the committee today.

THE CHAIRMAN. Thank you, Senator Murphy.

Dr. Gottlieb, we now invite you to give your opening remarks. Your written statement will be entered into the record in its entirety.

STATEMENT OF SCOTT GOTTLIEB, M.D., WESTPORT, CT, NOMINEE TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

DR. GOTTLIEB. I would like to just take a moment to introduce my family.

My wife Allison is here with my three daughters, Alex, Em, and Dillon. Do you want to say hi?

My mother and father are here. My mother is a school teacher in New Jersey. My father is a physician and a veteran of the Vietnam War. He was stationed in Cam Ranh Bay and wounded in that theater.

Chairman Alexander, Ranking Member Murray, members of the committee, thank you for the invitation to testify this morning. I am honored to appear before you today as the President's nominee to be the next Commissioner of Food and Drugs.

I come before you today humbled by the realization that the lives and futures of families like mine are affected by the decisions made by the FDA.

Should you choose to confirm me, I will make it my mission to fight for those families every single day, and ensure that the FDA puts their interests first in everything we do.

I have seen the importance of FDA's work as both a doctor and a patient.

I graduated from Wesleyan University in Middletown, CT and went on to graduate from the Mount Sinai School of Medicine, where I also completed a residency in Internal Medicine.

I have had the honor to serve in senior roles at both CMS and FDA.

I have practiced medicine as a hospitalist physician, taking care of hospitalized patients. I have tried to ease suffering and illness as a physician, and I have had both visited upon me. I am a cancer survivor. I was treated for cancer during my last tour at FDA, so I know the importance of what American medicine does and what the FDA does for every one of us.

For the last 10 years, I have been a policy analyst and an entrepreneur starting and building businesses. I have advised and invested in early stage medical technology and healthcare services companies with the hope that some of these innovations could improve the medical technology that we use and the systems through which we deliver care.

Some of these endeavors were successful. Some were not. For many others, it is still too early to tell. That is the unpredictable nature of innovation in this dynamic sector. It is a dynamism that I have come to know well from working on the regulatory, policy, clinical, and business aspects of these enterprises.

I am proud of the projects I have worked on, and what I have learned in the process. The things I have done—my accomplishments, my failures, and everything in between—have shaped who I am today. Collectively, they have helped inform my values and my perspectives. But among other things, they have taught me the need for an absolutely objective regulatory watchdog over this field.

If confirmed, I will lead the FDA as an impartial and passionate advocate for the public health. I know what is at stake here.

People's lives are literally on the line when it comes to the decisions that the FDA makes in its oversight and its enforcement of

Congress' laws. The American people deserve to trust that the agency is led in an impartial manner, guided only by the science that informs its work and an abiding faith to the public health. That is the mandate by which I would lead this agency, if I were fortunate enough to win your approval.

I will respect the intent of Congress. I will make sure the laws you passed are implemented in a timely fashion and in the way you intended. Every decision I make will be guided by the advice of career experts. I will be guided by the scientific rigor that the public deserves and the rigor that the hard challenges before this agency demands. It is to take on these challenges that I seek this role.

We are at an inflection point in biomedical science. New technologies give us a fundamental chance to cure many intractable diseases. We have more opportunities to improve our diets and our health with the foods we eat.

In areas where there is an inherent, obvious, and seemingly unavoidable risk related to certain consumer products—whether it is combustible tobacco or dangerously addictive opioid drugs—we have the opportunity to help consumers move to less risky alternatives.

This owes to the foresight of Congress in envisioning paths to reduced harm as an animating principle in FDA regulation. I want to build on these opportunities and achievements.

I want to use the authorities Congress recently included in the 21st Century Cures Act to develop a template to lean forward in these areas. We need to make sure we are getting the most bang for our regulatory buck. That means being cognizant of the risks and being sure that we are not adding to consumer costs without improving consumer safety.

We must constantly ask ourselves are we doing everything we possibly can? Does the FDA have the policies and processes in place to play its part in tackling the important public health issues of our day?

We should be reminded always that we save lives by allowing good things to happen, but we also save lives when we keep bad things from happening. FDA's enforcement tools are a bedrock of its mission. We should reject the false dichotomy that it all boils down to a choice between speed and safety.

If the FDA is leaning forward in these areas of new technology—if it is investing in good tools for doing its own work, and better science for evaluating regulatory questions, in other words, if we are doing our jobs and leveraging the authorities you have given us in new congressional mandate—we could have better efficiency and better safety, and also remain faithful to FDA's gold standard for regulatory conduct.

I have seen FDA's positive impact in my prior roles at the agency. I am seeking this new role because I am drawn to FDA's unique spirit of public health protection that inspires its work and its workforce.

I am drawn to the opportunities we have to leverage FDA's platform and its new authorities and resources to enable advances in medicine and science to safely reach consumers.

I am drawn by the challenges the agency confronts as it tries to address and enable Americans to make the most of this unique moment in science.

I hope to earn your confidence and support in delivering on these opportunities.

Thank you again for the opportunity to appear before you this morning and I look forward to answering your questions.

[The prepared statement of Dr. Gottlieb follows:]

PREPARED STATEMENT OF SCOTT GOTTLIEB, M.D.

Chairman Alexander, Ranking Member Murray, members of the committee: Thank you for the invitation to testify this morning.

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Thank you again for the opportunity to appear before you this morning. I would be happy to answer any questions.

THE CHAIRMAN. Thank you, Dr. Gottlieb.

We will now begin two rounds of 5-minute questions for Senators who wish to ask those.

Dr. Gottlieb, you have written a lot and said a lot. If one were looking for your articles, where would one find them?

DR. GOTTLIEB. I sent you most of the URL's, I believe.

THE CHAIRMAN. Are they on the Web?

DR. GOTTLIEB. They are. Most of them are on the Web except for the ones that are very old. I have put together, we have put together, a binder of all of them. I would be happy to make it available to the committee.

THE CHAIRMAN. Thank you.

As far as the opportunity to review, Dr. Gottlieb, I would go back through what I said in my statement. He has visited with every Senator who wanted to visit with him on the committee. He has complied with all the requirements of the Office of Government Ethics who have agreed that with the recusals he has agreed to do, he will not have a conflict of interest.

All of his papers are in, in a timely way according to the rules of our committee. We will have a chance to question him today through two rounds of questions, if members would like to do that. It will be at least 2 weeks before we have a chance to have a markup. Members will have a chance to thoroughly consider him and his

record before casting a vote as to whether to report him to the full Senate.

As to his work with companies that have to do with drugs and food, that is not so unusual for someone who is going to be head of the FDA. In my view, it helps to have somebody who knows something about the subject.

An example would be Dr. Califf, his predecessor, who supports Dr. Gottlieb's nomination. Dr. Califf from Duke University was previously employed by over 20 drug and device companies between 2010 and 2014, before he became Commissioner of the FDA. That did not disqualify him from serving. I supported him. He was approved by the Senate 89 to 4.

I am glad to know that you have a background and experience in the issues before you.

As far as Dr. Califf goes, let me say a question to you that I asked him. When we were working on 21st Century Cures, I asked him his No. 1 priority for the Food and Drug Administration. He said it was to be able to hire and pay personnel at the FDA so they could deal with these lifesaving drugs and devices that are coming the way of the FDA. The Administration has placed a hiring freeze that seems to be interfering with that.

Should you be confirmed, what would you do about that?

DR. GOTTLIEB. Senator, thanks for the question.

I understand how important a strong workforce is to FDA and helping FDA maintain its gold standard. I think FDA is unique among Federal agencies in that it does not pass through most of its money. Most of the money that Congress allocates to the FDA gets spent at the FDA on the work.

It is incumbent upon us to have a world class workforce that we are providing the proper tools to and the proper training to, to maintain that very high standard.

I have, through my career and my time at FDA, been committed to making sure we have a very strong workforce at FDA. I have spoken out about that. I will continue to make my views known on that issue.

THE CHAIRMAN. I hope that you will because this was not a minor issue with us. It was his top priority and it was a top priority of ours, both Democrats and Republicans. We want 21st Century Cures to be a reality and that is an important part of it.

Dr. Collins, the head of the National Institutes of Health, has predicted a number of medical miracles over the next 10 years. One of the most important would be the possibility of the discovery of non-addictive pain medicines, which would make the opioid epidemic much less of a problem by providing a substitute. The President has indicated a similar priority. Many of us have on both sides of the aisle.

What could you do as Commissioner of the FDA working with Dr. Collins, the President, and others in the Administration, and with us to be forward leaning on accelerating and finding a discovery of non-addictive pain medicines, which might be more than anything else to relieve the opioid epidemic?

DR. GOTTLIEB. Thank you, Senator.

The opioid epidemic in this country is having staggering human consequences. I think that this is the biggest crisis facing the agen-

cy, and is going to require dramatic action on the part of whoever steps into the agency, and I hope the Senate confirms me to take on this challenge.

It is going to require an all-of-the-above approach. There are some things we are going to have to do to really push the boundaries of the policy framework in this area, and that does include re-evaluating the framework for how we can develop alternatives to opioid drugs.

It also includes looking at device alternatives to opioid drugs and looking at devices in the context of drugs. I would also add to that looking at medically assisted therapy to help people live a life of sobriety after they have become addicted.

There is going to be a need—

THE CHAIRMAN. Thank you.

DR. GOTTLIEB. Thank you.

THE CHAIRMAN. My time is running out. It is out.

I will submit for the record a question about a persistent issue with the FDA not properly clearing medical device shipments, and I hope you will look into it.

DR. GOTTLIEB. Absolutely.

THE CHAIRMAN. Thank you.

Senator Murray.

SENATOR MURRAY. Dr. Gottlieb, you do wear an extraordinary number of hats. You are a partner in an investment bank, a venture partner in a large venture capital firm, a CEO or co-CEO of two health companies, and an individual investor in more than 20 health companies. You have sat on various types of boards for 16 companies including two of the world's largest pharmaceutical companies. You also publish regularly, make speeches, consult for a number of large drug companies, and practice medicine.

My question for you is about one of those hats, your role as a venture partner for New Enterprise Associates, the largest venture capital firm in the world. You revealed in your ethics agreement that you hold a direct financial interest in six client companies including a laboratory and pathology test company, two health insurance companies, a medical equipment and supply company, a rapidly growing company that buys radiology practices, and the third largest dialysis firm in the country. You have also received hundreds of thousands of dollars from New Enterprise Associates as a consulting retainer.

If confirmed, you are committed to making the required steps to divest and recuse yourself from a select number of companies. Those were really just the tip of the iceberg.

Until recently, you were also a consultant and an investor in two large firms operated by NEA. Those funds respectively have investments in an additional 75 health-related companies who have dozens of new drugs that could potentially come before FDA for approval.

Those companies include Cerecor, which is a biopharmaceutical company with eight drugs in its pipeline; Galera, a biotechnology company with cancer drugs in preclinical and clinical trials; CRSPR, a company developing novel therapeutics based on the new gene editing technology; and Intact Vascular, it is a medical device company focusing on treating vascular disease.

Your involvement in so many companies likely to have business before the FDA—including key decisions by the agency on the safety and effectiveness of the company's drugs, devices, and products—is unprecedented.

Will you recuse yourself for the 2 years laid out in the Trump Ethics Pledge from all companies in which NEA is an investor?

DR. GOTTLIEB. Thank you, Senator. Thank you for the question.

I recognize the importance to maintain my impartiality in this role and make sure I am taking the proper steps. I have taken the proper steps through the OGE process and I look forward to working with the ethics officials at HHS and FDA to have continued discussions about what additional steps I should take to make sure I am fully compliant with the law if I am confirmed into this role.

As you noted, all of the investments I have made in NEA are healthcare services companies and a lot of my work at NEA was related to healthcare services, not to their life sciences portfolio.

SENATOR MURRAY. I am aware that you have met all your minimum legal obligations, but that does not mean you are recused from involvement in decisions that affect all of those companies.

What I am concerned about is how your involvement with so many companies shapes your priorities. Tell me how you answer that.

DR. GOTTLIEB. Senator, I am going to work hard to make sure I preserve my integrity in this role and the integrity of the FDA. I get it. I understand how important the impartiality of this agency is so that people can continue to have trust in the decisions that FDA makes.

I am going to make sure that I have a process in place, if I am confirmed into this role, in my front office for helping me to manage whatever recusals I do have to put into place, and I will consult with ethics officials. This is exceedingly important to me. I want to earn and keep the public's trust.

SENATOR MURRAY. OK. The FDA is considered the gold standard for approval around the world because the FDA reviews raw data to determine if a new drug is both safe and effective, and that scientific and nonpolitical process is critical to the trust of patients and families across this country.

Do you commit to upholding that standard?

DR. GOTTLIEB. Yes, I do, Senator.

SENATOR MURRAY. That is good to hear, but the Trump administration you will be working under has been clear about their disregard for our country's leadership in this respect.

Trump claims the FDA approval process is slow and burdensome. Secretary Price has said, "One of my passions is to get Government out of the way of innovation."

Do you commit to making decisions on safety and efficacy of new products based on the standards in the current law and the science, and not bow to political pressure from the Administration?

DR. GOTTLIEB. Senator, thank you for the question.

I am going to be guided by the science, I am going to be guided by the expertise of the career staff, and I am going to be guided by impartiality and what is good for patients as a physician.

SENATOR MURRAY. OK. I have an additional question on that, but to be clear here, you are willing to stand up to the Administration if they put political pressure on you?

DR. GOTTLIEB. Senator, thanks for the question.

For those who have worked with me, I have not been shy about offering my unvarnished advice. We mentioned 866 articles I have written where I offered very clear thoughts, and I am going to continue to offer people my very clear thoughts on whatever issues I am asked to apply it on, including my bosses.

SENATOR MURRAY. Thank you very much.

THE CHAIRMAN. Thank you, Senator Murray.

Senator Enzi.

STATEMENT OF SENATOR ENZI

SENATOR ENZI. Thank you, Mr. Chairman.

Thank you Dr. Gottlieb for being willing to take this on and obviously to leave all those things behind that were very profitable. Working in Government is not that profitable and your expertise is greatly needed.

One of the most common themes that we talk about in medical innovation is precision medicine and advances in science that put formerly inconceivable cures within reach. The FDA has the authority and, in some cases, does work with manufacturers to do adaptive trial designs that meet the needs of a particular disease population more appropriately.

I also hear about frustrations—that it can be difficult to work out with the FDA an approach to clinical trial design for small or more complicated populations.

When I hear this, I think about the difficulty that manufacturers with their innovative products can face in the drug approval process. They have to fight it out with the FDA, and that can be a delicate balance for these companies, and can mean significant delays in moving forward through the approval process. You have written extensively about this sort of thing.

Can you tell me what you view as the biggest challenge to addressing this problem?

DR. GOTTLIEB. Senator, thanks for the question.

We have a real opportunity to try to improve the efficiency of the development process and give us better tools for ensuring the safety and effectiveness of drugs at reduced costs with more efficiency. What was done in the Cures Act gives us a great template for doing that.

If I am confirmed into this role, I am going to look forward to trying to make efficient implementation of the Cures Act.

I do not want some future Commissioner to be sitting at this table 10 years from now discussing that they have not fully implemented Cures the way—when I was at FDA—we were still implementing provisions of FDAMA 10 years after it had passed.

I am going to be focused on doing that, and you provided those provisions in that bill.

SENATOR ENZI. Thank you.

Congress did enact the Food and Drug Administration Safety and Innovation Act in 2012 in which it reinforced its support for the use of accelerated approval to speed up access to novel treatments.

The FDA has been very clear that drugs approved this way do not have a different set of requirements to meet or a lesser standard. These are drugs reviewed for the same safety and effectiveness requirements as any drug that receives FDA approval.

However, there is some sense outside of the FDA that accelerated approval does mean a lesser standard. This is concerning as it can impact patients and their access to these drugs.

Will you commit to working to clarify that accelerated approval of drugs are not investigational? What do you see as any specific actions that the FDA can take to dispel the notion that these products are investigational in nature, and to clarify that these drugs are fully approved?

DR. GOTTLIEB. Thank you for the question, Senator.

There is one standard for safety and effectiveness, and no commissioner can change that standard. It has been enshrined in law many times. I will continue to affirm that there is a single standard for safety and effectiveness.

The FDA does have the ability to make certain accommodations owing to congressional statute in the kinds of requirements it can pose to demonstrate that standard; but the standard is a single standard.

SENATOR ENZI. Thank you.

Changing gears again. For years, we have talked in this committee about biosimilars. Since the launch of the Biosimilar User Fee Agreement in 2012, there have been four approvals. However, only two made it onto the market. By 2021, there will be more than 70 biological agents coming off of the patent protection and there could be a significant amount of activity in the biosimilar space.

What kind of progress do you hope to see in the review of biosimilars? Knowing that the FDA has been slow in implementing the biosimilar pathway, what do you see as improvements that can be made?

DR. GOTTLIEB. Thank you for the question, Senator.

Many of us have been disappointed by the economic savings we have seen from biosimilars so far. I do think that there is a lot of opportunity for these to have a meaningful impact on consumers and spending going forward.

I was at FDA when we first started to contemplate a pathway for biosimilars and started to do it through the 505(b)(2) process.

If I have the opportunity to be confirmed into this role, I am going to want to make sure that we are implementing guidance in a timely fashion to try to create the kinds of opportunities for competition. Issues like can biosimilars be used interchangeably in the market, could have a meaningful impact on the potential to get economic savings.

Congress recently directed the agency to put out that guidance. I want to make sure that we are putting out those documents in a timely fashion in evaluating these questions.

SENATOR ENZI. Thank you for the conciseness of your answers.

I have a couple of other questions that I will just submit.

Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Senator Enzi.

Senator Sanders.

STATEMENT OF SENATOR SANDERS

SENATOR SANDERS. Thank you, Mr. Chairman.

Welcome, Dr. Gottlieb. I enjoyed our conversation in the office, and welcome to your family, and all the first graders in Connecticut.

DR. GOTTLIEB. Thank you.

SENATOR SANDERS. Let me begin, Mr. Chairman, by expressing my amazement, I think, shared by millions of Americans that we have a President who ran for President, and perhaps won the election, by saying that he was a "champeen" of the working class of America.

He said that he would not cut Social Security, and Medicare, and Medicaid. You know what? He appointed his key advisors, people like Representative Mulvaney and Representative Price, who spent their entire careers trying to do exactly that.

He said that he would, "Drain the Swamp." He now has more billionaires in his administration than any President in American history.

He said he would provide, "Health insurance for everybody," but he just supported an embarrassing, disastrous healthcare proposal that would have thrown 24 million people off of health insurance.

He said he was, "Going to stop Wall Street from getting away with murder," but he has drained half of Goldman Sachs into his administration.

In other words, he ran for President saying one thing, and he ended up doing something exactly the opposite, which brings us to Dr. Gottlieb.

Candidate Trump and, in fact, President Trump after he was elected, made some very important and, in my view, correct statements about the outrageously high prices that we pay for prescription drugs in this country.

I must say, Mr. Chairman, that if you go out to the American people and you ask them the most important issue that concerns them in healthcare, do you know what it will be? It is the fact that we pay, by far, the highest prices in the world for prescription drugs, an issue which has not yet been even mentioned in this hearing.

The fact that almost one out of five adults in this country, who get a prescription from their doctor, cannot afford to fill that prescription.

The fact that in my State, and I expect in Tennessee, you have senior citizens who are cutting their medicine in half.

We have heard from oncologists and other doctors that people are dying. Their patients are dying because they cannot afford the outrageously high prices of prescription drugs.

You know what? Trump talked about that and he was right. As Senator Murray indicated, he nominates somebody who has received millions of dollars from the pharmaceutical industry. According to the "*New York Times*," he has received more than $150,000 in compensation from Vertex Pharmaceuticals, a company that is charging more than $250,000 a year for drugs to treat cystic fibrosis.

Even more interestingly, Trump runs for office and he says,

> "Look. There are, among other things, two ways that we can deal with the high cost of prescription drugs. We should be able to re-import lower cost prescription drugs from Canada and other countries. We should be able to negotiate prices with Medicare."

Yet, Dr. Gottlieb writes an Op Ed for "*Forbes*," in which he directly contradicts what Trump has to say about re-importation. That was the thrust of his Op Ed.

I ask Dr. Gottlieb, why would President Trump appoint somebody to the very important position of head of the FDA whose views run diametrically opposite to what he said during the campaign?

Do you support, as Trump does, the re-importation of low cost medicine from Canada and from other countries, allowing Americans to save significant sums of money on the medicine they need?

DR. GOTTLIEB. Thank you, Senator, for the question.

I obviously cannot speak to why the President of the United States nominated me for this role. I can tell you, as we discussed in your office, I have a lot of ideas that I want to work on right away for how I think we can get more product competition onto the market.

You and I talked about the fact that many complex drugs have monopolies effectively in perpetuity because of—

SENATOR SANDERS. I apologize for having interrupted you. I have very little time left.

A quote from your article in "*Forbes*,"

> "The problem is that drug importation does not address any of these core challenges. In fact, the imported drugs may end up being quite expensive."

That is fine. That is your opinion.

It happens not to be the opinion of the guy you will be working with, and I just find it amazing that Trump says something during the campaign, and then appoints people who have radically different ideas.

What is your view on the need for Medicare to negotiate prescription drug prices with the pharmaceutical industry?

DR. GOTTLIEB. Senator, it is true. I have written a lot of things on a lot of different subjects, including issues around Medicare.

I am coming before you for the position at the FDA and I am going to get asked my position on a lot of different subjects that fall outside of FDA's purview. I would do the agency, that I hope to lead, no favors by wading into other territory.

SENATOR SANDERS. Dr. Gottlieb, as you are more than aware of, part of the FDA's mission is to make medicines—this is the FDA mission not Bernie Sanders' idea—"More effective, safer, and more affordable."

That is within the jurisdiction of the FDA.

DR. GOTTLIEB. that is my goal, Senator.

SENATOR SANDERS. Your goal is, from what I am hearing, you oppose the ideas that President Trump said he was going to do to the American, for the American people.

Sounds a little bit strange to me, Mr. Chairman.

THE CHAIRMAN. Thank you, Senator Sanders.

Senator Young.

STATEMENT OF SENATOR YOUNG

SENATOR YOUNG. Dr. Gottlieb, thanks so much for being here today.

First to my colleagues who are concerned about the price of prescription drugs, there are a number of ways we can tackle that issue. I look forward to engaging with them for, perhaps, some alternative paths to get where I know others want to go that I think could be palatable in a bipartisan way. With that said, we will discuss that offline, as opposed to negotiating publicly here.

On the issue of safety and efficacy, which has already been addressed in a fulsome way, you have responded to some of the questions. Thank you.

I just want to give you the opportunity to discuss the existing standards. You have indicated you support the existing standards, Doctor, with respect to the drug approval process.

Do those standards, however, provide enough flexibility for rare and common diseases, chronic and acute diseases, and the varying levels of knowledge we have about different diseases?

DR. GOTTLIEB. Thank you for the question, Senator.

There are parts of the agency that have leaned forward to try to use some of the new authorities that Congress has given to the FDA to contemplate how to incorporate better scientific principles into the evaluation of products, particularly targeted to unmet medical needs.

I would commend, in particular, the Oncology Division and what they have done, as an outside observer, to try to lean forward in new areas, to find new metrics for the approval of products that incorporate new science.

I think there are other parts of the agency that have not focused as much on the adoption of some of these new opportunities. And I would hope in leading the agency, if I am confirmed into this role, to bring more consistency to how different parts of the FDA look at the authorities that Congress has given to the agency to achieve the kinds of things you talk about.

SENATOR YOUNG. As a follow up, some of FDA's review divisions perform incredibly well, as I understand it. The Oncology Division being perhaps the most notable positive example. They collaborate with patients, manufacturers, and other stakeholders to proactively facilitate innovation. However, I understand not all review divisions are as forward leaning or as flexible as others.

As FDA Commissioner, specifically, how will you work to raise the performance or consistency of all review divisions regardless of the therapeutic areas they focus on?

DR. GOTTLIEB. Thank you for the question, Senator.

One of the things that I tried to do last time I was at the agency was to compel the agency to look at how it was performing. By doing that, we sometimes were able to help people who were working in the divisions reveal these things for themselves, and that was a healthy exercise.

I would hope to do the same thing, if I am confirmed into the role, again to allow review staff and leadership in the Centers the opportunity to evaluate how different parts of their Centers are

working, and to find those places where we might be able to adopt some best practices and broaden them.

SENATOR YOUNG. Sounds as though it is a bottom-up approach, which strikes me as good management.

DR. GOTTLIEB. Everything is a bottom-up approach at the FDA. The ideas really need to come from the career staff in the Centers.

What leadership can do is help facilitate the opportunities to recognize places where there could be underperforming parts of the agency.

SENATOR YOUNG. Doctor, you have spoken of biosimilars and some changes that might be made to improve the approval process and expedite the ability of bringing them to market.

What about in the area of generics? Are there certain regulations or guidances you think are particularly burdensome, or obsolete that should be withdrawn, or significantly revised? In generics, you could touch on medical devices or pharma as well, if you like.

DR. GOTTLIEB. Thank you for the question, Senator.

One of the issues I have looked at recently is the issue of so-called high-value generics or complex generics where the FDA struggles to put certain drugs through the ANDA process because it is difficult to demonstrate substantial equivalents using just the traditional tools, which is bioequivalence and bioavailability studies.

Congress did not envision with Hatch-Waxman that certain drugs would have monopolies in perpetuity long after their intellectual property has expired but for the inability of the FDA to have a scientific process that can prove interchangeability for those drugs.

This is an area where we can make a lot of progress. We might need to come back to Congress, to talk to Congress about what additional steps we need to take. There are things the FDA could contemplate administratively.

This is an area I want to work on. There is literally billions of dollars worth of drugs each year that are sold as branded drugs at high prices, but should be subject to generic competition.

SENATOR YOUNG. Very encouraged that you intend to be forward leaning in this area of delivering to this committee, and perhaps others, some solutions that we might work with you on, and I would like to play an active role in that effort. Thank you.

DR. GOTTLIEB. Thank you, Senator.

THE CHAIRMAN. Thank you, Senator Young.

Senator Kaine.

STATEMENT OF SENATOR KAINE

SENATOR KAINE. Thank you, Mr. Chair.

Thank you, Dr. Gottlieb for your testimony. I want to talk to you about opioids, which you addressed in your opening comment.

Two million Americans today have a substance abuse disorder with prescription pain relievers and in the most recent year, more than 20,000 died of overdoses on prescription drugs, prescription opioids.

Another 600,000 Americans have a substance abuse disorder because of addiction to heroin. Four-fifths of new heroin users began

by using prescription opioids. An additional 12,000 Americans died last year from heroin overdoses.

In 2012, the last year for which we have very good statistics, 259 million opioid prescriptions were written in this country—prescriptions with multiple doses of prescription opioids.

There are many at fault for this scourge. There was bogus research that was published and perpetrated suggesting that these drugs do not have addictive qualities, which they do.

There was unscrupulous advertising, a drug developed that provided pain relief in emergency situations. There was a realization that there was not a big enough patient base, and so there was a decision to market it more broadly to people suffering from chronic pain conditions.

There are dishonest providers who have been caught, pill mills and there might be doctors, there might be allied health professionals or pharmacies that were being caught.

There has been inadequate training about pain management, often in medical schools and other places. Without any malice, the absence of appropriate training about how to manage pain has contributed to this.

The FDA has played a role in it too. The FDA approved Zohydro, despite the fact that the advisory committee at the FDA recommended that that not be the case.

The FDA approved use of Oxycontin by adolescents, despite the fact that the advisory committee expressed grave reservations about that.

You and I chatted a little bit about this yesterday. I would like to hear you talk about in your leadership of the FDA, should you be confirmed, what would be your strategy for taking on this challenge that the FDA has been somewhat complicit in, even if unwittingly, in the past?

DR. GOTTLIEB. Thank you for the question, Senator.

I enjoyed our discussion yesterday.

This is a staggering human tragedy that, as I said at the outset, is going to require dramatic action on the part of the agency. It is going to an all-of-the-above approach. There are a number of things we can do.

I feel I have a bipartisan mandate through my discussions with this committee to try to push the agency to look harder at what the right framework would be.

To give you some examples, FDA does take on as part of its review process the mandate for looking at the potential for abuse and diversion as a component of the approval process. I think we need to ask hard questions whether or not the agency has the adequate authorities, resources, and policy framework for doing that, to make sure it is being done appropriately.

We need to look at opioid drugs in the context of medical devices that could provide alternatives. The safety and benefit of a systemic opioid drug might look a lot different when it is juxtaposed against a device alternative that is delivering localized therapy. That we might need to look at a different framework.

Congress has given the FDA some authority to look at drugs and devices in conjunction. We have done that with the Oncology Division.

We have to look harder about how to create generic standards for the drugs that have abuse deterrents, so that we feel more confident clearing the market of the older drugs that do not have abuse deterrent features. We need good guidelines for how we are going to genericize those drugs so that we are not just forcing people onto high-cost drugs when we take the older, generic drugs off the market.

We need to do all these things and we need to look at alternatives to opioids, and do we have the right framework in place, and the guidance in place to accelerate the development of non-opioid alternatives for the treatment of pain. We are going to need to push harder on all these things.

It might be the case that when we look at these questions in a hard way, I might have to come back to Congress, if I am fortunate enough to be confirmed into this role, and have another conversation with all of you about how to make these things happen.

SENATOR KAINE. Dr. Gottlieb, if I could just follow up on that.

As I think about the FDA, I am not an expert, but as I think about it, I think of the work of this agency as largely around applications and then the testing to determine—when whether it is a device or a drug—is it available, and ready, and proven efficacious, and safe for use by the public. An application, we are going to look at this particular application to see when it is ready for prime time.

What I would hope that the FDA would be able to do is look more broadly at the issue of pain management. Do we have the right set of tools and strategies, devices and pharmaceuticals that can effectively manage pain in a way that is safe? To the extent that we do not, I would hope the FDA could look in a proactive way about, what do we not have? What do we still need?

If you need to come back to us and tell Congress that the FDA's mission is to fine tune narrowly just around the approval process rather than being proactive to deal with an issue that is as massive as the management of pain, I hope you will come back to us and tell us that because I would think we would need to. You would probably find some bipartisan support for altering and expanding the mission of the FDA so that we could take a proactive approach to this public health scourge.

DR. GOTTLIEB. Senator, this will be my highest immediate priority and I am committed to do that.

SENATOR KAINE. Thank you, Mr. Chair.

THE CHAIRMAN. Thank you, Senator Kaine.

Senator Scott.

STATEMENT OF SENATOR SCOTT

SENATOR SCOTT. Thank you, Mr. Chairman.

Dr. Gottlieb, thanks for being here this morning.

You bring a healthy balance, or equilibrium, to this opportunity. You are a doctor. You have also been a patient. Not just a patient, but a cancer survivor. You appreciate the necessity of new drugs, and sound quality, and safe drugs.

You have worked for the FDA on a couple of occasions, but you have also worked with industry for a long time. You also have the support of Dr. Hamburg and Dr. Califf, the Commissioners of the FDA. So I like the equilibrium that we see here.

One of the comments that you made during your opening statement, or at least the comments that I read in your opening statement, was that you see a false dichotomy that it boils down to either speed or safety. I would appreciate you expounding on that because there has been much conversation around the pricing. Price, oftentimes, is a component of how long it takes to get to market.

There is a successful venture from Clemson University, in my home State of South Carolina, of tissue bioprinting. I would imagine that, given the current investment in capital and time to get a drug to market, we should encourage every tool possible that helps us get there faster and safer.

I would love to hear your comments on tools like bioprinting, as well as your comments about the dichotomy that may be a false paradigm.

DR. GOTTLIEB. Thank you for the question, Senator.

It is the case that drugs do get priced to some measure of the cost of capital to create those drugs. The longer the timeline—the more costs, and the more uncertainty of that process—the higher the cost of capital to fund an endeavor to try to find a new innovation.

Anything we can do to try to make that process more predictable, to create bright lines, to use better tools to evaluate safety and effectiveness that could bring down the cost—while not doing anything to sacrifice our ability to ferret out the safety of a product—are things we should be looking at.

I come back to the Cures Act because I think that there is a lot of opportunity for that to be a template for policymaking in this regard, not just what Congress directed the agency to do with respect to adaptive clinical trial designs. Also what Congress directed the agency to do with respect to modeling and simulation as a tool to helping better evaluate safety and effectiveness.

All of these things can make the process more efficient and perhaps less costly while still allowing us to fully evaluate safety and effectiveness.

This is one place, if we are doing our jobs right, we can have our cake and eat it too.

SENATOR SCOTT. That is awesome. Thank you.

Another question for you, I spend a lot of time every Valentine's Day, I enjoy going to the Medical University of South Carolina and visiting the pediatric unit, specifically the oncology center because you have an opportunity to see children who are going through incredible situations, challenging times, but they are optimistic; they are positive.

The care that they receive at the Medical University of South Carolina is outstanding care. But there are times when doctors do not have all the tools necessary. As you are well aware, cancer affects children and adults differently and often the type of cancer that develops in a child is very different than what might develop in an adult.

Given this, and the fact that pediatric cancer is so rare, what can the FDA do to continue to enable innovation in this space?

DR. GOTTLIEB. Thank you for the question, Senator.

Congress has given the agency certain authorities to try to encourage the development of clinical data in the pediatric setting. As

you noted, there are still obstacles to getting drugs studied in these ways.

This is something I would be committed to trying to work with you and others on to see if there are additional steps we could be taking to try to create incentives for the development of information around the use of products in the pediatric population, and also finding ways to conduct more feasible clinical trials in these settings. Sometimes it is hard to run the same kinds of perspective, large, randomized trials in very small populations where children are involved, and I think we need to look at different clinical trial constructs as well.

I, again, come back to the issue of adaptive designs and alternative clinical trial designs as being something that could be particularly applicable in this area. I would be committed to working on this if I am confirmed.

SENATOR SCOTT. Last question and probably, perhaps, a quick answer because we have little time left.

A lot of the smaller biotech companies are working on cutting edge research and development. They may have one drug in the pipeline and none on the market. Working with small staffs and, frankly, private capital.

What are some of the ways that the FDA can support these smaller companies and help more drugs come to market at the lowest cost?

DR. GOTTLIEB. Thank you, Senator.

As it was noted at the outset, I have helped create some of those smaller companies.

SENATOR SCOTT. I did note that.

DR. GOTTLIEB. I have seen this experience from both sides.

The most important thing when you are trying to raise capital to develop a new innovation is understanding exactly what your costs are going to be. Obviously, there is an inherent unpredictability to the scientific process, and you can never fully anticipate that.

Understanding what the benchmarks are, and what the clinical requirements are going to be, is very important. It becomes important for the FDA to have very clear guidance, especially in areas of unmet medical needs so that people who are trying to find capital for these endeavors know what their costs are going to be.

THE CHAIRMAN. Thank you, Senator Scott.

Senator Warren.

STATEMENT OF SENATOR WARREN

SENATOR WARREN. Thank you, Mr. Chairman.

In the 1950s, a German company began selling a drug called Thalidomide all over Europe, a sleep aid that was also marketed for nausea during pregnancy. Pregnant women, who took Thalidomide, starting having babies with severe birth defects most notably deformed flipper-like arms and legs.

More than 10,000 children were born with severe disabilities caused by Thalidomide, but fewer than 100 of those were born in the United States and that is because an FDA reviewer kept the drug off the market over concerns about the shoddy data to support the drug's safety.

Following that episode, public outrage led Congress to strengthen the FDA so that drug company profits would never be put ahead of the safety of our children.

I was surprised, Dr. Gottlieb, to read in a 2012 article that you asserted that the Thalidomide episode had a harmful effect on the FDA. You said the incident,

> "Fostered an idealization of FDA reviewers as 'championing' an issue of safety against the prevailing orthodoxies especially when it meant taking on corporate interests."

You were critical.

Dr. Gottlieb, do you think the FDA puts too high a priority on championing safety and protecting unborn babies and other consumers?

DR. GOTTLIEB. Absolutely not, Senator.

The thrust of that article was about a much different point, but I absolutely believe the FDA needs to be answering these questions in full. In fact, the modern FDA does a very good job ferreting out risks of teratogenicity preclinically, actually because of the modern tools that we use in the drug development process.

SENATOR WARREN. I am not quite sure that I am following because you talk about,

> "In so heavily prioritizing the protection of consumers, the FDA has 'subordinated and neglected' its obligation to 'guide new medical innovations to market.'"

In other words, it sounds like to me you are saying in this piece that you think that the FDA places too much emphasis on consumer protection.

DR. GOTTLIEB. Senator, I remember the piece well and the thrust of the piece was focused on my concern that the agency was losing confidence in physicians and felt that it needed to step into the regulation and the practice of medicine to try to supplant its judgement for the judgement of doctors in certain situations. Moreover, I was concerned that the agency did not have the enforcement tools to follow up on what it was doing.

One thing I learned when I was at FDA was you have had to be careful about imposing a requirement that you are not capable of enforcing, and that was the thrust of the article as I remember it.

SENATOR WARREN. I have to say that is not how I read the article, and I worry about your language, in that you criticized FDA reviewers saying that they, "Believe it is appropriate to prioritize safety over speed."

I know there are always judgments to be made, but belittling reviewers who are concerned about safety makes me very uneasy. I want to get innovative products to market as fast as possible, and I support more resources for the FDA to be able to do that. I support better science for the FDA. I have written bills to do both of those.

Your view of the FDA's response to the Thalidomide problem is deeply disturbing and it raises, for me, real questions about your commitment to the FDA's basic safety mission.

As my colleagues have pointed out, you have spent your life entrenched in the companies that would benefit from looser regulations. I think it raises the very real question of whether someone

who seems to oppose the FDA's basic safety mission should be running the agency. I just have real concerns here.

I also have concerns about off-label marketing. I see that I am running out of time and it is a long series of questions.

In deference to the Chair, I will do those as questions for the record.

I just want to say the position of the head of the FDA is one in which all of America and, indeed, all of the world places its trust.

For me, that means it is profoundly important that you be committed to safety and that you be committed to the role of the FDA; not the drug companies, not others outside who stand to profit, but to the FDA itself to watch out for that safety.

DR. GOTTLIEB. I agree, Senator.

SENATOR WARREN. Thank you, Mr. Chairman. Thank you.

THE CHAIRMAN. Thank you, Senator Warren, for respecting the time. There will be an opportunity for another round of questions if you wish.

Senator Burr.

STATEMENT OF SENATOR BURR

SENATOR BURR. Thank you, Mr. Chairman.

Dr. Gottlieb, to your parents, congratulations; you did a great job. I hope you are proud of him. All the criticism is about his successes.

To your wife and to your children, thank you for the sacrifice that you are making. It is a job I have always wondered as people get nominated why they do it, and especially somebody with as many irons in the fire as Dr. Gottlieb has.

Let me ask you, Dr. Gottlieb, do you think the FDA follows the 1997 FDAMA statutes today?

DR. GOTTLIEB. It follows important elements of the FDAMA statutes in part because of the foresight of this committee in recodifying some of those and reinvigorating them for the Breakthrough Therapies.

SENATOR BURR. We went through a period of time where the FDA did not even follow the statute of law. Right?

DR. GOTTLIEB. I have been on the record of being critical of that. Yes.

SENATOR BURR. As the author of it, that was discouraging to me. Yet, I hear you having to be held to a standard of following the letter of a statute. Yet, you are inheriting an agency that had not done that.

Let me ask you. In 2017, should there still be double-blind studies where the doctor does not even know whether the patient is getting a placebo or not?

DR. GOTTLIEB. Senator, thank you for the question.

I believe that there are opportunities to modernize how we do clinical trials in ways that are not going to sacrifice on the gold standard of safety and effectiveness, but perhaps could think of clinical trial constructs that do not require the tight randomization that current clinical trials do. Congress believes this as well because it has directed the agency to look at alternative clinical trial design as the component of the review process.

To your point about FDAMA, I believe that getting sufficient implementation of Cures and following Congress' intent in that regard is going to be an essential part of what I hope to do if I am confirmed into this role.

SENATOR BURR. In fact, Congress in 2012 passed Breakthrough Therapy legislation on drugs. We followed it up in the Cures Act with a Breakthrough Therapy Pathway for devices. That was an acknowledgement by Congress that there was a risk aversion within the culture of the FDA.

If confirmed, what are you going to do to change the culture of the FDA; not the standard, the culture?

DR. GOTTLIEB. Thank you for the question, Senator.

I want to find ways to look at what is working well within the agency, if I am confirmed into this position, and try to bring those best practices to the parts of FDA that might not be adopting the tools, especially the tools that Congress has instructed FDA to start to incorporate.

We have seen, for example, I think to your point, uneven adoption of the principles embedded in the Breakthrough Therapy Pathway, and I think there are ways to try to inspire more consistency and more broad adoption of that ethos.

That would be something I hope to work on. That is something we were able to do when I was at FDA the last time in part by challenging the agency to examine its own processes to see how it was performing against these kinds of benchmarks and against the prerogatives of Congress.

I would hope to bring back those same tools, those same techniques, to try to do that again with respect to these new sets of authorities that Congress has given the FDA.

SENATOR BURR. When Andrew von Eschenbach was the commissioner of the FDA, Dr. von Eschenbach recognized at the time that the success of the FDA was in his ability to have the talent that he needed in the future to be able to address technology changes that they were going to be presented with from the standpoint of reviewers.

If you are confirmed as the next FDA Commissioner, how will you ensure that the FDA is ready to regulate cutting edge products coming before the agency today and in the future? I might add, that Dr. von Eschenbach set up a whole mechanism to identify future employees, recruit future employees, train future employees that was dismantled after Dr. von Eschenbach left as commissioner.

What are your plans?

DR. GOTTLIEB. Thank you for the question, Senator.

This is one of the most critical issues facing the agency right now. I think it is critical, in part, because the complexity of the science coming before the agency is going to require the FDA to have more and more specialized talent.

It is also critical insofar as we have a workforce at the FDA that is aging to the point where you are going to have, a spate of retirements. When you look at the demographics of the agency, you are going to lose a lot of very senior professionals over a short period of time. Replacing that kind of expertise and institutional knowledge is going to be a real significant challenge.

This is something, if I am confirmed into this role, that is going to be something I need to work very hard on and a significant challenge to the job.

I do believe what Congress has done in Cures—in giving the agency certain hiring authorities and certain abilities to go out and target people with specialized knowledge—does provide the basis for trying to address this challenge. Getting that implemented as Congress intended is something I hope to do working with my administration, if I am confirmed into this role.

SENATOR BURR. I thank you for that commitment.

Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Senator Burr.

If I may editorialize, that is a commitment that almost all of us share.

Senator Casey.

STATEMENT OF SENATOR CASEY

SENATOR CASEY. Thank you, Mr. Chairman.

Doctor, good to be with you. Thank you for coming to visit our office to talk about some issues. I will raise some other issues with you now that we did not have a chance to review in my office.

The first is the Over-the-Counter Monograph System, which I think many would argue is ineffective and in need of improvement. I have been working with Senator Isakson on legislation to reform the Over-the-Counter Monograph process, to modernize it. In particular, to modernize drug regulations, and ensure that both safety and efficacy information is communicated to consumers in a timely fashion.

I would ask you first about that system, your view of it. Second, ask you if you would commit to work with us in this process to create a better, safer, and more efficient regulatory structure for over the counter drugs.

DR. GOTTLIEB. Thank you for the question, Senator.

Anytime a problem persists from when I was there 10 years ago to today is an indication that it requires immediate action.

I am familiar with what Congress is working on. I have the sense from what I read outside of the agency—I do not have the benefit of being inside the agency—that there is support in the agency for Congress' ideas. I also believe, I think like you, that this is a system that is in need of modernization.

This is something I would be very committed to work with you on, if I had the opportunity to be confirmed into this role.

SENATOR CASEY. I wanted to ask you as well about a rather recent development.

A January 2017 white paper from the FDA analyzed 22 cases of drugs, vaccines and devices where promising Phase 2 results were not supported by subsequent trials in Phase 3. Alarmingly, seven of these products had safety problems that were not detected until Phase 3 trials were completed.

Based upon that report, and the concerns that emanate from that, I would ask you about the Phase 3 process in particular. You have been critical of FDA's reliance on data from Phase 3 clinical trials for drug approvals.

Do you continue to hold that view?

DR. GOTTLIEB. Thank you for the question, Senator.

I am not sure insofar as I am critical of Phase 3 trials. I have articulated a point of view that with more modern clinical trial designs, you could compress the Phase 2 and Phase 3 clinical trials into one, big adaptive design. That is a view that the FDA has had and FDA officials in terms of trying to design modern clinical trial constructs.

That a proper clinical program is an essential feature of ensuring the safety and effectiveness of products, and I am familiar with the study you talk about. Having proper post-market enforcement tools is an essential part of the overall paradigm of regulatory approval.

SENATOR CASEY. Do you believe in allowing market forces to be the judge of efficacy in Phase 3? Do you believe that?

DR. GOTTLIEB. I believe in the gold standard for safety and effectiveness, and I believe Congress has delineated a single standard for demonstrating that, Senator. That is something that needs to be demonstrated through a regulatory process guided by science and the public health.

SENATOR CASEY. Do you support, or I should say, do you continue to support the requirement that all new drug applications must include Phase 3 trial data for a drug to be approved for marketing?

Dr. Gottlieb. Congress has directed the FDA to allow certain drugs in certain situations to be approved on the basis of Phase 2 data under the Breakthroughs Pathway under some of the provisions in FDAMA. Congress has given FDA the tools to make certain accommodations in areas of unmet medical need.

I support following the directive of Congress in making sure your laws are faithfully implemented.

SENATOR CASEY. I wanted to ask you as well something we raised initially yesterday with regard to preparedness for all kinds of threats to public health. We have had so many lately that we are reminded all the time of the emerging—not just the threats we have seen—but emerging diseases and bioterrorism concerns.

Senator Burr and I have worked for years on medical countermeasures, policy, and legislation. The development of these new countermeasures to combat these threats is, of course, a huge priority for everyone here. The FDA plays an important role in that, but here we are now facing a hiring freeze and potentially facing adverse budget impacts.

I would hope, and I will ask you the question, it is a simple yes or no question. Would you advocate within the Administration against the views of the Administration apparently? Would you advocate in the Congress for appropriations needed to meet FDA's mission as a public health agency including FDA's obligation with respect to medical countermeasure development?

DR. GOTTLIEB. I am going to be committed, Senator, to advocating for a strong FDA.

SENATOR CASEY. I would hope that means that you would advocate against proposals with regard to a hiring freeze or the budget.

Would you or not?

DR. GOTTLIEB. I am going to be committed to advocating for proper resources at the FDA and a strong user fee program, making sure that the mandates that you have given FDA are properly resourced, so we could fulfill our mission.

SENATOR CASEY. That was not the answer I was waiting for, but I know my time is over.

THE CHAIRMAN. Thank you, Senator Casey.

Senator Paul.

STATEMENT OF SENATOR PAUL

SENATOR PAUL. Dr. Gottlieb, congratulations on your nomination.

It is my considered and biased opinion that we have plenty of lawyers in Government, so I am always happy to see a fellow medical doctor being appointed to something.

It is important just to reiterate maybe and tell us your approach in general and motives. Would you ever let drug profits—drug company profits or medical device company profits—would you ever let that obscure your duty to safety and efficacy?

DR. GOTTLIEB. Absolutely not, Senator.

SENATOR PAUL. That is important, because that goes to character. To me it is sort of your honor is on the line when you say that. We can argue back and forth, but you only can tell us that, and I think that is your stated opinion, and I accept that.

While your primary duty is safety and efficacy, there are sort of market forces that ultimately determine prices of drugs, availability of drugs, whether there are monopolies or not. The FDA gets in the middle of that.

My hope is that we can get to a point where generics are, obviously knowing that safety and efficacy is our primary duty, but that we can maybe get them approved quicker so we can have more competition. That we cannot have markets where we only have one generic, that we are doing things to allow more competition, understanding that competition will bring prices down.

I guess what I would like to hear from you is just in general your approach to how we balance that, patented drugs versus generics. What are the things you think we can do better in the generic market?

The one you and I have talked about, the EpiPen, where the generic, applied for approval like in 2009, and still does not have approval. The FDA will say, "Oh, we are doing a lot better and we are only doing them in a year and a half now. We used to do them in 25 years," or whatever.

It still has to be even better, and I hope you will see that as something that we can work on, and that you will give us feedback on how you are going to make that better. I would just appreciate your general comments.

DR. GOTTLIEB. Thanks for the question, Senator.

This is something I would hope to work on early if I am fortunate enough to be confirmed into this role.

That when it comes to generics, there are really two problems. The first is just the ordinary generic approval process where we have seen situations where certain drug markets have fallen to one or two drugs, prices have been raised, and the market is not self-correcting because trying to get in an application and get it approved could take up to 4 years.

You have people who have been able to take advantage of regulatory arbitrage by buying a product that might not face generic competition, even though it is a generic drug, jack up the price, and

it takes a long time for other people to come into the market even though the high price should be attracting competition.

That is a solvable problem and something I would hope to work on.

The other problem, which is more complex, are the generic drugs that we have talked about here today where the agency does not have good standards for demonstrating substantial equivalence because the drug is a complex formulation.

Simply looking at the blood levels of the drug, which is a standard by which we approve generics under Hatch-Waxman, is not sufficient for demonstrating substantial equivalence.

This might be a drug that acts topically where measuring the blood levels does not approximate the effect. It might be a drug that acts inside the lungs, like a metered dose inhaler. It might be a drug that acts inside the gut, a pill you swallow that acts inside the gut.

In all these cases, you cannot simply look at blood levels as a proxy for how the drug is going to have its therapeutic effect.

In those cases, we need to develop better scientific principles for doing that. There is opportunity to do that within the framework of Hatch-Waxman. I would want to challenge the agency to do that. But this might be an area where we need to come back to Congress and have a broader discussion around what that should look like.

This is a situation where you have drugs that Congress intended for them to be subject to vigorous competition, but we did not envision it when we passed Hatch-Waxman because the drugs themselves have had 10 more complex.

SENATOR PAUL. Thank you.

THE CHAIRMAN. Thank you, Senator Paul.

Senator Murphy.

SENATOR MURPHY. Thank you very much, Mr. Chairman.

Dr. Gottlieb, I think you are hearing from this side a level of discomfort with your nomination, certainly connected to your private sector history. It is also fairly unprecedented to have a nominee before this committee for this position that has such an extensive political history as well.

It is very well known you were one of the most outspoken opponents of the Affordable Care Act. There is virtually no piece of that legislation that you did not have a strong opinion on that was very strongly worded. You have been a political advisor to Republican candidates running for President.

The worry about impartiality is certainly connected to the private sector experience, but it is also to your very deep political involvement as well.

I may want to ask a question about where today politics and science are intersecting, in a way that make a lot of us on this committee uncomfortable, and that is on the issue of vaccines.

I am encouraged that you have commented and published on multiple occasions in support of vaccinations based on scientific data.

However, you are going to be working for a President who has been a frequent critic of vaccinations. He has also suggested that he might convene a political commission that will look into the connection between vaccines and autism, for instance.

Let me just ask you these two questions. No. 1, is there any medical evidence that you know of to support the idea that vaccines cause autism or that vaccines administered in the current recommended vaccination schedule cause autism?

If this political commission is convened, if there is an attack on vaccinations from this Administration, will you commit to publicly opposing that effort?

DR. GOTTLIEB. Thank you for the question, Senator.

As a physician, I share the concerns that parents have about putting any product in an otherwise healthy child. I understand that this issue elicits a lot of emotion.

That this has been one of the most exhaustively studied questions in scientific history.

You had the 540,000 patient Danish study. You have had exhaustive studies by the IOM and other esteemed bodies. I think we need to come to the point where we can accept no for an answer around this question, and come to a conclusion that there is no causal link between vaccination and autism.

At some point, we have to accept no for the answer after we have invested, and Congress has invested, enormous resources in studying this question.

I have a history of not being shy. I think to your original premise of your question, when you talked about some of my writings, not being shy about speaking truth to power, and making my views known sometimes in an unvarnished way on the editorial pages of America's newspapers.

I will bring the same operating platform to this position. I will give people my direct advice, my unvarnished opinion, my science-based judgement, and the science-based judgement of the people of the agency I hope to lead. I will make that known in the proper venues.

SENATOR MURPHY. The worry is that there will be industry-supported reforms that will find a voice inside the agency because of your connection to the industry.

Let me talk about a piece that you wrote, I believe, in the "*New England Journal of Medicine*" that discussed your "National Affairs" article in 2012, where you proposed a major shift in the FDA drug approval process where you suggested that there should be a politically accountable board that ultimately makes decisions on drugs, which is a revolutionary change from the way that we do things now.

It seems like it would be a big gift to the drug industry being able to use their political donations in order to ultimately put a group of "friendlies" on a process or a commission that decides approval rather than having that process sheltered from the political process.

Can you talk a little bit more about that proposal and explain to this committee why that ultimately would not lead to the politicization of drug approvals if you put that process into the political realm outside of the protected area of the FDA?

DR. GOTTLIEB. I appreciate the question and a chance to clarify what the article said.

In that article, if I remember correctly—and it has been a while, I have written a lot of things on a lot of different topics as you

noted—I lamented the fact that the advisory committee process itself, in my view, was already becoming politicized.

My point was, and it was sort of a rhetorical point, perhaps we should be more transparent about what is happening and just allow Congress to appoint the members to the boards or the GAO as we do with other advisory committees in Congress. Because it might be a more transparent and deliberate way to achieve what seems to have been the effort underway, which was to influence the appointment of members to its board.

It was in some respects a rhetorical exercise, but in some respects an acknowledgement of what I thought was a trend that was underway with respect to the appointment of those members.

SENATOR MURPHY. I hope that you will see that it is your role to depoliticize that process to the extent that you think it is politicized rather than to elevate the politicized process.

DR. GOTTLIEB. I agree with you, Senator.

SENATOR MURPHY. Thank you. Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Senator Murphy.

Senator Hatch.

STATEMENT OF SENATOR HATCH

SENATOR HATCH. Thank you, Mr. Chairman.

I just want to compliment you for the experiences you have had in this life. You have had a wealth of experience. Yes? A lot of it in business, and a lot of it in industry, but on the other hand, there is nothing that should discourage you from being head of the FDA because you have had extensive industry experience as well.

I am going to personally compliment you because I am wondering, why are doing this? Why go through all this pain? You do not have to give a long answer.

DR. GOTTLIEB. Senator, I could think of no better time to serve the public health in this capacity than right now.

Given the opportunities we have with science and technology to find fundamental cures for many diseases because of the new scientific platforms that we are seeing. The authorities that Congress has recently passed, I think will give the agency a fundamentally different way or the opportunity to enact a fundamentally different way of looking at these new technologies.

We have within our grasp the ability to cure pediatric inherited diseases. We have within our grasp the ability to cure many cancers with immunotherapy and other applications, regenerative medicine, cell therapy, gene therapy. These are enormous scientific opportunities, and I think the FDA stands at a tremendous opportunity to try to make these come to the market.

SENATOR HATCH. I want to commend you for your attitude because there should be no question about your being selected here. In all honesty, you bring a tremendous amount of experience and ability to the agency. You know where business is right and where business is wrong too.

I am absolutely convinced that you will stop some of the things that are wrong in the agency and outside of the agency. I have great confidence in you.

Take Hatch-Waxman, can we improve Hatch-Waxman?

DR. GOTTLIEB. There are opportunities to make sure that Hatch-Waxman is having its intended effect on the market, Senator.

Sitting here today without the benefit being briefed by the staff at FDA and better understanding these issues—because issues always look different from the inside than they do outside—I think that there are opportunities to make sure the law is having its intended impact.

If that requires us to look at certain aspects of the statute, I would certainly come back to Congress and have that discussion.

SENATOR HATCH. I would like you to do that because as the author of Hatch-Waxman, I want it to be perfect for the agency and for our country, and not just what I thought at the time was perfect. I appreciate your answer on that particular subject.

We are very fortunate to have you willing to do that with the vast experience that you have. Having worked with the FDA for, really, years, and years, and years, this is a pleasant experience as far as I am concerned.

Let me just ask you this. The independent Office of Government Ethics, in consultation with the Department of Health and Human Services' Ethics Division, approved your public financial disclosure form and your ethics agreement.

Is that correct?

DR. GOTTLIEB. They did, Senator.

SENATOR HATCH. They went into that thoroughly?

DR. GOTTLIEB. They did, Senator.

SENATOR HATCH. OK. Based on information the OGE—the Office of Government Ethics—concluded, Dr. Gottlieb is in compliance with applicable laws and the regulations governing conflicts of interest. According to your ethics agreement, upon confirmation, you will resign from 13 positions.

Is that correct?

DR. GOTTLIEB. I have not counted, Senator, but it sounds about right.

SENATOR HATCH. Within 3 months of confirmation, you will divest yourself from 30 financial interests?

DR. GOTTLIEB. That could be right, Senator. That sounds about right. Yes.

SENATOR HATCH. How stupid can you be?

The reason I am asking that rhetorical question is because I do not think people appreciate what it means for somebody like you, with the tremendous expertise that you have, to walk out of the private sector into this Government job, with all the sacrifices that are going to be required and the huge commitments that are required.

I do not think they appreciate what you are doing here. They should.

I want to personally thank you for your willingness to serve this country in this position, with your vast background, and with your reputation as an honest, decent, very scientific person.

There should not even be any question about your ability to do this job and to do it well. I personally want to congratulate you for being willing to do it and to tell you how much I appreciate it.

DR. GOTTLIEB. Thank you, Senator.

THE CHAIRMAN. Thank you, Senator Hatch.

Senator Bennet.

STATEMENT OF SENATOR BENNET

SENATOR BENNET. Thank you, Mr. Chairman.

Dr. Gottlieb, congratulations on your nomination and welcome to the committee.

I wanted to go back to the opioid and heroin epidemic that is happening in this country. I have, like my colleagues on this panel, spent a lot of time having town hall meetings throughout my State. I have noticed over time that families are ripped apart and communities are having profound difficulties coping with this problem, which, by the way, we do not have an answer for right now in terms of addiction treatment especially in rural areas of this country. I am going to park that observation and ask you the question.

How did we get here in your view? Not just from the FDA point of view, because the problem of very addictive opioid prescription drugs being approved without a sense of how addictive they were, if you look at the history, and then cheap heroin coming in behind those drugs that have perpetuated the addictions that we face.

I wonder if you could give us a perspective, not just as the potential Commissioner of the FDA, but also as a physician in thinking about the way these drugs have been prescribed and used to manage pain.

What do we need to learn from this experience? So that we not just do not make the same mistakes, but we can dig ourselves out of this horrible epidemic across our country.

DR. GOTTLIEB. Thank you for the question, Senator.

I have stated here a number of times, I think this is a public health emergency on the order of Ebola and Zika. We need to treat it that way. We need to treat this as a public health crisis that is going to require dramatic action.

For a long period of time, we did not fully recognize the scope of this evolving problem and our actions to try to address it might have been too incremental in nature. I do not say this to try to pass judgement on people who have preceded me at the FDA. I was at the FDA for part of that time as well.

I do not think we fully recognized the scope of the emerging problem, the true addictive nature of these products. Clinical medicine and physicians, and I am a physician who has prescribed these drugs, are partly responsible for that.

To your point, this is now a problem that is big enough that whereas at one time it might have been within the scope of FDA to address this problem in a more robust way—I do not want to say solve the problem—but address it in a more fulsome way. It has now grown so large that it has grown outside of FDA's ability to address by itself.

This is a public health challenge that we are going to need to address through the full gamut of our public health resources. That does not mean that the FDA does not have an important role to play, but I will say from the standpoint of FDA, I think in order to address it now, the types of actions we are going to need to take are going to be far more dramatic, perhaps, than the types of actions we would have needed to take if we had done more 10 years ago to get ahead of this.

Again to your point, we now have the problem that people move to the lowest cost alternatives. It is no longer just opioids. Having become addicted on opioid, people are moving to heroin.

SENATOR BENNET. I am delighted to hear you say that and the Chairman's very first question was about opioids today. You now probably have a sense of the priority this is for this committee.

I agree that this is beyond the purview of just the FDA. We are going to have to find a way to get agencies to collaborate to deal with these issues, and you calling it an Ebola-like crisis, is very helpful to the cause.

I want to shift gears just for the remainder of my time. Am I out of time, Mr. Chairman?

THE CHAIRMAN. No.

SENATOR BENNET. For the remainder of my time just to talk a little bit about the Breakthrough Therapy legislation Richard Burr and I worked on.

That is, as I said the other day in the committee, we have seen great breakthroughs as a result of that in oncology, not so much in neurology.

I wonder if you have some views of why that has been? Whether in the progress that you are seeing or predicting, whether neurological diseases will be part of that as well?

DR. GOTTLIEB. Thank you for the question, Senator.

We have seen some parts of the agency work exceedingly well with respect to implementing the spirit and the practicality of the Breakthrough Pathway.

We have seen uneven application of it, but I think that that is resolving inside the FDA. You are starting to see more uniform application of both the spirit and the letter of the law in that regard.

I would hope if I am confirmed into this role to find ways to try to install a broader embrace of this Pathway. It is an exceedingly important Pathway. It has provided the opportunity for patients who have unmet needs to get therapy that might not have been available as efficiently without this in place. It has had a real positive impact.

As a physician, I can say I think this has had a real positive impact on the ability of patients with unmet medical needs to get safe and effective therapeutics in a timely fashion.

SENATOR BENNET. Thank you for that.

Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Senator Bennet.

Senator Cassidy.

STATEMENT OF SENATOR CASSIDY

SENATOR CASSIDY. Dr. Gottlieb, enjoyed our conversation.

DR. GOTTLIEB. Thank you.

SENATOR CASSIDY. One thing I remember is that when I almost tempted you to criticize the staff, you said no. You thought you must first look at the systems. That oftentimes you can improve the performance because you just put in better systems. That was obviously the insider's perspective, but also very generous. Some who have suggested, that you are not going to be supportive, and I just thought you were incredibly supportive.

That said, there is a GAO report that I am looking at from May 2016 in which—just a comment on this briefly because this will lead to the next question—in which the GAO was somewhat critical of the FDA saying it lacks measurable goals to assess its progress in advancing regulatory science. The science supporting its effort to assess the products it regulates.

It goes on further to say there are lots of resources that have been given to the FDA, but that indeed they have not systematized how they account for the spending.

Any thoughts on that?

DR. GOTTLIEB. Thank you for the question, Senator.

I am familiar with the report. I have reviewed it in the past. That this is both a challenge and an opportunity trying to make sure that we not only have the best workforce possible in order to ensure the FDA gold standard. That they have the best training, the best tools, and are being forward leaning in trying to adopt the best science into the principles that they use to govern the review process.

This is something—when I was at the FDA with Dr. McClellan, we initiated a critical path initiative to try to democratize an effort to try to improve the quality of the tools that were being used. Not just by reviewers, the tools on their desk, but also the tools that they were enabling sponsors to use as part of the requirements by which they judged drugs.

This would be a high priority of mine if I was fortunate enough to be confirmed into this role to continue to push on these opportunities.

Ultimately, this is how we are going to make the review process more efficient without sacrificing on the gold standard. I think it is ultimately how we are going to make the development process less costly, while still meeting FDA's high bar.

SENATOR CASSIDY. You said it is a false dichotomy, science versus safety or speed versus safety. This would be one way you could achieve both.

DR. GOTTLIEB. This is the way you can achieve both. Absolutely.

SENATOR CASSIDY. Let me ask you something else. I am going to hit a tangent and then come back.

One of my favorite historical figures is William Wilberforce, many reasons why, but among them is that he realized there were a lot of problems with drunkenness related to gin. The way he mitigated that was he had pushed the sale of beer. The idea is you would get so bloated, you have to urinate, et cetera, etc., that you could only drink so much beer as opposed to drinking a lot of gin. It was really successful.

About that because tobacco is a scourge in terms of health, but I sometimes think maybe the way to address tobacco is by tobacco mitigation. If you look at the Center for Tobacco Products, it seems as if there is less than openness about looking for products that would be an alternative to a cigarette, although still a nicotine delivery system, that would have less of the untoward effects associated with cigarettes.

It does seem like the Center for Tobacco Products does not really use the traditional notice and rulemaking process. You know more

about this than I, but it seems to not follow a process that would allow some of these mitigating products to be released.

Any thoughts on that?

DR. GOTTLIEB. Thank you for the question, Senator.

If I am confirmed into this position, I am committed to the goals of the TCA and making the TCA work.

Congress had great foresight in envisioning the opportunity for reduced harm products to transition smokers off of combustible tobacco onto reduced harm products that posed less of a risk as an animating principle as part of a comprehensive regulatory scheme for nicotine containing products. I am committed to trying to make that component of the TCA work along with all of the other components of the TCA.

These are ultimately questions that can be adjudicated in a proper regulatory context. An e-cigarette, for example, or a vaping product might be a good smoking cessation tool and an e-cigarette flavored like chocolate chip cookie dough might not be.

That in the proper regulatory context, we have the tools, thanks to Congress, to adjudicate these questions.

I do think that, to your point, I think there is an opportunity to make this framework much more comprehensive and much more viable.

SENATOR CASSIDY. I have 16 other questions, but I have 15 seconds, so I will yield back and thank you.

THE CHAIRMAN. Thank you, Senator Cassidy. We will have a second round if you want one.

Senator Franken.

STATEMENT OF SENATOR FRANKEN

SENATOR FRANKEN. Thank you. I am struck by the gin for beer because I would just like to throw it open to anybody here. That does not actually work.

SENATOR CASSIDY. It worked in England. That was actually seen as a milestone. I do not want to use your time, but it is used as a milestone in the cessation of alcoholism.

SENATOR FRANKEN. I am skeptical.

Sorry, it just threw me.

Let us talk a little bit about, first, conflicts of interest. You are taking yourself out of this for a year and you have recused yourself from decisions that would impact 20 or so healthcare companies that you have been involved in for a period of a year.

President Trump pledged that all his appointees would recuse themselves for 2 years. Why do you not just do that?

DR. GOTTLIEB. Senator, I appreciate the question.

That was the discussion that I had with the Office of Government Ethics and what they required me to do. I am going to have a separate discussion, if I am fortunate enough to be confirmed into this role, with the ethics officials at FDA and HHS. They might very well impose additional requirements, and I will follow whatever advice and counsel I get from those officials.

SENATOR FRANKEN. OK. I would prefer it, too.

You mentioned on opioids, you said we need an all-of-the-above strategy, but I did not hear you mention some of the obvious all-of-the-above. One is treatment. Treatment now in ACA is an essen-

tial health benefit, but there was an attempt to take that away in the House bill.

I just want to know how you feel about taking that essential health benefit away?

DR. GOTTLIEB. I thank you for the question, Senator.

I did mention MAT, Medically Assisted Therapy, and I think within the context of my responsibilities at FDA, if I were to be confirmed—

SENATOR FRANKEN. What did you say?

DR. GOTTLIEB. I said within the context of my responsibilities—if I was going to be confirmed into this role—would be, in the context of this problem, to look at what the principles are for evaluating Medically Assisted Therapy, MAT.

SENATOR FRANKEN. OK.

DR. GOTTLIEB. Medically Assisted Therapy as a component of treatment.

SENATOR FRANKEN. I thought you said medications.

DR. GOTTLIEB. Yes it is medication, but—

SENATOR FRANKEN. OK. That is what you mean.

DR. GOTTLIEB. Right. Medication for people who are addicted, yes.

SENATOR FRANKEN. That is different than in-house treatment. I am sorry. That is different than rehab.

DR. GOTTLIEB. You are talking about a service. I am talking about the medication that is used in the context of a service.

My responsibility as FDA Commissioner would be to approve—

SENATOR FRANKEN. I am talking about the essential health benefits in the ACA. That was my question.

DR. GOTTLIEB. Right. I appreciate the question.

SENATOR FRANKEN. You can answer the question without it having to be directly related to your duties at FDA, please.

DR. GOTTLIEB. Senator, I appreciate the question. If I am confirmed into this job, I am going to have a lot of people asking me to opine on issues that fall outside of the scope of FDA. I think I would do—

SENATOR FRANKEN. OK. Never mind. I am just saying that residential treatment for opioid addiction is a really good thing. That is what I wanted to say, and if you are talking about all-of-the-above, if you are talking about all of the above that is really important to people.

If you are talking about a crisis that is the scope of Ebola, and you do not keep residential treatment as part of the essential benefits package of insurance, I do not think you are taking it as seriously as you would an Ebola-level crisis.

I want to talk about something more maybe in your purview which is Naloxone, which you have not mentioned either. If you are taking an all-of-the-above approach, I think you would talk about Naloxone.

I spent a minute on beer, Mr. Chairman, so I want 30 seconds.

A two pack dose of the auto-injector for Naloxone rose from $690 in 2014 to $4,500 today. This goes to the prices of drugs, which everyone in Minnesota talks about when I go around the State.

You did not mention Naloxone which saves a tremendous number of lives. It is part of the all-of-the-above, believe me.

What are you going to do to keep down the cost of drugs?

DR. GOTTLIEB. Thank you, Senator, for the question.

I talked about the importance of MAT generally, which all of these things fall under. I share your concerns.

With respect to Naloxone, that falls into the scope of complex drugs that I have talked about today. It is a drug-device combination that is hard to ANDA those processes. It is hard to put alternatives through the generic drug approval process.

I do think that there are ways that the FDA can administratively, perhaps, and it might require a statute, allow a pathway to make it easier to put generic alternatives to some of these drugs through the generic drug approval process so we can create more competition.

Some of these issues relate to instructions for us under the current guidelines. The instructions for use for drug-device combinations needs to be precise or the same for the branded drug and the copy drug in order to go through the ANDA process. There might be opportunities to relook at that framework.

This is something I have spoken about a number of times here today that I am committed to working on with you.

SENATOR FRANKEN. OK. I hope you address that.

Thank you, Mr. Chairman, for indulging.

THE CHAIRMAN. Thank you, Senator Franken.

Senator Roberts.

STATEMENT OF SENATOR ROBERTS

SENATOR ROBERTS. Doctor, congratulations on your nomination and thank you for being here today.

I want to associate myself with the very pertinent remarks by Senator Hatch regarding your decision for public service. Your background, as a physician and prior service at the FDA make you an excellent choice to lead the agency.

We talked in my office, or to be more accurate, I talked and you listened. I am confident in your commitment to public health and in putting patients first in decisionmaking. I am going to vote for you and I am not going to ask you a yes or no question.

I am chairman of the Agriculture Committee, as well as a member of this committee. I am particularly interested in your thoughts on the FDA's role in ensuring food safety.

Under the previous administration, it is my opinion, that we saw increased activity and regulation actions on nutrition policies such as issuing voluntary guidance. Yet, at the same time, requesting additional money to comply with statutory requirements under the Food Safety Modernization Act, the acronym for that, by the way, is FSMA, which I find somewhat unique.

I have concerns that the agency has not prioritized the FDA's mission to protect our Nation's food supply and instead focused on nutrition policies.

How will you focus on core FDA duties such as implementing the law that Congress passed rather than agenda-driven nutrition policy guidance as we saw with sodium and added sugars?

DR. GOTTLIEB. Thanks for the question, Senator.

This is an agency that has a statute that has been amended over 100 times since 1938 and has a vast scope of responsibilities. We

do need to focus on core mission and make sure we are achieving what Congress intended in terms of protecting and promoting the public health.

FSMA was a significant advance in terms of giving the agency authorities it needed and the resources it needed to ensure the food supply is safe. My mandate is going to be to make sure FSMA is implemented in a proper way and that we are striking the right balance with respect to that implementation.

SENATOR ROBERTS. Last year in the Agriculture Committee, we worked the whole year and we are finally successful in passing the Biotech Labeling bill of which the Department will be working to implement in the next couple of years.

At the same time, FDA has been working to update the Nutrition Facts Panel, which is set to go into effect next summer.

There is a great deal of concern that the FDA has not provided the guidance necessary for compliance. This includes guidance for dietary fibers, which we discussed previously when you were in my office.

In addition, hundreds of millions of dollars could be lost due to lack of coordination between the Department of Agriculture and the Food and Drug Administration on these label change timelines.

Will you please work to ensure proper guidance is available and consider postponing the current deadline for the Nutrition Facts Panel to help reduce regulatory burdens?

DR. GOTTLIEB. Senator, this is something I would certainly be delighted to work with you on if I was confirmed into this role.

I am philosophically in favor of trying to make sure that we do these things efficiently. Not only because it imposes undue costs on the manufacturers if they are constantly updating their labels, but we also have to keep in mind it does create confusion for consumers if the labels are constantly changing.

You want to try to consolidate the label changes when you are making changes as a matter of public health so the information is conveyed accurately and efficiently to the consumers.

This is something that I do care about, and I would look forward to working on it if I am confirmed.

SENATOR ROBERTS. I appreciate that.

Mr. Chairman, I have further questions. I will submit them for the record.

Thank you very much.

THE CHAIRMAN. Thank you, Senator Roberts.

Senator Baldwin.

STATEMENT OF SENATOR BALDWIN

SENATOR BALDWIN. Thank you, Mr. Chairman.

Welcome to the committee.

DR. GOTTLIEB. Thank you.

SENATOR BALDWIN. I had to step out to attend another committee meeting and missed some of the questioning, but hopefully I will not be covering all the same ground.

I want to start by saying that I share some of my colleagues' concerns about both the optics and the potential for conflict of extensive financial ties and relationships with companies that you would directly regulate at the FDA.

In addition to your financial holdings in multiple medical companies and board memberships, you have also long served as an advisor to and invested in New Enterprise Associates, a venture capital firm.

During our meeting, and I appreciate you taking the time to visit with me, you noted that the FDA should focus on a more holistic approach to chronic pain to address, in particular, the opioid epidemic that we talked at some length about.

One of the things you talked about was looking to medical devices as therapy options, but it turns out that New Enterprise Associates has invested in one such company, Nevro Corporation, which markets devices for chronic pain.

I would like to ask you beyond what is already in your ethics agreement, what assurances can you give us that those significant business and financial relationships will in no way influence or bias your work directly regulating these companies at FDA, should you be confirmed?

DR. GOTTLIEB. I appreciate the question and I appreciate the opportunity to answer it, Senator.

Just by way of background, and I am proud of my relationship with NEA. It has been one of the premiere venture capital firms in the country starting a lot of innovative ventures.

Over the time period that I was there, they invested about $14 billion in 500 different companies. Per my ethics agreement, I disclosed that I had investments in five of those, all healthcare services companies.

I was not actively involved on the medical device portfolio. A lot of my time was spent on the healthcare services portfolio, and that is not to say that it was exclusively spent on the healthcare services portfolio, but a lot of my time was spent working on healthcare services companies. That is just sort of a general understanding of my role at FDA [sic].

I recognize the importance of bringing impartiality to this position. I recognize that someone could look at my background and have these questions. I appreciate the opportunity to answer them.

I am going to be cognizant of trying to make sure I preserve the integrity of my role and do nothing in exercising my obligations, if I am confirmed into this role that would besmirch the agency and reduce people's confidence in the agency's mission.

This is exceedingly important to me. I get it. I know why people care. The FDA's decisions are literally matters of life and death and I do not want to do anything in my conduct to reduce people's confidence in the agency's mission.

SENATOR BALDWIN. Thank you.

You have also stated that the FDA should approve drugs faster and that too much regulation is the main barrier to lower prices, and these are certainly positions supported by the drug industry.

To me it is about much more than just speeding more drugs to market. The FDA should address this through robust oversight of industry tactics especially when they are meant to game the system; simply to boost their bottom line. For example, by seeking to add or prolong market exclusivity periods or creating misleading direct-to-consumer advertisements.

Will you commit to working with Congress to advance policies, which may be unpopular with drug companies, but yet give the FDA more authority to crackdown on abuses that lead to higher prices?

DR. GOTTLIEB. Thank you for the question, Senator.

I agree with your concerns here. I think the FDA is constantly getting drawn into commercial disputes, which puts the agency in a very difficult position because it is a public health agency. It is not the FTC.

It is hard for the FDA to simultaneously design policies intended to protect and promote the public health, and design policies intended to try to prevent companies from trying to use the regulatory process for commercial advantage.

This is a problem that I am uniquely suited to try to look at and solve because of my background. Because I understand how companies have tried to game the process in the past. It is not illegal to try to use the regulatory process to gain commercial advantage.

We should try to design policies that prevent those abuses because we do not want to be playing whack-a-mole with companies and going after them one by one.

What I want is a framework in place that prevents those kinds of things from happening so people cannot use the regulatory process as a commercial arbitrage to gain unfair advantages. I could think of other places where I think that goes on.

These are things I want to look at and frankly, I think these are things I am uniquely positioned to look at, hopefully, because of my background. That is where my work does inform some of these issues.

SENATOR BALDWIN. Thank you.

THE CHAIRMAN. Thank you, Senator Baldwin.

Senator Murkowski.

STATEMENT OF SENATOR MURKOWSKI

SENATOR MURKOWSKI. Thank you, Mr. Chairman.

Dr. Gottlieb, welcome. I look forward to our visit this week.

I want, as a kind of follow-on to what Senator Baldwin has raised in your response here, but I want to speak about it in the context of a specific example, and that relates to genetically engineered salmon.

As you know, there were millions of Americans that wrote to the FDA opposing the approval of genetically engineered salmon. A whole number of grocery stores have announced that they will not sell it.

Despite all of this immense opposition, in November 2015, the FDA approved AquaBounty Technologies' application for this new animal drug process. It was approved through that process despite the application being for Genetically Engineered AquAdvantage salmon for human consumption. It was the first G.E. animal approved for human consumption through this process.

The FDA did not have any mandatory labeling requirement. Instead it said, well, it can be labeled voluntarily. We refer to this G.E. salmon as "frankenfish," nobody is going to voluntarily label it as such.

The valid question and concern is whether or not this fish should even be called a salmon, and there is great fear that lies with these mutated fish that have not gone through a proper EIS.

The question to you this morning is whether or not you believe that genetically engineered fish and other animals for human consumption should be approved through the animal drug process?

I am looking for your commitment to work with me to ensure that we have a better process, and hopefully a better solution, to what many of us, particularly in Alaska, are quite concerned about as a big problem.

DR. GOTTLIEB. Senator, I am familiar with the issue.

I was not at the FDA when these issues were adjudicated as part of the approval process. The FDA has recently issued guidance on this matter that does not address all the issues that you have raised here.

You have my commitment, if I am confirmed into this role, to work with you on it after I have had the opportunity to study the issue more closely once I am at the agency, if I am confirmed.

SENATOR MURKOWSKI. Good. Well another, keeping in that vein of seafood or fish, let me continue with an issue that is very, very concerning to us. This stems from FDA published advice on January 19 of this year, and it was advice for pregnant and nursing women on seafood consumption. This advice that came out purports to update the prior version of the same advice that was published back in 2004.

When you look back at that scientific authority that speaks to regular seafood consumption by pregnant and nursing women, and the benefits that it provides, it is important information.

The FDA's peer-reviewed study on maternal seafood consumption for fetal brain development, this is the Net Effects report, concludes that regular seafood consumption by pregnant and nursing mothers adds 2.63 IQ points to a child's growing brain. You have the additions for the cardiovascular and general health benefits of eating fish by the mothers themselves.

What we then see is we have this guidance that comes out, or this advice that comes out, on January 19 that is based not on the Net Effects report. Instead on EPA's mercury reference dose, which is a toxicological standard that ignores the benefits of seafood and measures risks in isolation.

What we have seen from this is that this advice is confusing. It does not give clear guidance to pregnant or nursing women. It widens the gap between the seafood advice and the dietary guidelines for Americans. It gives the EPA a more prominent role in developing a better nutrition policy.

We have a great deal of concern about this particularly with regards to the latest information relating to halibut and sable fish.

I would like your commitment to me that, if confirmed, you will revisit this seafood advice and consider modifications to what was issued in January of this year.

DR. GOTTLIEB. Senator, you have my commitment to making sure that the FDA guidance is fully science-based and providing proper information to consumers.

I am familiar with the issue, but again, have not had the benefit of studying it and being fully briefed on it. You have my commitment that I will take a look at it and work with you on it.

SENATOR MURKOWSKI. It is something that we will have an opportunity to discuss further, but I will tell you this is one of those issues that I am really running out of patience on.

We need to make sure that full consideration is given to the FDA science that was the basis for updating the advice in the first place, instead of this EPA mercury data that has nothing to do with ocean-caught fish. I want to work with you on that as well.

Mr. Chairman, my time has expired.

I thank you and I look forward to further conversation.

THE CHAIRMAN. Thank you, Senator Murkowski.

Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

SENATOR WHITEHOUSE. Thank you, Mr. Chairman.

Thank you, Dr. Gottlieb, for being here. A-plus to your girls for the super-good behavior they have had. It is probably an exceedingly boring morning for them.

SENATOR WHITEHOUSE. Back to the question of New Enterprise, I have been told that there are 82 companies that New Enterprise has investments in that might have products, or do have products that are before the FDA.

Because of the nature of your relationship with New Enterprise, you were paid directly by New Enterprise. You were cut out from having a direct, financial relationship with those companies, which would have triggered more recusal requirements.

I am not an investment person, but I do believe that very often people have pretty close working relationships on the investment banking side with the companies that they are invested in and are often *de facto* managers.

When those—assume I am right about it being 82 companies—when those 82 companies crop up with applications at the FDA, assuming that you are confirmed, who will take a look at that to make sure that the relationship is not one that you should recuse from?

DR. GOTTLIEB. Thank you for the question, Senator.

SENATOR WHITEHOUSE. By the way, this is not your fault. This is a question that has to do with the way the Government demands things of you. Your compliance is fine with what you have been asked to do.

A little bit like Miss DeVos, not having to answer questions about her dark money operation or Administrator Pruitt not having to answer questions about his dark money operation. We have these places where our disclosure rules have not caught up with, what you might call, the new technology.

I do not want to blame you for this, but I do think to what you said very clearly before about not impugning the integrity of the FDA. How would you manage that, or how would the FDA manage that for these exact companies?

DR. GOTTLIEB. Right. Thank you, Senator.

I do not fully know what the phrase "dark money" refers to, but we have been very transparent with the NEA portfolio including

putting the entire portfolio of my Form 278. The companies are all listed there with brief descriptions.

Just to table set with respect to my relationship to New Enterprise Associates, and since it has come up a couple of times today.

I was effectively a consultant to NEA and paid as a consultant to NEA, and advised them on a selected number of companies in their portfolio. Those companies are not entirely, but largely, reflected by the list of companies I recused from because a lot of my time was spent on the healthcare services portfolio at NEA, not on the life sciences and medical deice portfolio.

That is not to say that I did not occasionally get drawn into meetings related to other portfolio companies, but it is a circumscribed set of companies that I might have touched in that relationship.

This is another issue where I am looking forward, if I have the opportunity to be confirmed into this position, to talking to the ethics officials at the FDA and HHA about how to manage any potential conflicts that could arise with my relationship to New Enterprise Associates.

You and I spoke in your office about the importance of personal integrity in this position, and I took that to heart. That means a lot to me. I am going to make sure that I follow the rules and do what I am told to with respect to this relationship.

SENATOR WHITEHOUSE. We have talked a little bit in this hearing about pricing of pharmaceuticals and talked a lot about opioids. I associate myself with the questions and concerns of FDA's role in the opioid epidemic.

I do not think that we have talked much about antibiotics. I worry a bit that you described a "brave new world" in which new discoveries were going to lead to a whole new era of health and prosperity. At the same time, we are looking at potentially an end to a great era of health and prosperity brought on by antibiotics that were effective against most of the dangerous bugs that come after us.

The more those bugs adapt to our antibiotics, if we do not keep up, I understand that the Centers for Disease Control estimates that 2 million people develop antibiotic resistant infections in the United States every year, and it kills 23,000 of them. Antibiotic resistance is described by the World Health Organization as, "One of the biggest threats to global health."

In all of these areas, we have concerns that really impact the public health that do not relate narrowly to the product being safe when used as prescribed. Right? The opioids were going to be likely safe when used as prescribed. It was being overprescribed that was the problem. The antibiotics, obviously, you have that problem of resistance developing. And with respect to price, if you cannot afford it, you have a real problem. There is an access issue that affects the public health.

To what extent do you think the FDA should be venturing outside of that narrow question and into the broader questions of public health around those three points? Sorry, a long question.

DR. GOTTLIEB. As a hospital-based physician who has lost patients to resistant infections in the ICU, I recognize the gravity of the problem that you describe.

That the agency has taken steps in recent years largely owing to congressional statute to try to address the problem in different ways, both on the development side with the provisions embedded in Cures, as well as what they have done on the animal feed side with respect to the use of anti-infectives in animal feed.

What you describe is the broader stewardship question and whether or not it is within the scope of FDA's current authority to address that more societal question as a component of the review process.

My short answer is: I do not know. My instinct is to think that this is something Congress needs to contemplate, and I would certainly be happy to work with you on this question.

SENATOR WHITEHOUSE. Fair enough.

THE CHAIRMAN. Thank you, Senator Whitehouse.

Senator Hassan.

STATEMENT OF SENATOR HASSAN

SENATOR HASSAN. Thank you, Mr. Chair.

I will add my compliments to your girls. Senators have a hard time sitting still through these hearings, so you are doing really, really well. Thank you.

Dr. Gottlieb, I appreciated the visit we had in my office as well. I just do want to go on the record echoing the concerns that many of my colleagues have raised about the issue of conflict of interest.

To Senator Whitehouse's point, you are following the rules. That is good. You have extensive ties to the drug and biotech industry. If confirmed, you are going to be tasked with regulating the same companies.

You take the issue of personal integrity very seriously. I appreciate that. I will just say that part of this issue is about self-awareness, and perspective, and who you identify with. If you are confirmed, I hope you will take that to heart as well.

I wanted to spend a little bit more time on the issue of opioids. We spoke about it in my office and New Hampshire is one of the States which has just been devastated. We had about 500 deaths in New Hampshire in the last year; 70 percent of those deaths involved the drug Fentanyl, which is becoming even more of an issue around the country.

At a hearing that the FDA was at before this committee a few weeks ago, I asked about what are known as abuse-deterrent formulations, and you referred to them a little while ago in one of your exchanges.

The opioids in the abuse deterrent formulations are just as addictive as they are in other products without the so-called abuse deterrent properties. Experts have done surveys that show that 46 percent of primary care providers think that these abuse deterrent products are less addictive than other opioids.

That statistic is very high, but it does not surprise me because I can see how the term "abuse deterrent" could be confusing or misleading in this regard. What we are learning is that the opioid at issue may be packaged in a way that makes it hard to use in a traditional way for somebody suffering with addiction, but they just find a different way to use it.

Do you think the FDA has a role to play here in ensuring that there is a common understanding among providers that products called "abuse deterrents" are just as addictive as other opioids and are not abuse proof? Because they can still be abused easily by, for example, just swallowing them.

DR. GOTTLIEB. Right. I echo your sentiments in many regards, Senator. I appreciate the question.

The primary impediment to these abuse deterrent formulations becoming abused is that they are expensive right now. Once they go generic and become cheap, they are just as easily abused if you just take more of them.

SENATOR HASSAN. Right.

DR. GOTTLIEB. What we are talking about are drugs that are harder to divert or tamper with in ways that might make them more attractive abusable items.

The underlying issue that you surface as to whether or not we have the right nomenclature to describe these drugs—and whether or not the nomenclature that we are using in how we describe these drugs is conveying the right message, not only to patients but in particular to providers—is a reasonable question.

Within the scope of what I want to do to try to push the agency around looking at a different framework for how we address this problem, I would include that question.

You and I talked about it. I saw the press release that went out from one of the groups, and when I read it, it struck me as a reasonable question to be asking. I want to ask that question.

SENATOR HASSAN. Thank you.

One of the other tools that we know we can use to combat this public health crisis, and one of the ones that you have that the FDA has at its disposal, is the Risk Evaluation and Mitigation Strategies, otherwise known as REMS, which the agency uses to try to stem the risks associated with certain medications. As you know, that includes things like prescriber training.

You have been public in the past about your opposition to REMS saying that they put burdens on providers. Because we are in the middle of a public health crisis, as you have acknowledged with this addiction epidemic, and because I know that many providers in my State welcome guidance from the FDA or anybody else who has the expertise about how to curb this public health crisis.

Do you think physicians should be able to look to the FDA for guidance about how to prescribe drugs like opioids?

DR. GOTTLIEB. I do, Senator.

The article you reference—which was a "Health Affairs" article, I think in 2007, 10 years ago—spoke to a different issue, which was the use of REMS to start to address drugs where there was a known risk. The FDA wanted to attenuate the off-label prescribing of the drugs across the range of purposes for which a physician might want to use a drug under his discretion; very different than this issue.

I actually affirmed in that article—I largely affirmed the historical context in which the REMS had been used, which included the use of trying to prevent diversion and abuse of opioid drugs. That had been the historical use of REMS and, in fact, the early genesis of REMS under a different name—it was not called REMS back

then—was created under Subpart H for the purpose, largely, of trying to address the opioid problem back at FDA.

I do fully support the use of that tool in this context. In fact, I support the use of the tool across a lot of contexts. In many respects, the agency has gone on to use the program in ways that are far more judicious than what I was initially worried about when I wrote that article.

SENATOR HASSAN. Thank you.

I see I am over time.

I will submit for the record a question about some women's health issues because I am concerned about your involvement in what I thought, and many have thought, was a politically motivated delay of the emergency contraceptive Plan B when you were at the FDA. I will submit that in writing.

Thank you.

THE CHAIRMAN. Thank you, Senator Hassan.

Senator Murray.

SENATOR MURRAY. I will actually follow up on that because I am concerned about political pressure at the agency, and I personally am outraged by this Administration's continued efforts to undermine and rollback women's rights and access to healthcare.

This is not the first time I have had to fight a President and his administration to protect healthcare for women.

In fact, I fought back the last time you were actually at the FDA, and the Bush administration ignored overwhelming scientific consensus and recommendations of two advisory committees and FDA career staff by deciding not to sell Plan B emergency birth control over the counter.

I want to know if you will stand up for women and fight against any political attempts by President Trump and Vice President Pence to politicize decisions about women's health.

Let me ask you specifically. Do you think the Bush administration made the wrong decision to deny women access to Plan B over the counter?

DR. GOTTLIEB. Senator, I am fully supportive of efforts to promote women's health.

Insofar as there are concerns, I am not in my capacity, if I am confirmed into this role, going to re-litigate settled science and settled approval decisions in the absence of some compelling safety information that drives the agency to do that and a very clear recommendation from the career staff.

SENATOR MURRAY. Do you think they were wrong in denying Plan B?

DR. GOTTLIEB. Senator, I was not involved in adjudicating that decision. That decision was made at the time based on the science that was available and the judgement of the people who were involved in doing that.

I do not want to supercede the judgement of people retrospectively who made a decision at a certain point in time who were looking at certain data and certain issues, when I was not party to that evaluation.

SENATOR MURRAY. You will be under immense pressure from this President and Secretary Price who continue to put politics ahead of women.

Can you commit to me today that you will not allow them to use the FDA to further a political agenda against women's health?

DR. GOTTLIEB. In this regard, Senator, I appreciate the question. I am not going to relitigate settled approval decisions.

SENATOR MURRAY. I am not talking about the past. I am talking about the future.

We have watched the agenda of this Administration, and I am very fearful that they will put political pressure on you to make decisions not based on science and not based on evidence-based treatment, and ask you to make decisions. What will you do?

DR. GOTTLIEB. As a physician and someone who cares about women's health issues, I am going to be guided by the science, and the public health, and the judgement of the career staff in how the FDA makes decisions under my leadership.

SENATOR MURRAY. OK. This is very important because I asked Secretary Price during his confirmation hearing before this committee for his commitment that all 18 FDA-approved methods of contraception would continue to be covered, and he refused to make that commitment.

Your commitment to make sure that any decision is science-based, evidence-based is really important on this issue to me.

DR. GOTTLIEB. Thank you.

SENATOR MURRAY. I also want to ask you about tobacco, which we touched briefly on before. When we met, you said you would prioritize continued implementation of the Tobacco Control Act.

I have to tell you, I am concerned about your commitment to do everything you can to protect health under this really important landmark law in looking at your record in terms of this. Because while the Tobacco Control Act prohibited fruit and candy-flavored cigarettes, flavored e-cigarettes, and cigars have flooded the market in recent years. E-cigarettes are now available in thousands of flavors. You mentioned one a moment ago about Cookies and Cream. There is Pop Rocks.

This should come as no surprise to you. I know that you had a financial stake and then served on the board of directors of the interestingly named KURE, a company that sells liquid for e-cigarettes in huge numbers of flavors including Gummy Bear, and bases its business model on attracting Millennials. You also had a financial stake in a separate company that markets those products, KURE's products.

Children's use of these flavored tobacco products is a serious public health concern. Research supported, actually, by the FDA itself says 81 percent of children who have ever used tobacco products started with a flavored product. You cite flavors as the major reason for their current use of non-cigarette tobacco products.

If you are confirmed, do you commit to wholeheartedly addressing the clear, public health risk posed by flavored e-cigarettes and cigars by resisting industry pressure to weaken the so-called "deeming rule" which brought e-cigarettes and cigars under FDA's authority?

DR. GOTTLIEB. Senator, I appreciate the question.

I am committed to proper implementation of the TCA. As a physician and a cancer survivor, I am not going to countenance a rise in adolescent smoking rates in this country under my watch. I am

going to make sure that we appropriately implement the law and fulfill Congress' intent in this regard.

These are empirical questions, in my view, that you are raising about when a reduced harm product can be a useful tool for transitioning people off of combustible cigarettes onto a reduced harm product, and when they might be a gateway towards adolescent smoking to the point, you are making.

In a properly constructed, properly overseen regulatory process, we should have the capacity under the authority the Congress gave to the agency to make these determinations. I am committed to trying to make that work.

SENATOR MURRAY. What about banning flavored tobacco products and marketing practices that actually target our children?

DR. GOTTLIEB. Again, certainly marketing practices that target children, as I understand, are already illegal under the scope of the law.

The issues of the flavoring and all these other issues that deal with the specific qualities of the vaping products are those kinds of empiric questions that I think career staff should be adjudicating in the Center.

I want to provide the proper support to make these judgments. Make sure that we are finding a way to fulfill Congress' intent here, that there should be reduced harm products available to consumers to transition them off of combustible cigarettes.

I do not want to supercede my judgement sitting here today without having the expertise of the career staff and certainly the ability to talk to them for what might or might not be a proper product. Other than to say that I recognize that a vaping product or an e-cigarette manufactured and flavored in a certain way might be inappropriate in one context, appropriate in another.

SENATOR MURRAY. Gummy Bears? Cookies and Cream?

DR. GOTTLIEB. That I used the example of Cookies and Cream in my own comment, so I recognize that there is a line here somewhere, and I do not know where that line gets drawn. I think that that line needs to get drawn by people who are expert in evaluating that science, and I want to support them.

SENATOR MURRAY. My time has run out. I have gone over. I appreciate that, Mr. Chairman.

I do have a number of other questions and I appreciate your willingness to be here to answer them that I will submit for the record. I know a number of my committee members on this side do as well.

Your thorough and straightforward responses will be much appreciated.

DR. GOTTLIEB. Absolutely.

THE CHAIRMAN. Thank you, Senator Murray.

Thanks, Dr. Gottlieb, for your testimony this morning and let me join several of the Senators who commented on your children.

As a father and a grandfather, I do not think I have seen 5- and 7-year-olds sit so still for so long in a long period of time better than some I know pretty well.

We compliment you and your family on that.

Listening to the comments today, most of the criticism of you, to the extent that there has been any, has been because of your work

with industries, and companies, and agencies that have something to do with the job you are about to do.

We put public servants like you in an odd position. We ask someone to come in and run the Agriculture Department, and then we criticize them if they were a farmer.

We expect someone to come in and take jobs in the Pentagon and deal with very complex issues of war and peace, and assume most of the time it would help if they knew something about military strategy before they come.

The Secretary of Education, Miss DeVos, was heavily criticized because she had not worked for a public school or one of the public education agencies that she would be in charge of regulating as the Secretary.

I remember when Secretary Tillerson was nominated, some even on my side of the aisle raised great questions because he knew Vladimir Putin so well.

My own view is I like to have a Secretary of State who knows Vladimir Putin very, very well. I do not want someone in his pocket, but I want someone who does not spend 4 years getting to know him, trying to evaluate him, understanding his strengths and weaknesses, and what he might do right, and what he might do wrong.

I agree with those Senators who said we are fortunate that you do have this broad experience. You are asked to be responsible for product areas as diverse as prescription drugs for humans, prescription drugs for animals, medical devices, biologics, dietary supplements, cosmetics, over the counter medication, food, and tobacco products.

You are asked to implement a law we call 21st Century Cures that we worked on for more than 2 years and it is filled with nuance, and opportunity, conflicts, and differences of opinion.

I like the idea of having someone in your position who is experienced, who recognizes those nuances, who sees the conflicts, who knows what a company may be able to do to create a new drug and how a company may be trying to game the system.

Who might understand more rapidly than someone who does not have your background, how to look at a market that does not have competition and speed up competition so that it is, as you mentioned, less than 4 years and brings the price down so more families can afford the drug.

I welcome your experiences and your background. I am glad that you are willing to serve.

I would note that we had a very good experience with Dr. Califf, who had a distinguished career at Duke, who worked with 20 drug and device companies before he came. I think that made him a much better Commissioner of the Food and Drug Administration. He did what you have done. He signed an agreement with the Office of Government Ethics and he recused himself from any activity that he had that presented a conflict of interest.

On March 28, we received a letter from the Office of Government Ethics, which carefully reviewed your financial transactions, found that with several recusals—which you have committed to do—you are in "Compliance with the applicable laws and regulations governing conflicts of interest."

You have said here that while you are in your position, you will continue to consult, as all agency heads must do, with the appropriate ethics personnel. If there are other recusals or decisions that you need to make, you will make those decisions at that time.

Am I correct about that?

DR. GOTTLIEB. Yes, Sir.

THE CHAIRMAN. All these questions are appropriate about your past background, but in my view, I am delighted you have that background. I welcome your coming.

This is a committee that, in the Senate, it does not take a genius to notice that we are in a little bit of a disagreeable patch right now in the U.S. Senate on some issues and that this is a committee with a broad diversity of opinions.

We usually find an opportunity to work together on some big issues that benefit the American people.

You heard one mentioned several times today and that was to see whether you and other parts of the Government could be forward leaning on opioids and particularly the idea of non-addictive pain medicines, which Dr. Collins has talked about.

You have heard us emphasize the importance of the new hiring authority that you have and our hope that you will work with the Administration with our support to quickly move to fill those spots in the agency, so that you will be able to consider and approve rapidly those applications that deserve to be approved.

Senator Murray and I are committed to working together on the User Fees, which provide a lot of the funding, and it is important that we do that in a timely way.

Senator Bennet asked you about the Breakthrough Pathways that he and Senator Burr authored. The new legislation has Breakthrough Device Pathways. It allows regenerative medicine to be a part of the existing, accelerated pathway.

We hope that you will take advantage of all of those ideas and those authorities.

Thank you for your testimony today.

I ask consent to put into the record seven letters of support representing 29 groups including physician, pharmaceutical, and patient advocacy groups.

[The information referred to may be found in Additional Material.]

THE CHAIRMAN. If Senators wish to ask additional questions of our nominee, questions for the record are due by the close of business Friday, April 7.

For all other matters, the hearing record will remain open for 10 days. Members may submit additional information for the record within that time.

Thank you for being here today.

The committee will stand adjourned.

[Additional Material follows.]

ADDITIONAL MATERIAL

LETTERS OF SUPPORT

ALLIANCE OF SPECIALTY MEDICINE,
MARCH 31, 2017.

Hon. LAMAR ALEXANDER, *Chair*,
Senate HELP Committee,
U.S. Senate,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
Senate HELP Committee,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: The undersigned members of the Alliance of Specialty Medicine write to express our support for the recent appointment of Scott Gottlieb, M.D. to Commissioner of the Food and Drug Administration (FDA).

As a practicing physician and hospitalist for many years, Dr. Gottlieb has a deep understanding of the effect healthcare policy can have on patients as well as physicians. We believe he will bring a wealth of knowledge to the position and be an important advocate for the health care community.

He has also served in government in various capacities, including as senior adviser for medical technology, director of medical policy development, and deputy commissioner for medical and scientific affairs at the FDA. Given that wealth of policy experience, we believe he will provide a steady hand at the FDA to ensure that our patients receive products that are both safe and effective. In addition, his broad-based policy experience will hopefully help to guide a more collaborative effort between the FDA and other entities, especially the Centers for Medicare and Medicaid Services (CMS).

Like Dr. Gottlieb, our organization is dedicated to fostering patient access to the highest quality care. We look forward to working with him to improve health care policy for specialty physicians and their many patients.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery; American Association of Neurological Surgeons; American Society of Cataract and Refractive Surgery; American Society of Echocardiography; American Society of Plastic Surgeons; Coalition of State Rheumatology Organizations; Congress of Neurological Surgeons.

ASSOCIATION FOR ACCESSIBLE MEDICINES (AAM),
WASHINGTON, DC 20001,
April 4, 2017.

Hon. LAMAR ALEXANDER, *Chair*,
U.S. Senate,
455 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
U.S. Senate,
154 Russell Senate Office Building,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: On behalf of the Association for Accessible Medicines (AAM), formerly the Generic Pharmaceutical Association (GPhA), I am writing in support of the nomination of Dr. Scott Gottlieb, M.D. to serve as the next Commissioner of Food and Drugs. AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. I urge the committee to conduct its business promptly and approve the President's nominee without delay.

Dr. Gottlieb is one of the most formidable thought leaders in the medical field and makes an excellent choice to lead the agency responsible for ensuring the health of the millions of patients FDA serves. I believe his firm grasp on the science and his understanding of the pharmaceutical market, and specifically the generic and emerging biosimilar markets, is unmatched. Dr. Gottlieb has advocated for effectively addressing the backlog of generic drug applications pending at FDA and en-

suring that safe, effective and quality products are approved at their earliest possible date. This not only has the benefit of increasing competition to lower costs of drugs and biologics for millions of Americans, the Federal Government and other payors, but also improves public health by expanding access to quality treatments.

We stand ready to work with Congress, the President, Dr. Gottlieb and his entire team to ensure that generic medicines continue to keep lifesaving treatments within reach of all Americans. We strongly urge the Senate to move forward with his confirmation in order to begin addressing the important task of lowering prescription drug costs for Americans.

Sincerely,

CHESTER "CHIP" DAVIS, JR.,
President and C.E.O.

EVERY LIFE FOUNDATION FOR RARE DISEASES,
NOVATO, CA, 94949,
April 3, 2017.

Hon. LAMAR ALEXANDER, *Chair*,
455 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
154 Russell Senate Office Building,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: On behalf of the EveryLife Foundation for Rare Diseases, we write today to strongly endorse Dr. Scott Gottlieb for the next Commissioner of the Food and Drug Administration (FDA) and urge his speedy confirmation. The FDA is critical for advancing treatments for patients affected by rare diseases and we believe Dr. Gottlieb has the necessary skills, experience, and knowledge to lead the Agency.

In particular, Dr. Gottlieb's prior experience at FDA means that he has the institutional knowledge that will allow him to begin working immediately on enhancing the agency. He has spoken out about the workforce issues that continue to impact the FDA, as well as the need for flexibility in review of rare disease therapies and the importance of improving specialization and expertise among FDA reviewers. Improving specialization will help ensure potential rare disease therapies receive a thorough review by the agency staff and will improve health outcomes for rare disease patients.

Dr. Gottlieb has highlighted the importance of biomarkers in the use of development of novel treatments for rare diseases, which we view as a vital tool for helping to improve the efficiency and speed of drug development, while maintaining FDA's core and critical standards for safety and efficacy. If we are to successfully close the innovation gap that currently exists for the 95 percent of rare diseases without an FDA-approved treatment, new models and approaches are needed to help the 30 million Americans affected by a rare disease.

Dr. Gottlieb has a strong track record as a supporter of biomedical research and innovation for rare diseases and understands how to improve and enhance drug review at the FDA. We believe he is well-suited to be the next Commissioner.

The EveryLife Foundation for Rare Diseases is a 501(c)(3) nonprofit dedicated to accelerating biotech innovation for rare disease treatments through science-driven public policy. We can do more with the science we already have and bring life-saving treatments to millions of people suffering from rare diseases.

Sincerely,

MAX G. BRONSTEIN,
Chief Advocacy & Science Policy Officer.

JULIA JENKIN,
Executive Director.

HEALTHCARE LEADERSHIP COUNCIL,
APRIL 3, 2017.

Hon. LAMAR ALEXANDER, *Chairman*,
U.S. Senate,
Health, Education, Labor, and Pensions Committee,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
U.S. Senate,
Health, Education, Labor, and Pensions Committee,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: The Healthcare Leadership Council (HLC), comprised of leaders from all sectors of American healthcare, enthusiastically endorses the nomination of Scott Gottlieb, M.D., to serve as Commissioner of the Food and Drug Administration (FDA) and encourages your committee and the full Senate to support his confirmation.

Dr. Gottlieb's qualifications to lead the FDA are extensive and indisputable. In his previous roles at the FDA, the Centers for Medicare and Medicaid Services (CMS), and the Department of Health and Human Services, he has been centrally involved in some of the most important healthcare policy advances in recent years, including the implementation of the Medicare Prescription Drug, Improvement and Modernization Act, the generic drug user fee program, and expanding CMS coverage parameters to provide beneficiaries greater access to new medical innovations.

Additionally, he has acted as a health policy thought leader, helping to shape the Nation's discussion on key issues through his work at the American Enterprise Institute, the American Medical Association's "Pulse" journal, and op-ed pieces in many major publications. In his writings, Dr. Gottlieb has consistently demonstrated his vision for accelerated medical innovation in this country and greater patient access to the drugs and devices that extend and improve lives.

We need strong, active leadership at the FDA. In the ongoing effort to address concerns over healthcare pricing, enabling more robust competition in the biopharmaceutical marketplace is one of the most effective actions government can take. This can occur by expediting the processes through which generic drugs are approved for patient use. We believe this should be one of Dr. Gottlieb's highest priorities, should he be confirmed to lead the agency. As well, it is essential that the FDA take decisive administrative and regulatory actions in implementing the 21st Century Cures Act, enacted by Congress last year, and remove barriers that slow the movement of new, beneficial medical technologies to patients and healthcare providers.

In coming years, the FDA will be instrumental in supporting profound advances in healthcare and victories against cancer, heart disease, diabetes and other severe illnesses. We believe Scott Gottlieb is the right person to lead the agency at this critical time and, again, we urge his confirmation.

Sincerely,

MARY R. GREALY,
President.

SARCOMA FOUNDATION OF AMERICA (SFA),
DAMASCUS, MD 20872,
March 31, 2017.

Hon. LAMAR ALEXANDER, *Chairman*,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
466 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
154 Russell Senate Office Building,
Washington, DC 20510.

DEAR SENATORS ALEXANDER AND MURRAY: The Sarcoma Foundation of America (SFA), the leading national patient advocacy organization representing the needs of sarcoma patients and their families, would like to express our enthusiastic support for the nomination of Scott Gottlieb, M.D., as Commissioner of the Food and Drug Administration (FDA).

The SFA, a 501(c)(3) nonprofit charitable organization, advocates for increased research to find new and better therapies with which to treat patients with sarcoma. Sarcoma is a rare cancer of the connective tissue (bone, muscle, nerve, blood vessel, tendon, fat) with about 16,000 new cases and 6,000 deaths each year in the United States. At any one time, more than 50,000 patients and their families are struggling with Sarcoma. It is rather prevalent in children, accounting for about 20 percent of all childhood cancers.

The sarcoma community understands the importance of having strong leadership at the FDA. As a doctor and a cancer survivor, Dr. Gottlieb has proven through his distinguished career that he has the experience and knowledge to ensure that the agency successfully complete its important work, particularly in its efforts in drug review.

Dr. Gottlieb has an exemplary track record of supporting and spearheading efforts to ensure that safe and effective treatments are moved through the review process in an expedient manner. During his tenure as the Deputy Commissioner for Medical and Scientific Affairs at the FDA, Dr. Gottlieb championed the need for the FDA to be efficient and patient-focused in its job of evaluating new therapies. This prior experience at the FDA and his efforts to increase efficiency through the Critical Path Initiative demonstrate his ability to improve the FDA through thoughtful, science-driven reforms. For these efforts, the SFA honored Dr. Gottlieb in 2007 with our Visionary in Medicine Award.

As you complete your work to confirm the net Commissioner of the FDA, we ask that you take into consideration the needs of the sarcoma community and confirm Dr. Scott Gottlieb. The Sarcoma Foundation of America looks forward to working with Dr. Gottlieb upon his confirmation on the important issues that directly impact the lives of sarcoma patients.

Sincerely,

BERT E. THOMAS IV, PH.D., MBA,
Chief Executive Officer.

SOCIETY OF HOSPITAL MEDICINE (SHM),
PHILADELPHIA, PA 19130,
March 17, 2017.

Hon. LAMAR ALEXANDER, *Chairman*,
Committee on Health, Education, Labor, and Pensions,
428 Senate Dirksen Office Building,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member*,
Committee on Health, Education, Labor, and Pensions,
428 Senate Dirksen Office Building,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: On behalf of more than 50,000 practicing hospitalist physicians nationwide, the Society of Hospital Medicine (SHM) strongly supports the nomination of Scott Gottlieb, M.D., as Commissioner of the Food and Drug Administration (FDA).

Practitioners of hospital medicine include physicians ("hospitalists") and non-physician providers who engage in clinical care, teaching, research, or leadership in the field of general hospital medicine. In addition to their core expertise managing the clinical problems of acutely ill, hospitalized patients, hospital medicine practitioners work to enhance the performance of hospitals and healthcare systems.

As a hospitalist and active member of SHM, Dr. Gottlieb has served on SHM's Public Policy Committee since 2011. In this period, Dr. Gottlieb has been an invaluable asset to SHM in understanding and addressing the most pressing healthcare issues of the day. During his time with SHM, Scott has been very involved with our efforts around empowering hospitalists and the overall healthcare system to push forward in delivering quality, patient-centered care at lower cost. His expertise has been helpful to both hospitalists and the patients we care for.

Throughout his service to SHM, Dr. Gottlieb has shown his deep understanding of the many public health issues, delivery system reforms, and quality of care issues that are important to hospitalists and our patients. And he has been an invaluable resource and partner in developing solutions to these issues. His public service to the government in various healthcare-related roles, including his tenure at the Centers for Medicare and Medicaid Services (CMS) as Senior Policy Adviser to the Administrator, Senior Adviser for Medical Technology, Director of Medical Policy Development, and Deputy Commissioner for Medical and Scientific Affairs at the FDA will provide him with the deep and diverse experience that the role of FDA Commis-

sioner demands. His insight into both the CMS and the FDA make him a rare and invaluable asset linking approval of much-needed treatments with access to such care.

As a practicing hospitalist, and in his work with SHM, Dr. Gottlieb has shown an unwavering respect for physician autonomy and is a champion for the preservation of the patient-physician relationship. He is committed to putting the patient first in the delivery of high quality care.

Dr. Gottlieb has a track record of leadership and dedication to building a patient-centered, quality-focused and efficient health care system. As FDA Commissioner, Dr. Gottlieb will bring a demonstrated commitment to public service coupled with the quality-driven, results-oriented mindset of a hospitalist physician.

We urge you to vote in favor of his nomination.

Sincerely,

BRIAN HARTE, M.D., SFHM,
President, Society of Hospital Medicine.

APRIL 4, 2017.

Hon. MITCH MCCONNELL, *Majority Leader*,
U.S. Senate,
SR-317 Russell Senate Office Building,
Washington, DC 20510.

Hon. CHARLES SCHUMER, *Democratic Leader*,
U.S. Senate,
SH-522 Hart Senate Office Building,
Washington, DC 20510-6300.

Hon. LAMAR ALEXANDER, *Chairman*,
Senate HELP Committee,
SD-428 Dirksen Senate Office Building,
Washington, DC 20510-6300.

Hon. PATTY MURRAY, *Ranking Member*,
Senate HELP Committee,
SD-428 Dirksen Senate Office Building,
Washington, DC 20510-6300.

DEAR MAJORITY LEADER MCCONNELL, DEMOCRATIC LEADER SCHUMER, CHAIRMAN ALEXANDER, AND RANKING MEMBER MURRAY: The undersigned organizations, representing millions of patients, advocates, caregivers, and health care providers would like to reaffirm our support for President Trump's nomination of Dr. Scott Gottlieb as Commissioner of the Food and Drug Administration (FDA). We ask that Senators in the Republican and Democratic caucuses, and the Senate HELP committee, vote to confirm Dr. Gottlieb.

The United States is at a pivotal moment in terms of public health. The FDA and patients need the leadership and experience that Dr. Gottlieb will bring as soon as possible.

Dr. Scott Gottlieb is well-qualified and has received broad-based support. Equally important, as a physician who has treated patients, he knows the value of having the best available treatments based on the best science. As a survivor himself, he knows what it's like to fight cancer and understands the challenges that patients face every day.

Currently a resident fellow at the American Enterprise Institute focusing on the FDA and CMS, Dr. Gottlieb is also a member of the Federal Health IT Policy Committee. His previous experience includes public service from 2005 to 2007, as FDA deputy commissioner under President George W. Bush.

Dr. Gottlieb has not only the experience that will be critical to expand upon the agency's important work, but also firsthand expertise as a physician who has treated patients, understanding the breadth of work that needs to be achieved on their behalf.

Dr. Gottlieb's strong scientific base and in-depth knowledge of key regulatory processes will be key to his success in this position. Due to his knowledge and experience, Dr. Gottlieb is the right person to ensure the FDA keeps pace with science and innovation without sacrificing the safety and efficacy gold standard established by the agency.

Additionally, we know that Dr. Gottlieb can maximize value for patients through the FDA. Congress must ensure that FDA continues its important mission to pro-

vide patients with safe and effective treatments. We ask the Senate to do what is right for patients and immediately confirm Dr. Scott Gottlieb as FDA commissioner.

Sincerely,

Alliance for Aging Research; American Association for Cancer Research; Association of American Cancer Institutes (AACI); CancerCare; CEO Roundtable on Cancer; Coalition of Cancer Cooperative Groups; FasterCures, a Center for the Milken Institute; Friedreich's Ataxia Research Alliance (FARA); Friends of Cancer Research; Global Healthy Living Foundation; Grandparents in Action; Lung Cancer Alliance; LUNGevity; Lupus and Allied Diseases Association, Inc.; Men's Health Network; National Coalition for Cancer Research (NCCR); National Health Council; National Infusion Center Association (NICA); National Kidney Foundation; National Patient Advocate Foundation (NPAF); The Nicholas Conor Institute; Prevent Cancer Foundation; Swifty Foundation.

RESPONSE TO QUESTIONS OF SENATOR ALEXANDER, SENATOR MURRAY, SENATOR ENZI, SENATOR SANDERS, SENATOR BURR, SENATOR CASEY, SENATOR ISAKSON, SENATOR FRANKEN, SENATOR PAUL, SENATOR BENNET, SENATOR COLLINS, SENATOR WHITEHOUSE, SENATOR CASSIDY, SENATOR BALDWIN, SENATOR HATCH, SENATOR MURKOWSKI, SENATOR MURPHY, SENATOR ROBERTS, SENATOR WARREN, SENATOR KAINE, AND SENATOR HASSAN

SENATOR ALEXANDER

Question 1. I have heard that the FDA import clearance process does not allow critical medical shipments to be cleared in time to be delivered as required. Based on the FDA's data, 75 percent of the imports are subject to some type of review at the border, which can take hours, days, or even weeks to resolve. This problem will only get worse as new data requirements went into effect February 9.

As more FDA-regulated products are imported, people who expedite shipment of those products need to have confidence that the products are legitimate and that they will get to patients on time.

Under your leadership, what will the FDA do to improve?

Answer 1. As a physician, I am sensitive to the needs of patients who are seeking critical medical shipments. I am familiar with this clearance process and the new data requirements that go into effect in February. But I cannot speak to the specific reasons as to why the timelines for the clearance process are unpredictable. If confirmed by the U.S. Senate, I will commit to working with you and your staff to identify and address the underlying issues related to this process to ensure that patients are not waiting for critical medical shipments any longer than the necessary time it takes the agency staff to assure the authenticity of the medical product and the integrity of supply chain through which it is delivered.

Question 2. I have heard that the Center for Tobacco Products needs significant improvement and reconsideration with regard to the agency's regulatory path for newly deemed tobacco products, particularly premium cigars. Preventing long-term health effects of addiction to tobacco, particularly among youth, is an important aspect of FDA's public health mission. It is important that the tobacco center recognize the significant differences in newly deemed tobacco products, such as premium cigars, from traditional products covered under the Tobacco Control Act, and that the level of risk may be different depending on the product category. If confirmed, how could the FDA reconsider the regulation of premium cigars?

Answer 2. Through the Tobacco Control Act (TCA), Congress gave FDA regulatory responsibility over tobacco products. If confirmed, I will be committed to implementing the TCA, as intended by Congress, including section 911 related to modified risk products, which I recognize can provide helpful tools for current tobacco-users to transition off combustible tobacco. I will also commit to better understanding the decision FDA made with respect to premium cigars, and any changes that were made in regard to premium cigars between the proposed and the final rule. As I was not at FDA during the agency's initial TCA implementation activities, I am not fully acquainted with internal processes or specific decisions to-date. If confirmed, I will work with the staff to quickly get up-to-speed on this issue, and I will review current FDA policies, including the deeming rule, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is consistent with congressional intent under the TCA. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

SENATOR MURRAY

Question 1. 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 of raw data before they are marketed to consumers. Do you support upholding this gold standard?

Answer 1. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. If confirmed, I will uphold the Gold Standard by ensuring FDA makes regulatory decisions based on sound science, good regulatory practices, and the support of a strong staff. FDA should thoroughly consider regulatory approaches that could improve the efficiency of drug and device discovery, development, and regulation. But FDA should only adopt those sound scientific approaches that reliably improve on its gold standard for being both safe and effective.

Question 2. The field of regenerative medicine has immense promise for patients—from cell and gene therapies to stem cells. I am proud that some of this innovative research is taking place in my home State of Washington within both cutting edge companies and our leading research institutions. As part of 21st Century Cures, Congress established the regenerative medicine advanced therapy designation for cell-based therapies that have the potential to address unmet medical needs. There have been repeated reports of patients being harmed by experimental regenerative medicine treatments that are being sold both here in America and abroad—for example, last month the *New York Times* reported that a clinic blinded three patients by injecting their eyes with stem cells. As Commissioner, what steps will you take to ensure FDA takes action against unscrupulous providers and ensures continuing innovation, the success of the RMAT designation pathway, and patient and provider confidence in this emerging field?

Answer 2. Regenerative medicine is one of the most innovative and promising emerging advancements in our scientific approaches to the treatment of human disease. Regenerative medicine appears to hold great promise for new therapeutic options for patients and physicians, particularly in areas of unmet or underserved medical need. However, as with all products FDA regulates, the agency must have the appropriate policies and processes in place to assess and ensure the safety and efficacy of regenerative medical products before they are approved for use by American patients. FDA must also ensure patients and providers are appropriately educated about the potential risks and benefits of regenerative medicine therapies that fall within the scope of FDA's oversight, and that these products meet the agency's standard for safety and effectiveness. If confirmed, I will embrace the responsibility to facilitate important medical innovation in the regenerative medicine space, and will seek timely implementation of the new pathway created as part of 21st Century Cures, while maintaining the agency's Gold Standard of safety and efficacy.

Question 3. Antibiotic resistance is growing public health threat. CDC estimates that there are at least 2 million drug-resistant infections each year in the United States resulting in approximately 23,000 deaths. All antibiotic use increases the risk of development of antibiotic resistance. In order to minimize the growth of antibiotic resistance, antibiotics should be prescribed judiciously, but the CDC estimates that up to 50 percent of antibiotics in human healthcare settings in the United States are inappropriately prescribed.

What do you feel is the appropriate role for FDA in ensuring judicious use of antibiotics?

21st Century Cures established the Limited Population Approval pathway for antibiotics. Are you committed to following the strong labeling requirements for these products in the law and educating prescribers about appropriate use?

How will you work to prevent drug shortages of antibiotics, which can lead to overprescribing of broad spectrum antibiotics?

Answer 3. The availability and appropriate prescribing of antibiotics are vital to our Nation's public health. Additionally, antibiotic resistance is a significant and growing public health challenge facing our Nation. Within its statutory authorities, FDA should encourage the development of new antibiotics and ensure proper labeling to help address the issue of inappropriate prescribing and/or use. If confirmed, I would commit to following the law, as it relates to the Limited Population Approval pathway for antibiotics. Further, I would prioritize effectively preventing and decisively alleviating drug shortages, particularly those of antibiotics, many of which are parenteral drugs used in hospitalized settings.

Question 4. I believe that precision medicine relies on effective and meaningful lab tests to inform treatments, and that this area of innovation should be fostered. How-

ever, there are many recent examples of lab tests being marketed to physicians and patients that have no real clinical meaning, have led to patients being over- or undertreated for diseases, or exposed patients to inappropriate therapies or stopped them from receiving effective therapies. On October 3, 2014 the FDA issued a draft oversight framework for LDTs based on risk to patients, rather than whether they were an LDT of IVD. Since that time, Congress and stakeholders have been actively engaged in the discussion about how best to modernize lab oversight in the era of precision medicine. In January of this year, FDA released a white paper that updated the agency's position based on stakeholder feedback to the 2014 framework. You have argued that the regulation of these tests is best left outside of FDA's jurisdiction, and instead, CLIA should be updated to be more robust.

Do you support the framework in the January 2017 white paper?

What FDA role in oversight of LDTs do you believe is necessary to address the Agency's longstanding and well-publicized concerns about those tests?

Do you believe that FDA has the legal authority to regulate lab rests?

How will you work with Congress and CMS to ensure that lab tests are both accurate and clinically meaningful?

Are you committed to supporting a regulatory framework that would give patients and their provider's confidence in the quality and veracity of their tests, and level the playing field for innovators?

Answer 4. Defining an appropriate regulatory framework for Laboratory Developed Tests (LDTs) is important to FDA's mission to protect and promote public health. In order to both protect patient safety and encourage innovation and patient access, I believe we must strike the right balance between Clinical Laboratory Improvement Amendments (CLIA) and FDA regulation and regulatory requirements. If confirmed, I would commit to working with Congress and stakeholders to develop appropriate LDT regulatory policies that strike the right balance between encouraging innovation while making sure that patients and providers can be confident in the clinical validity of the results that they receive from LDTs.

Question 5. In your hearing, you were asked whether there should still be double-blind trials in 2017. While I agree that the FDA should consider all appropriate trial designs to assess the safety and efficacy of drugs, I am concerned that your response did not provide any examples in which you believed that a double-blind study would be appropriate. Are there any diseases or drug classes that you believe double-blind studies are the best way to determine efficacy or safety? If so please include examples. Or do you believe that there are no circumstances that warrant such a trial?

Answer 5. There are many clinical settings where double-blind, placebo controlled trials remain the gold standard for properly determining safety and efficacy and define the appropriate standard for FDA's approval requirements. While it might not be appropriate for me to opine on specific approval standards with respect to specific clinical circumstances and drug trials—as these determinations are best left to the expert judgment of FDA's career staff—I fully recognize that there is a continuum of clinical trial designs and evidentiary standards that FDA must require based on the clinical setting, the clinical appropriateness, the feasibility, and the underlying patient need. These requirements are exercised within the scope of the discretion that is afforded to agency staff by statute and regulation. This ability of FDA's staff to use judgment in how they apply the single gold standard for determining safety and effectiveness is a reflection of the careful consideration that FDA's staff must strike in order to properly balance access, innovation, and safety. If confirmed, I will support a strong FDA, with staff making these kinds of judgments through a rigorous, science-based process.

Question 6. I understand the urgency that patients and their families feel when they are desperate for new treatments. I believe that we must ensure therapies are available to those who need them most. I have concerns about so-called "right-to-try legislation," which could hurt those it is designed to help. I believe that access to investigational drugs should be done in a way that maintains and bolsters the drug development process that brings us lifesaving cures, and prevents a two-tiered system where those who can afford to buy an investigational treatment can have access and those that cannot have to wait. In your confirmation hearing I asked if you were willing to stand up to the Administration if they put political pressure on you, and you stated that you would give "unvarnished advice" and "clear thoughts" on issues you are asked to opine on. Given the Trump administration's support of right to try laws, please give your perspective on both the impact on patients, and drug development process, if the current Federal legislative proposal was enacted.

Answer 6. Access to off-label and investigational products for patients facing serious and terminal illness is not an abstract issue to me. As a cancer survivor who

used a commercially available combination therapy in an off-label manner, I understand, at a very personal level, that patients who are fighting serious or life-threatening diseases want the flexibility to try new therapeutic approaches, including access to investigational medical products, particularly when there is no other FDA-approved treatment option. I also believe that the clinical trial process is crucial to the development of innovative new medical products that can improve or save patients' lives. If confirmed, I would commit to ensuring FDA has the right policies and processes in place to appropriately balance individual patients' needs for access to investigational therapies while recognizing the importance of maintaining a rigorous clinical trial paradigm for testing investigational products and demonstrating safety and efficacy. I would be happy to work with Congress as it considers Right-to-Try legislative proposals.

Question 7. According to a *New England Journal of Medicine* study published earlier this week,[1] the FDA in recent years has approved more products, and approved them more quickly, than the European Medicines Agency. In a 2012 article published in National Affairs, you stated that the FDA puts up too many barriers to approval, and prioritized safety over speed.

Given the implementation of FDASIA and 21st Century Cures, do you still hold that view?

Can you give examples of products approved in recent years, that have since demonstrated a clear benefit to patients, and that you believe the FDA moved too slowly in approving?

Answer 7. FDA has made significant progress in recent years to ensure that patients in the United States have access to new, innovative therapies thanks to new legislative pathways like Breakthrough Therapy designation. The adoption of the Breakthrough pathway addressed many of the concerns I raised in that 2012 article. I believe we should continue to look for ways to improve the efficiency of FDA's medical product review program, modernize the scientific standards used in drug regulation, and seek more uniform adoption of pathways created by Congress like the Breakthrough Designation, and build on these opportunities through adoption of the new provisions in Congress in 21st Century Cures. We need to do all these things while continuing to ensure that new products meet FDA's Gold Standard for safety and efficacy.

Question 8. In my meeting with Tom Price, he stated that he believed in the gold standard of safety and efficacy for, but that it needed to be made "evergreen" so that it's easier for drug developers to innovate. Section 505(b) of the Food Drug and Cosmetic Act states that for a drug to be approved, a person must file an application which includes "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."[2] Please describe if you think this language is "evergreen" and applicable to today's technology. What specific current regulatory authorities and flexibilities does FDA currently have that makes the current standard "evergreen?"

Answer 8. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. But owing to opportunities created by evolving modern science as well as new policies created by Congress—including provisions in 21st Century Cures—there are now more opportunities to make sure that FDA is adopting the best science and most efficient and modern regulatory tools for demonstrating that standard. This creates opportunities to make the development process more efficient, less costly, and at times faster, while also improving upon our ability to demonstrate safety and efficacy. These basic principles have formed the basis of our collective public health goals with respect to drug review. I recognize that FDA must reject policies or processes that would in any way undermine the safety and efficacy of our Nation's drug and medical technology supply because, for example, we were inappropriately prioritizing speed over the gold standard for safety and efficacy. If we are adopting modern science and investing in a strong FDA workforce, we can strive to achieve greater efficiency while improving on our gold standard for safety and efficacy. Getting better efficiency, and taking a risk-based approach to FDA's work, means FDA needs the appropriate policies, resources, and processes to consistently utilize 21st century regulatory science. FDA should thoroughly consider regulatory approaches

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[1] Downing, Nicholas S., et al. "Correspondence: Regulatory Review of New Therapeutic Agents—FDA versus EMA, 2011–2015." *The New England Journal of Medicine*, vol. 376, no. 14, 2017, pp. 1386–1837, *http://www.nejm.org/doi/pdf/10.1056/NEJMc1700103*. Accessed 7 Apr. 2017.

[2] 21 U.S.C. Sec. 355(b). 2012. LexisNexis Academic. Web. 7 Apr. 2017.

that could improve the efficiency of drug and device discovery, development, and regulation, but only adopt approaches that reliably improve the ability to determine the safety and efficacy of medical products that Americans use.

Question 9. 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 Drug Snapshots released this year from FDA shows many drugs are still being tested predominately in white men—even those intended to treat conditions that can have a disproportionate impact on women or minorities.

Do you support requiring inclusion of women and minorities in clinical trial data submitted to the FDA?

Are you committed to supporting additional work by the FDA to improve the diversity of clinical trials used to support medical product approvals?

How will you ensure that doctors have information they need about how a new medication works in these subpopulations?

Answer 9. I think it is very important that clinical trials capture the diversity of the population who will likely use the medical product once it is marketed and becomes available. If confirmed, I will work to ensure that FDA policies support the conduct of clinical trials that represent the clinical diversity of the intended patient population, including through the implementation of Section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Question 10. This year, Congress needs to reauthorize FDA's authority to collect user fees from the drug, medical device, biosimilar, and generic drug industries. It is the first time that Congress has been charged with this task in the first year of a new administration—and the Trump administration has proposed to both "recalibrate" user fees and replace FDA budget authority with additional fees. In addition the President has issued a "Hiring Freeze" across the Federal Government.

Do you support reauthorization of the PDUFA, MDUFA, GDUFA, and BsUFA agreements as finalized and submitted to Congress by the Obama administration?

How does the FDA's appropriated budget contribute to the Agency's overall health and independence?

Do you believe that user fees are an effective replacement for congressional appropriations?

How will you ensure the FDA progresses toward its hiring and retention goals in the agreements and in the spirit of 21st Century Cures? In January, Senator Warren and I sent a letter to FDA Acting Commissioner Ostroff inquiring about the impact and implementation of the hiring freeze. When can we expect an answer to this correspondence?

Answer 10. The reauthorization proposals for PDUFA, MDUFA, GDUFA, and BsUFA were developed and submitted to Congress prior to the end of the previous Administration. I was not involved with the FDA-industry technical negotiations on any of these proposals. I was also not involved in the development of the President's Blueprint Budget. I recognize these user fee programs are critically important to FDA, and the patients the agency serves, as they provide significant resources to support FDA's regulatory activities related to innovative and generic medicines, biosimilars, and medical technologies. In order to ensure FDA is adequately resourced to facilitate the discovery, development, and regulatory review of safe and effective medical products to help American patients, if confirmed, I will work with my colleagues in the Administration, Congress, industry, and stakeholders to reauthorize these critical user fee programs in a timely manner. I will also commit to making sure that congressional correspondence is answered in a timely fashion.

Question 11. 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 support for timely review and approval of biosimilars. The biosimilar drug user fee agreement supports the review of these products.

Do you support the biosimilars pathway?

How will you work both within FDA and in collaboration with CMS to encourage and speed their development and availability to patients?

How do you plan to help educate physicians and the public about biosimilars to increase their uptake in the market?

Answer 11. Yes, I fully support the biosimilars pathway. This pathway is a critical part of the careful balance Congress prescribed between access and innovation, and the ability for consumers to get more value when it comes to the medical products they use. If confirmed, I intend to work closely with FDA staff and CMS to ensure the availability of biosimilar products. I recognize the importance of educating physicians and the public about the availability of, and FDA's confidence in, approved biosimilar products. I look forward to working with FDA staff, if confirmed, to increase education and build on current methods of outreach at FDA.

Question 12. In 2013, a fungal meningitis outbreak 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, which clarified and enhanced FDA's authority to regulate drug compounding. Are you committed to protecting patients who need compounded drugs through implementation and enforcement of this important public health law as written, including the limitations under 503A?

Answer 12. The practice of pharmacy compounding can serve an important role, allowing providers to develop individualized formulations of certain medicines for specific patients with unique needs. However, I know that there are examples of actors operating as manufacturers of unapproved new drugs under the guise of a pharmacy license, violating the careful framework created by Congress, circumventing the FDA oversight that Congress intended for certain products, and putting patient safety at significant risk. Congress clarified FDA's regulatory authorities related to compounding by passing the Drug Quality and Security Act (DQSA). If confirmed, I am committed to implementing DQSA, as intended by Congress, to both protect patient safety, and allow the safe and appropriate practice of pharmacy compounding to occur in the way that Congress intended.

Question 13. Generic drugs now comprise the vast majority of the pharmaceutical market, and in many cases are the only products available for patients after a brand name product is discontinued. However, generic drug manufacturers are not able to update their labels efficiently with safety information without prior FDA approval and without the brand drug's label being updated as well. The FDA has recognized that this is a public health problem, and issued a proposed rule to allow such updates, known as CBE–0, but the release of the final rule has been delayed repeatedly. You have spoken out against this rule in multiple publications. Will you support issuing regulations allowing generic drug companies to amend their labels in order for patients and physicians to have ready access to the most up-to-date information about their products?

Answer 13. I believe it is important that generic drug labels be kept up-to-date and generic firms engage in appropriate post-market safety surveillance. FDA's proposed rule would alter the legal responsibilities of generic firms. If confirmed, I will work with FDA staff as we consider future regulatory actions to best achieve the underlying public health goals.

Question 14. In 2013 in my home State of Washington, 32 patients were sickened with antibiotic resistant infections that were traced back to contaminated medical devices known as duodenoscopes. An investigation by my staff 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. Section 3059 of the recently enacted 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 when device modifications require the submission notification under 510(k). But just 2 weeks ago, another outbreak of antibiotic resistant infections was traced back to the same devices that the company said were fixed after the outbreak in Washington.

Are you committed to meeting the deadlines in 21st Century Cures statue for these publications?

What additional actions will you take to ensure reprocessed devices are safe for patients?

Answer 14. If confirmed, I will continue to emphasize the importance of maximizing patient benefit and reducing safety risks related to duodenoscopes and will work to implement the related provisions of the 21st Century Cures Act. I am committed to working with FDA staff and Congress, where necessary, to ensure that reusable devices are safe for patients.

Question 15. My investigation of contaminated duadenoscopes 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."[3] I believe that the FDA needs to do more to improve post-market surveillance for medical devices. 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?

Answer 15. The reauthorization proposals for PDUFA, MDUFA, GDUFA, and BsUFA were developed and submitted to Congress prior to the end of the previous Administration. I was not involved with the FDA-industry technical negotiations on any of these proposals.

However, I am generally supportive of data transparency and recognize the importance of collecting valid pre- and post-market data that can be used to bring new medical devices to market, expand indications for approved medical devices, and enhance the agency's ability to collect important patient safety information. If confirmed, I will commit to working with the FDA professional staff to quickly get up to speed on this issue and help the agency evaluate whether NEST could be an appropriate tool for post-market surveillance.

Question 16. In 2016, CMS and FDA wrote a joint letter in support of including unique device identifiers (UDI) in medical claims during the next update of the electronic form, the process for which is ongoing. Both agencies recognize that our health care system takes too long to recognize problems with devices and then take appropriate actions, harming patients and resulting in billions in preventable costs to Medicare. As pointed out by clinical societies (including the Society of Thoracic Surgeons, American College of Cardiology, and American Academy of Orthopedic Surgeons), health plans, hospitals, Democrats, Republicans, and registries such as the American Joint Replacement Registry and many others, adding medical device identifiers to health insurance claims would generate better data to detect these problems sooner.

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?

How will you engage with stakeholders, including CMS and the X12 Committee, to facilitate the adoption of a field for the DI in electronic insurance claims following the February recommendation of X12 to move forward such a field.

Answer 16. I am committed to reviewing the work done to date by staff at CMS and FDA on this issue. Appropriate policies that could enhance our ability to capture valid post-market data should be thoughtfully considered. This also includes achieving interoperable electronic health records with UDIs—a goal that is fully consistent with the health information technology provisions in 21st Century Cures. If confirmed, I look forward to working with my colleagues at CMS and the X12 Committee to explore all of these policies.

Question 17. Medical devices, including imaging equipment, can be used for many years and can undergo maintenance and repair. This medical device servicing, when done by the original equipment manufacturer, is subject to FDA regulation. However, if servicing is done by a 3d party, it is not subject to FDA oversight. This regulatory gray area causes uncertainty for doctors and patients who trust that medical devices are held to FDA standards, and for equipment manufacturers who are liable for the safe and effective performance of the devices. I was pleased that last year, the FDA opened a public docket for comments and held a public workshop on medical device servicing. What do you believe FDAs role is in ensuring that servicing of medical devices by original equipment manufacturers, hospitals, and 3d parties is held to the same standards?

Answer 17. An important part of FDA's responsibility to protect and promote public health is upholding the Gold Standard of safety and efficacy for medical products American patients use. With regard to the issue of medical devices that are serviced by 3d parties, if confirmed, I will commit to quickly engaging with FDA's staff to get up to speed on this issue, including a review of the public comments received

[3] "Preventable Tragedies: super bugs and How Ineffective Monitoring of Medical Device Safety Fails Patients."*United States Senate Committee on Health, Education, Labor, and Pensions*, 13 Jan. 2016, *https://www.help.senate.gov/imo/media/doc/Apples.pdf*.

by the agency. I look forward to working with FDA's staff, Congress, and stakeholders to ensure that the agency has in place the right policies and processes to ensure the safety and efficacy of medical devices.

Question 18. While some blood donor deferral criteria are based on an individual's risk of a transfusion transmissible infection, others are not. Non-risk-based criteria prevent many healthy people from donating blood, while still allowing some high risk donors to donate. In December 2015, the FDA published final guidance that overturned the non-risk-based criteria that banned on blood donations from men who have sex with men (MSM). The 2015 guidance replaced the lifetime ban with a 1-year deferral, but the 1-year deferral remains an arbitrary time-based deferral, not a risk-based deferral. 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?

Answer 18. Ensuring the safety and adequacy of our Nation's donated blood supply is critically important to public health. If confirmed, I will work with FDA staff to closely develop, implement, and monitor the impact of policies to promote blood safety. I will also commit to continuing to work with FDA staff to review its donor deferral policies to ensure they reflect the most up-to-date scientific knowledge.

Question 19. I am fully supportive of the bipartisan Food Safety and modernization Act, which has since helped to protect the public's health, strengthen consumer confidence in American food products, and level America's playing field with foreign competitors. FDA oversees 80 percent of the food supply and its oversight prevents countless incidents of foodborne illness every year. Critical to implementation are the major rules that are due to go into effect this year and funding for the States, which will take most of the responsibilities for on-farm inspections and other day-to-day work under the produce rule. Are you committed to requesting the funds in your budget necessary to support FDAs implementation of FSMA to ensure that consumers remain confident in our food supply?

Answer 19. The Food Safety Modernization Act (FSMA) provides FDA with important tools and authorities to support its responsibility to ensure the safety of our Nation's food supply. If confirmed, I will work to ensure the agency has the appropriate policies, processes, and resources in place to implement FSMA, as intended by Congress. FDA should implement FSMA in a way that protects and promotes public health by enhancing food safety, while also collaborating with the U.S. Department of Agriculture, State officials, and other government agencies to conduct regulatory activities in a manner that takes into account the unique challenges faced by small farmers and small businesses.

Question 20. According to the CDC, two million Americans develop antibiotic-resistant infections each year, costing 23,0000 lives and $20 billion annually. The World Health Organization's global assessment of antibiotic resistance concluded that antibiotic resistance "is now a major threat to human health." I am particularly concerned by the connection between the use of antibiotics in agriculture and increasing antibiotic resistance among foodborne pathogen, which CDC estimates cause nearly half a million Americans to become sick each year. Public health authorities, including CDC and the FDA, and the production agriculture sector itself have made important strides to begin to address these challenges. I was pleased the FDA finalized Guidance for Industry 209 and 213 which established judicious use principles and removed production indications for medically important antimicrobials. FDA's publication of the Veterinary Feed Directive (VFD) final rule provided veterinarians with clear direction for how to authorize the use of antibiotics that are important to human health in animal feed when they are needed to protect animal health; this will further reinforce the critical role of veterinarians in animal-health decisionmaking.

How do you plan to ensure that antibiotics are indicated for "disease prevention" at the same doses and duration as now removed production indications—meaning they could still be used non-judiciously—are being used for legitimate prevention uses?

How do you plan to collaborate with USDA to collect the on-farm data required to truly assess antibiotic use?

Answer 20. Antibiotic resistance is a significant and growing public health challenge facing our Nation. In addition to measures FDA should take to address this

issue within the context of human use, the agency must effectively collaborate with other government agencies and public health authorities to develop policies and processes to address the issue of antibiotic use in animals intended for human consumption. If confirmed, I will ensure FDA remains engaged on this important public health issue, making sure that animal drug labeling reflects the most up-to-date science, and working closely with the U.S. Department of Agriculture, the Centers for Disease Control, the U.S. Department of Defense, and other appropriate Federal and State agencies. FDA should also consider input from other important stakeholders, such as the farmers, the agriculture industry, and veterinarians. FDA's implementation of a voluntary plan with industry to phaseout the use of certain antibiotics is an important step in the direction of more appropriate stewardship and use of antibiotics.

Question 21. Drug companies are only allowed to market their products for the uses approved by the FDA. Proponents of relaxing this FDA standard to allow more so called "off-label communication" argue that such communication is critical for physicians in this age of rapid innovation. Opponents of off-label communication believe it will lead us back to an era where companies could peddle unproven products and reduce the incentive to invest in truly innovative research and development. In a *Forbes* column, you agreed with this point, writing, "[t]he most important incentive to developing useful information remains the ability for companies to market drugs based on what can be proven scientifically."[4] Can I have your commitment that, if confirmed, you will ensure that FDA regulation of communications will preserve physician and public trust in approved medical products and the important incentive of FDA approval?

Answer 21. Medical product labeling is one of the primary tools FDA uses to promote the appropriate use of medicines and technologies and communicate risk information. It is important that information on product labeling is accurate, clear, and scientifically based; and be the result of a sound regulatory process. Further, it is crucial that manufacturers continue to develop and submit to the agency clinical data demonstrating the safety and efficacy of medical products for new indications they seek to include on labeling and in their marketing communications with patients, payers, and providers. I also believe that patients and physicians make the best decisions when they have access to as much truthful, non-misleading, scientifically based information as possible. FDA has long recognized that there is public health benefits of allowing certain non-promotional communication about truthful, non-misleading, clinical information that is not previously incorporated into FDA-approved product labeling. If confirmed, I will commit to working with FDA's professional staff to get up to speed on the agency's latest thinking and actions on these matters, and providing clarity to manufacturers, payers, providers, and patients about acceptable truthful and non-misleading communications related to clinical data not already incorporated in a label.

Question 22. As a physician, I am sure you are aware that tobacco use is still the leading preventable cause of death and disease in the United States.[5] Nonetheless, when Congress was on the verge of approving the legislation which allowed FDA to regulate tobacco products in 2009, you were quoted as saying that, instead of addressing the public health threats posed by tobacco products, this legislation would "gut" the FDA's resources—and "distract it from its core mission."[6] Nearly 8 years have passed since Congress enacted the Family Smoking Prevention and Tobacco Control Act, and the law has not gutted FDA's resources or distracted it from its core mission. As FDA Commissioner, you would oversee the Center for Tobacco Products, which is funded by user fees from the tobacco companies. Have your views on FDA oversight of tobacco products changed? What initiatives do you envision the Center for Tobacco Products take to reduce the death and disease caused by tobacco?

Answer 22. If confirmed, I will be committed to implementing the TCA, as intended by Congress. As I noted during my confirmation hearing before the committee, as a physician and cancer survivor, if confirmed, I will be fully committed to the TCA's public health goal of reducing morbidity associated with tobacco use

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[4] Gottlieb, Scott. "Merck's Pain is Medicine's Gain." *Forbes*, 4 Oct. 2014, *https://www.forbes.com/2004/10/04/cz_sg_1004soapbox.html.*

[5] "Burden of Tobacco Use in the U.S.—Current Cigarette Smoking Among U.S. Adults Aged 18 Years and Older." *Centers for Disease Control and Prevention*, *https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html.* Accessed 7 Apr. 2017.

[6] Associated Press. "Lawmakers Renew Efforts for Government Regulation of Cigarettes." *Fox News*, 2 Mar. 2017, *http://www.foxnews.com/politics/2009/03/02/lawmakers-renew-efforts-government-regulation-cigarettes.html.*

in this country. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

Question 23. Last year, FDA issued a final rule under the authorities of the Family Smoking Prevention and Tobacco Control Act (TCA), which enabled the agency to begin to oversee e-cigarettes and other tobacco products. In the years before FDA completed this rule, e-cigarette manufacturers introduced thousands of nicotine-delivering devices and liquids to the marketplace, many with fruit and candy flavors, without having to meet any independent standards to protect consumers' and the public's health. During this absence of FDA oversight, youth use of e-cigarettes soared, eclipsing youth use of regular cigarettes. E-cigarette proponents argue that they are less harmful than regular combustible cigarettes and can help adult cigarette smokers to quit. However, many e-cigarette manufacturers do not want to develop the data to support these claims. They instead want to exempt e-cigarettes that were on the market before the effective date of the deeming rule from a scientific review by FDA. Under the product review requirement in the TCA, tobacco product manufacturers must provide information about their products so that FDA can assess the toxicity, addictiveness, and appeal to youth of a new product. This independent scientific review will help answer important questions about these products, like whether manufacturers—use of flavors is increasing youth use of e-cigarettes, whether adults are using e-cigarettes to quit regular cigarettes or do they continue to use regular cigarettes, and what the risks are of using e-cigarettes. It will enable FDA to block more harmful or addictive products from the market and incentivize manufacturers to develop products that pose less risk to public health.

Do you support the deeming rule, including the product review requirement?

Can I count on you to ensure that this rule is fully implemented and not weakened?

What will you do to help prevent new users from getting hooked on nicotine through electronic cigarettes?

Answer 23. If confirmed, I will be committed to implementing the TCA, as intended by Congress, including Section 911 related to modified risk products, which I recognize can provide helpful tools for current tobacco-users to transition off combustible tobacco. As I was not at FDA during the agency's initial TCA implementation activities, I am not fully acquainted with internal processes or specific decisions to-date. If confirmed, I will work with the professional staff to quickly get up-to-speed on this issue, and I will review current FDA policies, including the deeming rule, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is consistent with congressional intent under the TCA. Clearly, manufacturers should not be allowed to target minors through indefensible marketing options of any tobacco related products, including e-cigarettes. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

Question 24. The FDA was instructed by Congress to look into the addition of menthol to cigarettes and its impact on public health. In a 2011 report, the FDA found that menthol is a problem—it is more likely to initiate smokers and keep them hooked.[7] However, the FDA has not promulgated regulations to reflect this threat. What would you do to address the threat of menthol cigarettes?

Answer 24. I have not reviewed the scientific evidence related to the addition of menthol in cigarettes. If confirmed, I will commit to engaging with FDA's staff to quickly get up to speed on the regulatory history of this issue, and the agency's latest information, thinking, and actions. I would welcome the opportunity to work with Congress on this issue moving forward.

Question 25. In 2012, you wrote an op-ed in the *New York Post* on FDA oversight of premium cigars. In that article, you suggest that expanding FDA's oversight to premium cigars was "never envisioned by Congress" and that doing so could divert the agency's attention from other important duties. In 2014, FDA issued a proposed rule that sought comments on whether FDA should oversee all cigars or exempt premium cigars. In 2016, it issued a final rule that—based on its review of comments and the scientific evidence—concluded "there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule."[8] It

[7] "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes." *Food and Drug Administration*, 23 Aug. 2013, *https://www.fda.gov/downloads/UCM361598.pdf*.

[8] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,

concluded that all cigars pose serious health risks, all cigars are potentially addictive, and premium cigars are not exclusively used by adults.

As FDA Commissioner, would you accept the assessment of FDA's scientists about the health risks of cigars? Would you continue to implement and enforce the deeming rule as it applies to premium cigars?

I am concerned about the use of these products by children, particularly high school boys, who now smoke cigars at a higher rate than regular cigarettes. Are you concerned about efforts to exclude from FDA regulation a product that is so frequently being used by high school boys?

Answer 25. If confirmed, I will work with FDA's professional staff to quickly get up-to-speed on this issue, and I will review current FDA policies, including the deeming rule, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is consistent with congressional intent under the TCA. I will also commit to better understanding the decision FDA made with respect to premium cigars—and any considerations that were made in respect to premium cigars between the proposed and the final rule—and would be happy to work with Congress on this issue.

Question 26. Today, Americans consume sodium mostly through processed foods that they purchase from a grocery store or at a restaurant.[9] Researchers estimate that reducing current sodium intakes by 1,200 milligrams a day would prevent 60,000 to 120,000 cases of coronary heart disease, 32,000 to 60,000 cases of stroke, and 54,000 to 99,000 heart attacks annually. This reduction would also save an estimated $10 billion to $24 billion in health-care costs and 44,000 to 92,000 lives annually.[10] Last June, FDA proposed draft voluntary guidance to industry to reduce sodium in processed and restaurant foods and has received comments from industry, public health groups and consumers. Will you commit to the Agency's finalizing this voluntary guidance in 2017?

Answer 26. We need to ensure that everything FDA does is science-based and try to encourage science-based, voluntary action to reduce sodium levels in foods. I know some companies have already taken voluntary steps to reduce sodium levels, and I support these public health goals. In some cases sodium plays an important food safety role, but many companies are already reducing sodium levels, and we want to find ways to continue to encourage those actions in a risk-based and science-based manner. If confirmed, I will review the comments received from stakeholders and the scientific evidence related to salt intake as well as consult agency staff before proceeding on this issue. I am committed to taking science-based steps, within the scope of FDA's authority and mandate, to reduce the burden of heart disease.

Question 27. On January 19, 2017, FDA and EPA published a guidance document concerning seafood consumption by pregnant and nursing women, which was a significant departure from the draft advice on the same topic. While I have long urged FDA to finalize this advice, I also have emphasized that the advice must reflect the latest science and be presented to consumers clearly so they can make the best possible decisions about the nutritional value of seafood during pregnancy and nursing. I am concerned that the final advice appears not to meet that standard. If confirmed, will you consider revisions to this document to ensure it is in line with the latest science and provides clear advice to consumers?

Answer 27. If confirmed, I will ensure FDA's advice concerning seafood consumption by pregnant and nursing women is based on the most current and relevant nutritional science and appropriately takes into account both the nutritional benefits, and any toxicological risks associated with seafood consumption. I will also work to ensure effective collaboration between FDA and the U.S. Environmental Protection Agency (EPA) on this issue, and a range of other public health matters over which both agencies share regulatory authority.

Question 28. After many delays, the compliance date for menu labeling requirements is May 5, 2017. Calorie labeling at chain restaurants, supermarkets, convenience stores, and other food service establishments allows consumers to make their

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81 Fed. Reg. 90 (May 10, 2016). *Federal Register: The Daily Journal of the United States*. Web. 10 May 2016. *https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.*

[9] "Salt—Sodium and Food Sources." *Centers for Disease Control and Prevention*, *https://www.cdc.gov/salt/food.htm.* Accessed 7 Apr. 2017.

[10] Bibbins-Domingo, Kirsten, et al. "Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease." *The New England Journal of Medicine*, vol. 362, no. 7, 2010, pp. 590–99, *http://www.nejm.org/doi/full/10.1056/NEJMoa0907355#t=article.* Accessed 7 Apr. 2017.

own choices about what to eat and feed their families. This information is more important than ever because people are eating out more than ever before; in 2015, food sales at restaurants surpassed spending at grocery stores for the first time.[11] Furthermore, more than 70 percent of Americans support menu labeling.[12] Researchers have concluded that menu labeling could prevent up to 41,000 cases of childhood obesity and save over $4.6 billion in healthcare costs over 10 years.[13] The restaurant industry and over 100 nutrition and public health organizations and professionals supported the law, which was the result of a bipartisan compromise. Many food establishments including Starbucks, McDonald's, Panera, Publix Super Markets, Wegmans Food Markets, and many others recognize the importance of this public health measure and are already labeling or working toward the May 5 compliance date. Unfortunately, efforts to weaken the menu labeling law continue. If confirmed, how will you ensure that the FDA implements menu labeling beginning May 5, 2017, as planned, and does not penalize food establishments that have followed the law and prepared to meet the compliance date over food establishments that have not? How will you ensure that all Americans have access to basic nutrition information to allow them to make up their own minds about what to eat?

Answer 28. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the specific technical details. As a general matter, I support providing clear, accurate, and understandable information to American consumers to help inform healthy dietary choices. I believe information about caloric content can be a useful tool.

However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with FDA's professional staff to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing excessive compliance burden on businesses, particularly small, independent ones.

Question 29. In your November 2005 speech to the Grocery Manufacturers of America (GMA) as Deputy Commissioner for Medical and Scientific Affairs, you made a number of important statements about the importance of nutrition in public health:

- "Clearly, there is a correlation between food, diet and disease."
- "FDA has also emphasized that our policies need to be solidly based on the latest science, and must emphasize protecting and helping consumers."
- ". . . (A)ll of these efforts represent a significant update to the food label based on science that has been developed in recent years, and it represents a major opportunity to re-educate consumers about the food label, and the impact of diet on their health."
- "As people shop for food, they should have at their fingertips accurate, helpful, and understandable information about the most important nutritional implications of the products on the shelves, and they should be able to easily fit individual food products into overall healthy diets. People should not need a calculator or an advanced degree in math or nutrition to calculate the components that comprise a healthy meal."

Following up on these statements of yours, I have a few questions: Will you commit to prioritizing giving industry the guidance they need to move forward with updated packages and maintaining a compliance date no later than July 2019 for the revised Nutrition Facts label, which would be a 1-year delay from the current compliance date? Other countries, like the United Kingdom, France, and Chile, have implemented front-of-package labeling where a consumer does not "need a calculator" as you so aptly put it, and major international companies with strong market presence in the United States—Mars, Nestlé Mondelez, Coca-Cola, Unilever, and Pepsi—have already taken major strides toward uniform labeling across Europe. As

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[11] Jamrisko, Michelle. "Americans' Spending on Dining Out Just Overtook Grocery Sales for the First Time Ever." *Bloomberg Markets*, 14 Apr. 2015, *https://www.bloomberg.com/news/articles/2015-04-14/americans-spending-on-dining-out-just-overtook-grocery-sales-for-the-first-time-ever*.

[12] "Poll Data re: Support Caloric Labeling in Supermarkets, Vending Machines, Movie Theaters."*Center for Science in the Public Interest*, 27 May 2012, *https://cspinet.org/sites/default/files/attachment/restaurant-calorie-content.pdf*.

[13] Gortmaker, Steven L. "Three Interventions that Reduce Childhood Obesity Are Projected to Save More than they Cost to Implement." *Health Affairs*, vol. 34, no. 11, 2015, pp. 1932–39, *http://content.healthaffairs.org/content/34/11/1932.full?ijkey=lnFXpx4AIM506&keytype=ref&siteid=healthaff*. Accessed 7 Apr. 2017.

commissioner, would you move ahead with a uniform and useful version of front-of-pack labels?

Answer 29. I agree that providing industry sufficient information to comply with this rule, as with any rule, is imperative. I also agree that FDA should be open to considering and evaluating additional approaches, especially those that could promote better consumer awareness and understanding of nutritional information about the foods they eat.

Question 30. Currently, there is little knowledge around the safety and efficacy of medications used by pregnant and lactating women, due in large part to a lack of inclusion in clinical trials for medications and treatments. The 21st Century Cures Act created a Federal task force to examine some of the issues involved in doing so but much more remains to be done. What steps would you take to increase knowledge regarding safe treatments for pregnant and lactating women?

Answer 30. If confirmed, I would look forward to FDA's participation in the Federal task force to examine the inclusion of pregnant and lactating women in clinical trials. As always, my commitment is to seek advances in treatments that are useful to individuals in all stages of life. Understanding the impact of treatments on women who are pregnant and lactating is crucially important. I commit to working with scientific experts at the various agencies and participants of the task force to develop our body of knowledge on safe treatments for this population and help to make sure FDA policies reflect this science.

Question 31. We know that you would like to see FDA partner with industry to bring innovative products more quickly to market for the benefit of patients, who are the ultimate beneficiaries of breakthroughs and improved drugs and devices. However, you disapprove of ACA provisions intended to make preventive care more widely available to patients, especially women. What is the appropriate role of government in ensuring that all women can benefit from newly approved preventive care like contraception and pre-exposure prophylaxis?

Answer 31. As the nominee to be the next Commissioner of Food and Drugs, I do not believe it would be appropriate to comment on questions about issues that are outside the jurisdiction of FDA.

Question 32. Dr. Gottlieb, you are aware of the history of the Thalidomide disaster in the 1960s, which was fortunately averted in the United States because of our rigorous drug approval standards. Pregnant women in other countries were not so fortunate. They were prescribed Thalidomide, a treatment for morning sickness that was not thoroughly tested, and which resulted in severe birth defects and complications. You cited this case in a lengthy article criticizing the "culture" of the FDA. You grudgingly concede that FDA's rejection of Thalidomide was a success story, avoiding the disastrous results women experienced in other countries. Yet you conclude that the Thalidomide episode led FDA to become overcautious, and too concerned with product safety. Do you believe, when it comes to any experimental product for women's reproductive health, that today's FDA should prioritize speedy approval over thorough study and understanding of long-term effects?

Answer 32. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. There are also unique risks and challenges when it comes to studying drugs used in pregnancy, and for this reason, we have not seen the sort of innovation and investment in drugs to treat conditions of pregnancy as we have achieved in other areas of clinical medicine. Because of the unique safety issues related to drugs used during pregnancy, we need to make sure we are investing in, and using, the best science to fully evaluate the benefits and potential long-term effects of any drug used in this setting. Making sure we maintain the gold standard for safety and effectiveness in this clinical setting, while finding ways to help facilitate investment and innovation in medicines used to support pregnant women, should be one of our highest public health priorities.

Question 33. FDA's own guidance states that advisory committees should be empaneled when the matter before the agency is one of significant public interest. However, through the years, the FDA has been inconsistent in convening external advisory committees for opioid approval decisions, often bypassing this step all together. The Comprehensive Addiction and Recovery Act (CARA), passed in July 2016, requires FDA to convene an Advisory Committee for any new drug that is an opioid, except if the agency finds that that such referral is not necessary for public

health and notifies Congress.[14] But in the FDA's "Opioid Action Plan," released September 2016, the agency only committed to empaneling an external advisory committee for every opioid under consideration for approval without abuse-deterrent properties.

In 2011, FDA approved a reformulated, abuse deterrent version of Opana ER without the benefit of review from an advisory committee. Just last month, a post-market review of Opana ER found that the risks of Opana ER substantially outweighed the benefits. Given examples like this and the goal of CARA, do you believe opioids with claims of abuse-deterrent properties should also go through an advisory committee, as appropriate?

How will you determine whether a new opioid drug should go to an advisory committee?

Do you commit to ensuring that those who serve on advisory committees for the FDA are held to its current high standard of impartiality to avoid conflicts of interest?

Answer 14. I believe FDA should have the benefit of independent advice from outside experts and convene Advisory Committees, when appropriate. I understand that this advice is often critical to FDA as they consider challenging regulatory decisions. I believe that FDA should develop a comprehensive and consistent policy with respect to the types of opioids that should be reviewed by an Advisory Committee. Whether an Advisory Committee is convened should not be made only on a product-by-product basis. There should also be clear guidelines used to make these determinations. I believe it is important that potential Advisory Committee members are screened for conflicts of interest.

Question 34. In 2015, more than 650,000 opioid prescriptions were filled in the United States.[15] One-in-five individuals experiencing non-cancer pain or living with a pain-related diagnosis received an opioid prescription from an office-based setting.[16] And a survey of primary care physicians found that 46 percent of doctors mistakenly believed that abuse deterrent formulations are less addictive.[17] These statistics indicate that many in the provider community are dangerously unaware of the risks of prescribed opioids. An advisory committee to the FDA suggested that the agency put in place mandatory training for prescribers. Currently, this opioid prescriber education is voluntary and fewer than 15 percent of prescribers have availed themselves of this training. The FDA has determined that it does not have authority to mandate prescriber training, but the agency and others inside and outside of the government have called on Congress and the DEA to institute a mandatory training/education requirement for DEA-controlled substances license, with input on the content of training coming from HHS.

Do you agree that all prescribers should have some minimal education and familiarity with the dangers of opioid addiction and overdose as well as best practices for prescribing?

How will the FDA engage with the CDC, the CARA-established task force on best practices, and the Trump administration's taskforce on opioids to ensure appropriate use of prescription painkillers?

What steps need to be taken to ensure the FDA can help facilitate this type of prescriber education?

Answer 34. Opioid abuse, misuse, and addiction constitute one of the most urgent and immediate public health threats facing our Nation. It is also the biggest public health crisis facing the FDA. The human and economic toll of this crisis is staggering. If confirmed, this will be my highest immediate priority. I will make sure FDA is aggressive, forward leaning, and fully engaged in combating this epidemic. I will work with FDA's professional staff to ensure FDA has the right policies and processes in place to:

- Facilitate the developments of new approaches and technologies to reduce the abuse/addictive potential of painkillers American patients use;
- Support the development of non-opioid analgesic alternatives for physicians and patients;

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[14] Public Law 114–198, Section 106.

[15] "The Opioid Epidemic: By the Numbers." *U.S. Department of Health and Human Services*, *https://www.hhs.gov/sites/default/files/Factsheet-opioids–061516.pdf*. Accessed 7 Apr. 2017.

[16] "Opioid Overdose—Prescribing Data." *Centers for Disease Control and Prevention*, *https://www.cdc.gov/drugoverdose/data/prescribing.html*. Accessed 7 Apr. 2017.

[17] Hwang, Catherine S., et al. "Primary Care Physicians Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion." *The Clinical Journal of Pain*, vol. 32, no. 4, 2016, pp. 278–84, *http://journals.lww.com/clinicalpain/Citation/2016/04000/Primary__Care__Physicians Knowledge__And__Attitudes.1.* aspx. Accessed 7 Apr. 2017.

• Assess whether FDA's current approach to opioid regulatory decisions, including labeling, REMS, and physician/patient education are appropriate, robust, and fully effective;
• Encourage the development of new pharmacological tools for physicians and patients to both prevent opioid misuse and abuse, and support treatment and recovery for patients struggling to overcome opioid addiction;
• Enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools to better target this information;
• Taking steps to make sure that providers are appropriately educated on identifying, and helping to property intervene with, abuse-prone patients;
• Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
• Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign imported narcotics;
• Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
• Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA around the two agencies' shared goals.

Question 35. In 2007, you openly criticized the REMS program in writing[18] and in speeches.[19] During your confirmation hearing, however, you indicated that your original concerns about REMS did not manifest because FDA used the REMS process more judiciously than initially proposed. Recognizing the overuse and addiction potential of all opioid painkillers, in 2012, the FDA approved a post-market shared REMS for a subset of highly potent prescription opioid painkillers known as extended-release (ER) and long-acting (LA) formulations, of which OxyContin is included. In developing the class-wide ER/LA REMS established in 2012, FDA convened an advisory committee that overwhelmingly indicated that the REMS proposed was not sufficient to address the risks associated with use of opioid painkillers.[20]

Do you believe the REMS process has sufficiently mitigated the risks of opioids as originally intended?

Do you think REMS are a good tool to manage public health risks associated with opioids?

How would you strengthen this process?

Answer 35. REMS are an important tool for helping to address the risk of diversion, misuse and addiction related to opioids. But they are only one tool. Clearly FDA needs to be taking many more, and more aggressive steps, to address this staggering human catastrophe of addiction and abuse. To date, no tool or policy, or combination of approaches, has sufficiently mitigated the risk of opioids. If confirmed, I will immediately work closely with staff at FDA to see what additional steps we can take across the full range of FDA's authorities and responsibilities, including through the use of the agency's authorities under the REMS provisions, to more aggressively address this crisis.

Question 36. During your confirmation hearing, you referred to the opioid crisis as an important public health emergency on the same scale as Ebola. For Ebola, in a matter of a few months, the U.S. Government increased funding and resources

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[18] Gottlieb, Scott. "Drug Safety Proposals and the Intrusion of Federal Regulation Into Patient Freedom and Medical Practice." *Health Affairs*, vol. 26, no. 3, 2007, pp. 664–77, *http://content.healthaffairs.org/content/26/3/664.* Accessed 7 Apr. 2017.

[19] Gottlieb, Scott. "Remarks by Scott Gottlieb, M.D., Deputy Commissioner for Medical and Scientific Affairs, Food and Drug Administration." American Medical Association, 12 June 2006, *https://www.fda.gov/NewsEvents/Speeches/ucm051908.htm*.

[20] "Summary Minutes of the Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and the Drug Safety and Risk Management Advisory Committee." *Food and Drug Administration*, *http://www.supportprop.org/wp-content/uploads/2014/12/Minutes__20100722–23-ALSDAC-DSaRM-M1-Minutes.pdf*. Accessed 7 Apr. 2017.

and stood up centers of excellence to better understand and combat this epidemic. The FDA responded by doing the following:[21]

• Created an Ebola Task Force to help accelerate the development of medical products, which included direct engagement with industry and academic experts.
• Deployed staff to the heart of the epidemic.
• Collaborated with other agencies and regulators to share insight and information.
• Used the agency's Emergency Use Authorization to test unapproved products or uses of products to help stymie the spread of the disease.
• Monitored fraudulent or misleading claims from companies about the efficacy of their products.

If confirmed, will you advocate for similar initiatives to address the opioid epidemic to happen immediately?

What could the FDA have done differently to help prevent, or at least stem, the opioid crisis?

If confirmed, how will you incorporate these lessons into your leadership agenda?

Answer 36. If confirmed, I will take immediate and aggressive steps to try and get ahead of this crisis. In my opinion, one of the many lessons learned from our Nation's inability to effectively combat the opioid epidemic to-date is that we didn't take aggressive action early enough in the throes of this crisis to stem its tide, and to get ahead of its evolution from a problem of prescription drugs to one that now also involves illicit street drugs. That will be one of among other lessons that I take to this task if confirmed—that to adequately address the opioid crisis, it will require us to take perhaps even more aggressive measures than we might have originally contemplated, since we have not been accurate in measuring the full scope of this growing crisis, or in effectively calibrating our regulatory steps to confront the epidemic. I also believe, among other things, effectively combating this crisis is going to require much closer collaboration between different Federal and State agencies, and it would be my immediate goal to seek even closer partnerships with agencies such as DEA and CMS and other Federal and State entities that play an important role in confronting aspects of this crisis.

Question 37. In 1995, the FDA approved the original formulation of OxyContin, which FDA considered abuse-deterrent based on premise that its extended-release properties would make it less likely to be abused. However, we know from OxyContin that abuse-deterrent formulations do not make opioids less addictive. Unfortunately, many prescribers appear to be unaware of this pivotal implication. In fact, a survey of primary care physicians found that nearly half of all primary care doctors incorrectly believed that abuse-deterrent formulations are less addictive.[22]

Do you think "abuse deterrent formulation" is good terminology that the agency should continue to use?

What steps would the FDA need to take to make a labeling change that better characterizes the fact that abuse deterrent does not mean addiction proof?

Answer 37. We need to make sure we are using the appropriate terminology to describe these technologies and not creating misperceptions with respect to how we label these products. If confirmed into this role, I would be committed to working with the professional staff at FDA to make sure we are asking the appropriate questions about how we describe these features in labeling, and what perceptions are conferred to providers by those descriptions.

Question 38. Last year, the CDC issued guidelines on the use of opioid pain medication for chronic pain that reflects the rise in opioid addiction and overdoses.[23] These guidelines recommended, among other things, that opioids should be prescribed at the lowest effective dose, and that an upper limit of 90 milligrams/day should not be exceeded. The CDC has made clear that a dose above 90 milligrams/day is dangerously high. Yet opioid formulations come in dosage units that are so high, just one pill twice a day can exceed 90 mg of morphine. For example, a patient

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[21] Hamburg, Margaret A. "FDA as Part of a Coordinated Global Response on Ebola." *Food and Drug Administration*, 28 Oct. 2014, *https://blogs.fda.gov/fdavoice/index.php/2014/10/fda-as-part-of-a-coordinated-global-response-on-ebola/*.

[22] Hwang, Catherine S., et al. "Primary Care Physicians Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion." *The Clinical Journal of Pain*, vol. 32, no. 4, 2016, pp. 278–84, *http://journals.lww.com/clinicalpain/Citation/2016/04000/Primary__Care__Physicians Knowledge__And__Attitudes.1.aspx.* Accessed 7 Apr. 2017.

[23] Dowell, Deborah. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016." *Morbidity and Mortality Weekly Report*, vol. 65, no. 1, 2016, pp. 1–49, *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.* Accessed 7 Apr. 2017.

taking Opana ER 40 mg twice a day is taking the equivalent of 240 mg of morphine. That is more than 2.5 times the CDC's upper dose limit. Yet the patient and prescriber may be unaware that this is a dangerously high dose, because it is only one pill taken twice a day. If confirmed, how can FDA incorporate some of the CDC guidelines on opioid medication into FDA policies related to approvals and labeling?

Answer 38. If confirmed, I would be committed to working with staff at FDA to fully evaluate the CDC guidelines as one part of a comprehensive effort to try and address this crisis, and to making sure we are properly and fully leveraging the expertise at sister agencies like CDC and other government partners in addressing these challenges.

Question 39. You said during your confirmation hearing that the opioid epidemic is larger than the FDA, and that we must use an "all-of-the-above approach" to tackling this epidemic. In addition to spending several years at the FDA, you were also a senior adviser to the Centers for Medicare and Medicaid Services (CMS). CMS also has levers to pull to help combat the opioid crisis, including coverage for and availability of treatment options for mental health and substance use disorders. Given your knowledge of both CMS and FDA, and your experience working on behalf of pharmaceutical companies navigating these agencies, how would you ensure these agencies work together and coordinate on policies to address the opioid epidemic?

Answer 39. I believe there are many opportunities for agencies to more closely collaborate to address this crisis. Indeed, properly addressing it is going to require much closer coordination between law enforcement and public health agencies at both the local and Federal level.

Among other things, CMS can help FDA better understand patterns of use and abuse that can help inform the drug review process, both pre- and post-market, as well as assist the FDA in its post-market surveillance. If confirmed, it would be one of my immediate goals, in an all-of-the-above approach, to seek new ways to collaborate more closely with other local and Federal agencies, including CMS, to see where we can gain more alignment and leverage in combating this public health crisis.

Question 40. In a 2015 op-ed published in the *Wall Street Journal*, you argued that the ACA permits a "government takeover of drug pricing." Specifically, you cite the Centers for Medicare and Medicaid Innovation (CMMI) as a mechanism for this government control. Even private sector payers and drug manufacturers agree that value-based models of drug pricing could help ensure patients have access to affordable prescription drugs. What types of drug pricing demonstrations do you think would be reasonable for CMMI to test?

Answer 40. As the nominee to be the next Commissioner of Food and Drugs, I do not believe it would be appropriate to comment on questions about issues that are outside the jurisdiction of FDA.

Question 41. In your OGE Form 278, you stated that Venture Partner at New Enterprise Associates (NEA) was simply a working title. It is unclear what that means and to what extent you were involved in the company's broader healthcare portfolio. Collectively, NEA's client companies have at least 40 drug products in the product pipeline for which they may seek approval from the FDA. In your ethics agreement, you committed to recuse yourself from matters involving NEA and two client companies—American Pathology Partners and Collective Health—for 1 year.

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge, from matters involving all of NEA's clients? If not, why will you not take this extra step promised by the President who nominated you?

You have committed to recusing yourself for 1 year from the date of your resignation for matters involving NEA, American Pathology Partners, and Collective Health. Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for those companies? If not, why will you not take this extra step promised by the President who nominated you?

Answer 41. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives

the American public confidence in the integrity of the FDA's decisionmaking process.

Question 42. In your OGE Form 278e, you disclose that you were an investor in NEA 14 Limited Partnership ("NEA 14"). You further disclose that NEA 14 holds an investment in Cerecor, Inc., a biopharmaceutical company with two compounds—CERC–501 and CERC–611—currently being tested in clinical trials. While I understand that you have divested yourself from NEA 14 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which Cerecor Inc. is a party, including, but not limited to, proceedings concerning CERC–501 and CERC–611?

Answer 42. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 43. In your OGE Form 278e, you disclose that you were an investor in NEA 14 Limited Partnership ("NEA 14"). You further disclose that NEA 14 holds an investment in Loxo Oncology, Inc., a biopharmaceutical company with three compounds—LOXO–101, LOXO–195, and LOXO–292—currently being tested in clinical trials or slated to begin Phase I trials imminently. While I understand that you have divested yourself from NEA 14 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which Loxo Oncology, Inc. is a party, including, but not limited to, proceedings concerning LOXO–101, LOXO–195, LOXO–292?

Answer 43. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 44. In your OGE Form 278e, you disclose that you were an investor in NEA 14 Limited Partnership ("NEA 14"). You further disclose that NEA 14 holds an investment in Lumena Pharmaceuticals, Inc. a biopharmaceutical company with two compounds—LUM–001 and LUM–002—currently being tested in clinical trials. While I understand that you have divested yourself from NEA 14 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which Lumena Pharmaceuticals, Inc. is a party, including, but not limited to, proceedings concerning LUM–001 and LUM–002?

Answer 44. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 45. In your OGE Form 278e, you disclose that you were an investor in NEA 14 Limited Partnership ("NEA 14"). You further disclose that NEA 14 holds an investment in TRACON Pharmaceuticals, Inc., a biopharmaceutical company with three compounds—TRC–105, TRC–102, and DE–122—currently being tested in clinical trials. While I understand that you have divested yourself from NEA 14 pur-

suant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which TRACON Pharmaceuticals, Inc. is a party, including, but not limited to, proceedings concerning TRC–105, TRC–102, and DE–122?

Answer 45. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 46. In your OGE Form 278e, you disclose that you were an investor in NEA 15 Limited Partnership ("NEA 15"). You further disclose that NEA 15 holds an investment in Ardelyx, Inc., a biopharmaceutical company with three compounds—Tenapanor, RDX–8940, and RDX–7675—currently being tested in clinical trials. While I understand that you have divested yourself from NEA 15 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which Ardelyx, Inc. is a party, including, but not limited to, proceedings concerning Tenapanor, RDX–8940, and RDX–7675?

Answer 46. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 47. In your OGE Form 278e, you disclose that you were an investor in NEA 15 Limited Partnership ("NEA 15"). You further disclose that NEA 15 holds an investment in Millendo Therapeutics, Inc., a biopharmaceutical company with two compounds—ATR–101 and MLE–4901—currently in clinical trials. While I understand that you have divested yourself from NEA 15 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which Millendo Therapeutics, Inc. is a party, including, but not limited to, proceedings concerning ATR–101 and MLE–4901?

Answer 47. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 48. In your OGE Form 278e, you disclose that you were an investor in NEA 15 Limited Partnership ("NEA 15"). You further disclose that NEA 15 holds an investment in ObsEva SA, Ltd., a biopharmaceutical company with three compounds—OBE–2109, OBE–001, and OBE–022—currently in clinical trials. While I understand that you have divested yourself from NEA 15 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which ObsEva SA, Ltd. is a party, including, but not limited to, proceedings concerning OBE–2109, OBE–001, and OBE–022?

Answer 48. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my serv-

ice to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 49. In your OGE Form 278e, you disclose that you were an investor in NEA 14 Limited Partnership ("NEA 14") and NEA 15 Limited Partnership ("NEA 15"). You further disclose that NEA 14 and NEA 15 hold investment in the following biopharmaceutical companies: Amplyx Pharmaceuticals, Inc. (NEA 15); Cleave Biosciences, Inc. (NEA 14); Clementia Pharmaceuticals Inc. (NEA 15); Envisia Therapeutics Inc. (NEA 14); Galera Therapeutics, Inc. (NEA 14); Lumos Pharma, Inc. (NEA 14); Mersana Therapeutics, Inc. (NEA 14); Mirna Therapeutics, Inc. (NEA 14); NightstaRx Ltd. (NEA 15); SetPoint Medical Corp. (NEA 15); Vtesse Inc. (NEA 14); and Ziarco Group Ltd. (NEA 14). While I understand that you have divested yourself from NEA 14 and NEA 15 pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which any of the companies listed above is a party?

Answer 49. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 50. In your OGE Form 278, you stated that managing director of investment banking at T.R. Winston & Company was simply a working title.[24] It is unclear what that means and to what extent you oversaw transactions specifically as part of the healthcare banking team. Since you started in April 2013, T.R. Winston was involved in 12 large healthcare transactions involving 9 healthcare companies.[25] You have financial interests in five of those nine companies.[26] Additionally, you have financial interests in two other T.R. Winston healthcare client companies that were not involved in transactions since the beginning of your tenure. Collectively, T.R. Winston's client companies have at least 77 drug products in the products pipeline for which they may seek approval from the FDA.

Did you oversee the 12 healthcare transactions as managing director of investment banking? If not, what was your involvement in those transactions? Will you recuse yourself for the 2 years laid out in the Trump ethics pledge, from matters involving all of T.R. Winston's clients? If not, why will you not take this extra step promised by the President who nominated you?

You have committed to recusing yourself for 1 year from the date of your resignation for matters involving T.R. Winston, Cell BioTherapy, Tivorsan Pharmaceuticals, and Kure.

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for those companies? If not, why will you not take this extra step promised by the President who nominated you? Will you recuse yourself from involvement in decisions that affect all of T.R. Winston's investment banking healthcare clients?

Answer 50. As a general matter, my role at T.R. Winston was to provide clinical and healthcare policy support to the transaction team. I did not oversee transactions. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service

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[24] Executive Branch Personnel Public Disclosure Report (OGE Form 278e), Scott Gottlieb (U.S. Office of Government Ethics Certification Mar. 28, 2017).

[25] T.R. Winston & Company, Transactions (online at *http://www.trwinston.com/transactions/*) (accessed Apr. 7, 2017).

[26] Letter from Scott Gottlieb, M.D., to Elizabeth J. Fischmann, Esq., Associate General Counsel for Ethics/Designated Agency Ethics Official, U.S. Department of Health and Human Services (Mar. 28, 2017).

I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 51. In your ethics agreement, you noted that you do not "hold any financial interest in T.R. Winston & Company;" however, you disclosed that you do hold a financial interest in 13 of T.R. Winston's client companies—one of which is Inspyr Therapeutics, Inc. (previously known as GenSpera).[27] You have not committed to recuse yourself from matters involving Inspyr. This company is currently developing a platform technology to deliver its active ingredient to tumors in a way that is less toxic to the body. Inspyr's lead investigational agent, mipsagargin (G–202), is a prodrug in human clinical trials for patients with hepatocellular carcinoma, glioblastoma, and prostate cancer. Inspyr has four different products in ongoing or completed Phase II clinical trials.[28] The decision whether to approve these products may occur during your tenure at FDA if you are confirmed.

Though you will have divested your financial interest in the company, do you think you can truly be impartial and independent as the agency makes approval decisions for these products?

To avoid any appearance of impropriety, do you think it would be better to recuse yourself from these decisions?

Answer 51. If confirmed I will undertake and perform the duties of FDA commissioner impartially, as a passionate advocate for public health and in the best interests of the American people, guided by the science that informs the FDA's work. I will abide by all applicable ethics laws and regulations, including those that govern recusals, and am committed to performing my official duties in a manner that gives the public confidence in the integrity of the FDA's decisionmaking process.

Question 52. Neuralstem is a biotechnology company that specializes in developing commercial-scale production of multiple types of central nervous system stem cells. While you were managing director of T.R. Winston's Investment Bank, T.R. Winston oversaw a $4,556,000 capital markets transaction in September 2014 and a $20,000,000 capital markets transaction in January 2014.[29] Additionally, you have stated that you hold financial interests in this company. According to your OGE Form 278, you have 22,308 warrants to purchase shares at $39 a share.[30] You have not committed to recuse yourself from matters involving Neuralstem. Neuralstem has at least six products in clinical trials that will require FDA approval.[31] For example, Neuralstem is expecting to initiate a Phase II trial evaluating NSI–189 a treatment for major depressive disorder (MDD). Do you think your previous business and financial ties to the company have compromised your ability to be impartial when approval decisions come before the agency?

Answer 52. If confirmed I will undertake and perform the duties of FDA commissioner impartially, as a passionate advocate for public health and in the best interests of the American people, guided by the science that informs the FDA's work. I will abide by all applicable ethics laws and regulations, including those that govern recusals, and am committed to performing my official duties in a manner that gives the public confidence in the integrity of the FDA's decisionmaking process.

Question 53. Celgene is a global biotechnology company that is currently sponsoring more than 100 clinical trials examining on at least 25 compounds that Celgene may seek FDA approval.[32] Celgene is a T.R. Winston client company, but your ethics agreement does not indicate whether you will not be recused from mat-

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[27] Letter from Scott Gottlieb, M.D., to Elizabeth J. Fischmann, Esq., Associate General Counsel for Ethics/Designated Agency Ethics Official, U.S. Department of Health and Human Services (Mar. 28, 2017).

[28] Inspyr Therapeutics, Products Pipeline (online at *http://www.inspyrtx.com/product-pipeline*) (accessed Apr. 7, 2017)

[29] T.R. Winston & Company, Transactions (online at *http://www.trwinston.com/transactions/*) (accessed Apr. 7, 2017).

[30] Executive Branch Personnel Public Disclosure Report (OGE Form 278e), Scott Gottlieb (U.S. Office of Government Ethics Certification Mar. 28, 2017).

[31] NeuralStem, Cell Therapy Treatments in Development (online at *http://www.neuralstem.com/patient-info-treatments-in-development#celltherapy*) (accessed Apr. 7, 2017)

[32] Celgene, Product Pipeline (online at *http://www.celgene.com/content/uploads/product-pipeline.pdf*) (accessed Apr. 7, 2017).

ters involving Celgene.[33] Will you be recused from working on matters involving Celgene?

Answer 53. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 54. Two T.R. Winston companies in which you have a financial interest—Angion Biomedica Corp. and Emmaus Life Sciences—have products in clinical trials. While I understand that you will divest yourself from these two companies pursuant to your ethics obligations, will you recuse yourself personally and substantially in any particular matter in which any of the companies listed above is a party?

Answer 54. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 55. AMAG Pharmaceuticals—a T.R. Winston client company in which you do not have a financial interest—has at least two products in clinical trials. Your ethics agreement does not address whether you will be recused from matters involving AMAG Pharmaceuticals. Will you recuse yourself personally and substantially in any particular matter in which AMAG Pharmaceuticals is a party?

Answer 55. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 56. You have served as an independent member of the board of directors for Gradalis, a position for which you earned approximately $65,000 last year.[34] In addition, you have stated that you have a financial interest in the company—25,000 stock options to purchase shares at $3.16 a share and 25,000 options at $3.57 a share. You have noted that these are vested stock options and you intend to divest within 90 days of your confirmation.[35] Further you have noted that you will recuse yourself from 1 year after your resignation, which should expire March 2018 since you resigned your position in March 2017. Gradalis is a late-stage biopharmaceutical company developing a platform technology which may have multiple cancer indications, and currently have at least five products in clinical trials that may re-

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[33] Letter from Scott Gottlieb, M.D., to Elizabeth J. Fischmann, Esq., Associate General Counsel for Ethics/Designated Agency Ethics Official, U.S. Department of Health and Human Services (Mar. 28, 2017).

[34] Executive Branch Personnel Public Disclosure Report (OGE Form 278e), Scott Gottlieb (U.S. Office of Government Ethics Certification Mar. 28, 2017).

[35] Letter from Scott Gottlieb, M.D., to Elizabeth J. Fischmann, Esq., Associate General Counsel for Ethics/Designated Agency Ethics Official, U.S. Department of Health and Human Services (Mar. 28, 2017).

quire FDA approval.[36] Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for Gradalis? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 56. I have previously resigned from the Gradalis board and surrendered my stock options. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 57. Daiichi Sankyo is a global pharmaceutical company; you have served as an independent member of the board of directors since April 2015 and you have agreed to resign upon your confirmation. You have agreed to recuse yourself for 1 year after your resignation from matters affecting Daiichi Sankyo, which has at least 28 products being tested in clinical trials that may seek FDA approval.[37]

Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for Daiichi Sankyo? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 57. I have previously resigned from the Daiichi board of directors. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 58. GlaxoSmithKline is a global pharmaceutical company that you have served as member of the Product Investment Board (PIB), and you have agreed to resign upon your confirmation. You have agreed to recuse yourself for 1 year after your resignation from matters affecting GlaxoSmithKline, which has nearly 100 products being tested in clinical trials, for which it may seek FDA approval.

Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for GlaxoSmithKline? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 58. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters,

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[36] Gradalis, Platform & Pipeline (online at *http://www.gradalisinc.com/index.php/pipeline/pipeline.html*) (accessed Apr. 7, 2017).

[37] Daiichi-Sankyo, Pipeline Chart (Jan. 2017) (online at *http://www.daiichisankyo.com/rd/pipeline/development__pipeline/index.html*).

including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 59. In your ethics agreement, you explained that you established Innovating Healthcare LLC for the purposes of a single consulting project with Bristol-Myers Squibb. You have agreed to recuse yourself for matters involving Bristol-Myers Squibb for 1 year from the date you last provided service to the company. Bristol-Myers Squibb has at least 30 products being tested in clinical trials, for which it may seek FDA approval.

Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for Bristol-Myers Squibb? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 59. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 60. You served as member of the board of director of Tolero Pharmaceuticals until December 2016. You have agreed to recuse yourself for 1 year after your resignation from matters affecting Tolero Pharmaceuticals, which has two products being tested in clinical trials, for which it may seek FDA approval.

Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for Tolero Pharmaceuticals? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 60. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 61. In your ethics agreement, you explained that you provided consulting services for Vertex Pharmaceuticals through YourEncore. You have agreed to recuse yourself for matters involving Vertex Pharmaceuticals for 1 year from the date you last provided service to the company. Vertex Pharmaceuticals has at least seven products being tested in clinical trials, for which it may seek FDA approval.

Do you think your 1-year recusal sufficiently removes any bias posed by your investment and ties to this company?

Will you recuse yourself for the 2 years laid out in the Trump ethics pledge for Vertex Pharmaceuticals? If not, why will you not take this extra step promised by the President who nominated you?

Do you think it would be better and more likely to avoid conflicts if your recusal were longer?

Answer 61. If confirmed, I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials

at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement. I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process.

Question 62. The FDA Commissioner will need to be deeply engaged when we face another public health crisis. Given the scope of your financial entanglements, I am concerned that you may be unable to effectively lead the agency in this scenario. You are, unfortunately, familiar with being recused when FDA responds to an emerging threat. When you were the agency's deputy commissioner in 2005, you could not participate in many decisions about how to combat the avian flu because you had worked for two drug companies—Roche and Sanofi—who worked to develop products to fight back against the deadly flu.[38] Now, in order to comply with Federal conflict-of-interest and ethics laws, you have committed to recuse yourself from decisions related to more than 20 companies where you hold, or previously held, positions. While this represents a small fraction of the medical product companies in which you have a financial stake, this includes seven pharmaceutical companies and two clinical lab companies. Of particular concern is your recusal from matters involving GlaxoSmithKline. GSK is one of the top vaccine makers in the world, and they have been involved in developing vaccines in response to the Ebola and Zika outbreaks.[39] You received hundreds of thousands of dollars in compensation from the company in the last several years.[40] It seems possible—if not likely—that they would be involved in a response to the next disease outbreak. Any of these 20 companies could be called on to assist in the response to a public health crisis. Would the American people be better served in a time of crisis by an FDA Commissioner who was not recused from matters related to such a large number of companies and whose focus was guaranteed to be on the crisis and not on the sidelines?

Answer 62. I was compensated by GSK, for my services on the product investment board, through a retainer in the amount of $60,000 annually. I was also reimbursed for out-of-pocket travel costs to attend meetings. If confirmed, I intend to lead the FDA as an impartial and passionate advocate for the public health and am confident that I can fully perform the duties of the FDA commissioner. I do not believe that the recusals set forth in my ethics agreement will impair my ability to discharge the responsibilities of this office. All nominees come to their positions with a range of experiences, which necessitate some recusals to ensure compliance with relevant ethics standards. It is routine in those circumstances for other senior agency officials to be involved in the matter and I have every confidence that if I am recused, my team at FDA will ensure that Congress's laws will be properly implemented and the FDA's mission fulfilled.

SENATOR ENZI

Question 1. FDA's menu-labeling rule, even after an initial stay, will take effect 1 month from today. Grocery stores and other food retailers across America continue to be frustrated with FDA's handling of things, including for local and seasonal food items. Fresh and local food items may be sold at a few stores, under the same name, but the ingredients or recipe can vary, yet they would be considered "standard menu items" and subject to enforcement. The irony is that this will cause stores and restaurants to move away from fresh, local, and seasonal offerings. With just a month before the compliance date, we need FDA to act quickly to further delay, withdraw, or stay the rule so it can be rewritten to give businesses the flexibility to comply. Would you be willing to explore ways to encourage FDA to act before the compliance date to provide this much-needed flexibility for businesses?

Answer 1. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the technical specifics. As a general rule, I support providing clear, accurate, and understandable information to American consumers to help inform healthful dietary choices. I believe information about caloric content can be a useful tool. However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with the agency's staff

[38] *http://archive.boston.com/business/healthcare/articles/2005/11/12/fda__official__recused__in__flu__fight/*.
[39] *https://www.bloomberg.com/news/articles/2016–09–08/glaxo-proposes-global-body-to-tackle-outbreaks-like-zika-ebola*.
[40] *https://www.wired.com/2017/03/trumps-fda-pick-friends-big-pharma-doesnt/*.

to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing unnecessary compliance burden on businesses, particularly small, independent ones.

SENATOR SANDERS

Question 1. The FDA's mission statement includes the directive to make medicines "more effective, safer, and more affordable." Setting aside the ongoing debate over generic drug approvals, please discuss how you think FDA can make medicines more affordable.

Answer 1. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate product competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires.

Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some innovator products for which traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 2. It has been reported that you have received millions of dollars from pharmaceutical companies. Please explain how you would address your myriad conflicts of interest.

Do you believe you can be an effective Commissioner when you will need to recuse yourself so often? Do you think there is a tipping point where the conflicts are too great to overcome?

Answer 2. If confirmed, I intend to lead the FDA as an impartial and passionate advocate for the public health and am confident that I can fully perform the duties of the FDA commissioner. I will abide by all of the commitments set forth in my ethics agreement and will comply with all applicable laws and regulations. I will also be bound by the requirements and restrictions set forth in this Administration's Ethics Pledge (EO 13770). If confirmed, I will meet with the career ethics officials at the Department of Health and Human Services during the first week of my service to ensure compliance with all of these ethics standards. Throughout my public service I will consult with appropriate ethics officials for guidance on these matters, including with respect to any recusal obligations not already set forth in my ethics agreement.

I am committed to leading the FDA in an impartial manner that gives the American public confidence in the integrity of the FDA's decisionmaking process. I do not believe that the recusals set forth in my ethics agreement will impair my ability to discharge the responsibilities of this office. All nominees come to their positions with a range of experiences, which necessitate some recusals to ensure compliance with relevant ethics standards. It is routine in those circumstances for other senior agency officials to be involved in the matter and I have every confidence that, if I am recused, my team at FDA will ensure that Congress's laws will be properly implemented and the FDA's mission fulfilled.

Question 3. During our meeting in my office, you stated that the Nation's opioid crisis would be among your top priorities. As I am sure you know, it has hit my State of Vermont very hard. You also noted that the FDA took incremental actions that never managed to get ahead of the opioid crisis.

What role do you think FDA should play today in more aggressively addressing the opioid epidemic while also ensuring that Americans living with both acute and chronic pain do not suffer from poor pain management?

How do we balance the need for patient access to effective pain relief medications while also preventing opioid addiction?

Answer 3. Opioid abuse, misuse, and addiction constitute one of the most urgent and immediate public health threats facing our Nation. It is also the biggest public health crisis facing the FDA. The human and economic toll of this crisis is staggering. If confirmed, this will be my highest immediate priority. I will make sure FDA is aggressive, forward leaning, and fully engaged in combating this epidemic.

I will work with FDA's staff to ensure FDA has the right policies and processes in place to:

- Facilitate the developments of new approaches and technologies to reduce the abuse/addictive potential of painkillers American patients use;
- Support the development of non-opioid analgesic alternatives for physicians and patients;
- Assess whether FDA's current approach to opioid regulatory decisions, including labeling, REMS, and physician/patient education are appropriate, robust, and fully effective;
- Encourage the development of new pharmacological tools for physicians and patients to both prevent opioid misuse and abuse, and support treatment and recovery for patients struggling to overcome opioid addiction;
- Enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools to better target this information;
- Taking steps to make sure that providers are appropriately educated on identifying, and helping to property intervene with, abuse-prone patients;
- Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
- Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign-imported narcotics;
- Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
- Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA on the two agencies shared goals.

Question 4. Tobacco use is the leading cause of preventable death and disability in the United States. Cigarette smoking claims nearly half a million lives every year and more than 8.5 million people suffer from tobacco-related chronic diseases. In 2006, you recognized that cigarette smoking is "the single most preventable cause of death in the United States and is responsible for a growing list of cancers, as well as chronic diseases." But since then, you have made disturbing comments about where you stand on tobacco regulation. In 2009, you opposed FDA regulating tobacco because you said it would "gut the agency's resources and distract it from our core mission."

Why should we confirm someone to be the head of the FDA who does not believe the FDA should regulate tobacco?

Could you or any of the firms you have worked for financially benefit if the FDA weakens or eliminates regulations on tobacco or nicotine products?

Answer 4. Through the Tobacco Control Act (TCA), Congress gave FDA regulatory responsibility over tobacco products. If confirmed, I will be committed to implementing the TCA, as intended by Congress. As I was not at FDA during the agency's initial TCA implementation activities, I am not fully acquainted with internal processes or specific decisions to-date. If confirmed, I will work with staff to quickly get up-to-speed on this issue, and I will review current FDA policies, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is consistent with congressional intent under the TCA. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health. In pursuing these objectives, I will be guided only by the public health and the mandate of Congress.

Question 5. While the law bans companies from using flavors like cherry, vanilla and cinnamon in cigarettes, there was one exemption from that list of flavors: Menthol. Today, nearly one in every three cigarettes sold in the United States are menthol cigarettes and there are an estimated 20 million people who smoke menthol cigarettes.

Tobacco companies have long used aggressive marketing of menthol cigarettes to target our Nation's most vulnerable populations: Young people, women, LGBTQ populations and people of color. It is not a surprise that nearly 50 percent of all teenagers—many of whom are in middle school—who are addicted to cigarette smoking started by smoking menthol cigarettes because the minty flavor tastes better to first-time smokers.

Women are 1.6 times more likely than men to smoke menthol cigarettes. Additionally, 8 in 10 African Americans, more than half (53 percent) of Native Hawaiian and Pacific Islanders, and one-third of Latinos and Asians who smoke choose menthol cigarettes.

One of the things that the 2009 law did was give the FDA the authority to ban menthol cigarettes. The 2011 TPSAC report concluded that the "removal of menthol cigarettes from the marketplace would benefit public health in the United States." A separate study conducted by the FDA in 2011 and reported out in 2013 found that "menthol use is likely associated with smoking initiation by youth and young adults." This same report also found that "menthol in cigarettes is likely associated with greater addiction" and that menthol cigarettes post a greater risk to public health than non-menthol cigarettes.

Following these report findings, cigarette companies sued the FDA in 2011 in an attempt to prevent the FDA from acting on the TPSAC findings and recommendations. A tobacco-sympathizing judge (Judge Leon) initially directed the FDA to overlook and disregard the TPSAC report and findings. The FDA appealed the ruling and in January 2016, Judge Leon's decision was reversed, opening the door for the FDA to take action to regulate and even ban menthol cigarettes. Yet, menthol cigarettes remain on the shelves of stores across the country today.

Given all that we know about menthol cigarettes—none of which is good—do you support banning menthol cigarettes from the U.S. market and, if so, would banning menthol cigarettes be an action you would take during your first year as Commissioner?

Answer 5. I have not reviewed the scientific evidence related to the addition of menthol in cigarettes. If confirmed, I will commit to engaging with FDA's staff to quickly get up to speed on the regulatory history of this issue, and the agency's latest information, thinking, and actions. I would welcome the opportunity to work with Congress on this issue moving forward.

Question 6. Marijuana is currently listed as a Schedule I substance ("drugs with no currently accepted medical use and a high potential for abuse") under the Controlled Substances Act (CSA)—meaning under Federal law, marijuana is considered to be as dangerous as heroin, and more dangerous than opioids. The Drug Enforcement Agency could potentially take action to reschedule marijuana, pending evaluation from the FDA. If marijuana were rescheduled, the FDA would likely wind up with the authority to regulate marijuana and marijuana-derived drugs.

Do you believe that marijuana is properly classified under the CSA?

Do you think FDA should have the authority to regulate marijuana?

Answer 6. I am aware that in July 2016, DEA determined, in consultation with HHS, that marijuana continues to meet the criteria for Schedule I control under the Controlled Substances Act. I cannot speak to decisions that the DEA might take in the future or the likelihood of FDA regulating marijuana. I do know that FDA is currently involved in supporting scientific research related to medicinal uses of marijuana and its constituents.

SENATOR BURR

Question 1. The 21st Century Cures Act requires FDA to update guidance and regulations for regenerative therapeutic products and to hold a public meeting to encourage innovation. This is a great first step, and we are hopeful that you will prioritize the potential of these products as the new Commissioner of the FDA. If you are confirmed, how do you envision FDA's regulatory framework for these cutting edge treatments and therapies now and in the future?

Answer 1. Regenerative medicine is one of the most innovative and promising emerging advancements in our scientific approaches to the treatment of human disease. Regenerative medicine appears to hold great promise for new therapeutic options for patients and physicians, particularly in areas of unmet or underserved medical need. However, as with all products FDA regulates, the agency must have the appropriate policies and processes in place to assess and ensure the safety and efficacy of regenerative medical products before they are approved for use by American patients. FDA must ensure patients and providers are appropriately educated about the potential risks and benefits of regenerative medicine therapies that fall within the scope of FDA's oversight, and that these products meet the agency's standard for safety and effectiveness. If confirmed, I will embrace the responsibility to facilitate important medical innovation in the regenerative medicine space, while maintaining the Gold Standard of safety and efficacy.

Question 2. The Tobacco Control Act gave FDA the authority to regulate tobacco products. The tobacco industry has seen an evolution in the products available to

consumers, and the FDA has deemed new and novel technologies to be regulated the same way as traditional combustible products. These products vary based on risk, and because of these new technologies, consumers have the opportunity to choose a less harmful product. If you are confirmed, how do you envision new technologies being reviewed by the Center for Tobacco Products at the FDA?

Answer 2. If confirmed, I will be committed to implementing the TCA, as intended by Congress, including Section 911 related to modified risk products, which I recognize can provide helpful tools for current tobacco-users to transition off combustible tobacco. As I was not at FDA during the agency's initial TCA implementation activities, I am not fully acquainted with internal processes or specific decisions to-date. If confirmed, I will work with staff to quickly get up-to-speed on this issue, and I will review current FDA policies, including the deeming rule, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is consistent with congressional intent under the TCA. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

SENATOR CASEY

Question 1. The FDA plays an important role in responding to real and potential biological threats. Under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the FDA has important authorities such as the Emergency Use Authorization and the so-called "Animal Rule" regulation that outlines how FDA will consider animal data when it would be impossible or unethical to test a medical countermeasure. Another important consideration is the need for robust medical countermeasure development. Instead of a piecemeal approach that tackles one threat at a time—the so-called "one bug, one drug" approach—there is great potential to develop products so that one product can tackle multiple threats. Will you commit to considering the potential scale and scope of potential medical countermeasures during the FDA review process?

Answer 1. I recognize the important role FDA plays in supporting the development of medical countermeasures. I commit to considering the potential scale and scope of potential medical countermeasures during the FDA review process.

Question 2. Back in 2009, you wrote quite extensively about the Federal Government's response to the H1N1 pandemic flu,[41] both praising the speed of the Federal Government's decision to order vaccine and criticizing the speed at which the vaccines were produced and distributed. Since then, we have made significant improvements toward greater preparedness for influenza, including bringing new vaccine production capacity online and approving a new quadrivalent vaccine that protects against four strains of flu.

Do you agree that vaccines are an important part of our public health preparedness, and that we must continue to develop, produce and distribute vaccines (such as, but not limited to, flu vaccine) to improve the Nation's public health, preparedness and response capabilities for emergencies?

Do you think we are better prepared to approve and make available vaccines for vaccine-preventable illnesses? What further steps would you take as Commissioner to promote preparedness?

Answer 2. Yes, I strongly agree that vaccines are an important component of our public health preparedness. I believe that FDA has taken significant steps to support the development and approval of new vaccines. If confirmed, I will commit to ensuring that FDA has the appropriate policies and processes in place to protect and promote public health and working with FDA's partners to pursue a comprehensive strategy to increase our public health preparedness.

Question 3. Dr. Gottlieb, during our meeting you raised the possibility of steps that the FDA can take to increase what you termed "product competition," or the availability of generics. Yet of the roughly 2,000 Abbreviated New Drug Applications pending as a part of the generic backlog, only 15 are for first-in-class generics or for drugs that currently have a single manufacturer on the market.

I am not sure I understand how adding the tenth or twelfth generic of a common drug will address the high costs facing patients with branded drugs. What other steps would you take as Commissioner to increase generic competition?

Additionally, 8 of the 10 drugs that experienced the greatest drug price increases in 2014 were generic medications, with multiple manufacturers. What will you do to address these price hikes?

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[41] American Enterprise Institute Health Policy Outlook, November 2009, and the *Wall Street Journal*, *https://www.wsj.com/articles/SB10001424052748704335904574497324151841690*.

Answer 3. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition.

If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some innovator products for which traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 4. If confirmed as FDA Commissioner, what strategies do you support to share meaningful data on the safety of medical devices with the public, so that doctors and patients can make informed decisions?

Answer 4. I am a strong proponent of greater data transparency—for patients, physicians, and manufacturers. If confirmed, I will be committed to working with Congress, patients, industry, and stakeholders on the issue of data transparency and other ways FDA could potentially make important information available to the public.

Question 5. You have been a proponent of loosened restrictions on direct-to-consumer advertising of prescription drugs. If confirmed, what principles will guide you in revising industry guidance on direct-to-consumer advertising of prescription drugs to assure that patients have accurate information on the safety and efficacy?

Answer 5. I believe that providing consumers and providers with truthful, non-misleading, science-based information can promote public health by empowering Americans to make informed decisions about their health. This is especially true when it comes to truthful, non-misleading clinical information provided in a non-promotional context, which is the context for many of my prior statements on this topic. If confirmed, I will work with FDA staff to review FDA's current policies related to these issues. I would approach any policy considerations related to the sharing of truthful, non-misleading information mindful of the existing statute and regulations, and FDA's mission to protect and promote public health.

Question 6. In April 2015, the FDA published Guidance for Industry on abuse-deterrent opioids, which stated that the Agency considers the development of opioids that are formulated to deter abuse as a "high public health priority." In its 2016 action plan on opioids and in a fact sheet posted on Monday January 9, 2017, the FDA stated its strong support for transitioning from the use of non-abuse-deterrent opioids to opioids with meaningful abuse-deterrent formulations and stated,

> "The FDA looks forward to a future in which most or all opioid medications are available in formulations that are less susceptible to abuse than the formulations that lack abuse-deterrent properties."

What further actions can and should the FDA take to transition the market to one in which patients receive abuse-deterrent opioids?

Answer 6. Opioid abuse, misuse, and addiction constitute one of the most urgent and immediate public health threats facing our Nation. It is also the biggest public health crisis facing the FDA. The human and economic toll of this crisis is staggering. If confirmed, this will be my highest immediate priority. I will make sure FDA is aggressive, forward leaning, and fully engaged in combating this epidemic. I will work with FDA's staff to ensure FDA has the right policies and processes in place to:

- Facilitate the developments of new approaches and technologies to reduce the abuse/addictive potential of painkillers American patients use;
- Support the development of non-opioid analgesic alternatives for physicians and patients;
- Assess whether FDA's current approach to opioid regulatory decisions, including labeling, REMS, and physician/patient education are appropriate, robust, and fully effective;
- Encourage the development of new pharmacological tools for physicians and patients to both prevent opioid misuse and abuse, and support treatment and recovery for patients struggling to overcome opioid addiction;

• Enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools to better target this information;
• Taking steps to make sure that providers are appropriately educated on identifying, and helping to property intervene with, abuse-prone patients;
• Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
• Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign imported narcotics;
• Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
• Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA on the two agencies' shared goals.

Question 7. The Food and Drug Administration has moved forward with Food Safety Modernization Act implementation by finalizing seven rules required under the act. However, there are several required rules that remain to be addressed, including enhanced recordkeeping requirements for high-risk foods, in-store consumer notification of reportable foods and accreditation standards for food laboratories. There are also multiple guidance documents meant to help producers and food processors comply with FSMA that have yet to be developed.

Will you commit to developing these important rules and guidance documents by the end of 2018?

Answer 7. The Food Safety Modernization Act (FSMA) provides FDA with important tools and authorities to support its responsibility to ensure the safety of our Nation's food supply. If confirmed, I will work to ensure the agency has the appropriate policies, processes, and resources in place to implement FSMA, as intended by Congress. I am committed to timely implementation of the provisions of FSMA, consistent with congressional intent. FDA should implement FSMA in a way that protects and promotes public health by enhancing food safety, while also collaborating with the U.S. Department of Agriculture, State officials, and other government agencies to conduct regulatory activities in a manner that takes into account the unique challenges faced by small farmers and small businesses.

Question 8. The Food and Drug Administration is responsible for the safety of about 80 percent of the U.S. food supply. The Food Safety Modernization Act enhanced FDA's ability to do more to prevent foodborne illness, rather than responding to foodborne illness outbreaks. This goal will only be realized if FDA is given the funding necessary to help train growers and food processors, update IT infrastructure and develop its own staff of skilled professionals. Will you commit to advocating for the funding necessary to successfully implement FSMA and protect our Nation's food supply?

Answer 8. The Food Safety Modernization Act (FSMA) provides FDA with important tools and authorities to support its responsibility to ensure the safety of our Nation's food supply. If confirmed, I will work to ensure FDA has the appropriate policies, processes, and resources in place to implement FSMA, as intended by Congress.

Question 9. According to the U.S. Department of Agriculture National Agriculture Statistics Service, PA is home to 17,000 bee colonies, producing 901,000 lbs. of honey for a value of $3.26 million in 2016. Countries like China continue to smuggle potentially unsafe honey into the United States, which has a serious impact on jobs and economic growth in Pennsylvania. Will you work to establish a Federal standard of identity for honey to ensure that consumers and producers are protected from substandard or falsely labeled honey?

Answer 9. This is not an issue that I have previously considered, but I will look forward to working with you to better understand and advance policy in this area, if I am confirmed. I have always been a proponent of accurate labeling.

Question 10. In May 2016, FDA published its final Nutrition and Supplement Facts Label rule to update the nutrient fact label. This rule required the declaration of the amount of added sugar in a product. While I support the declaration of added sugars so that consumers can make healthy choices for themselves and their family,

I am concerned that this designation could cause confusion for consumers with regards to products like a jar of honey or maple syrup when the sugar content is naturally occurring.

According to FDA's final rule on the nutrient fact label, a jar of honey would be required to label the sugar content in the honey as an "Added Sugar," rather than solely the "Total Sugars" in the product. An "Added Sugar" declaration for a jar of honey or maple syrup could imply to consumers that the sugar in honey is added, rather than naturally occurring. This could be misleading for consumers and not accurately convey the sugar content of the product.

When crafting the final guidance for industry on added sugars will you provide clarity to the honey and maple syrup industry on the labeling of the sugar content of their packaged product (ex. a jar of honey)?

How do you believe that the sugar content of a jar of honey or maple syrup should be declared? Should packaged honey and maple syrup be subject to the "Total Sugars" declaration, rather than the "Added Sugars" declaration?

Answer 10. This is not a discussion that I have been privy to although I am familiar with the Nutrition and Supplement Facts Label rule. I believe in transparency for consumers, and that information must be understandable and clear and science-based. If confirmed, I commit to looking into this issue related to the labeling of sugars in honey and maple syrup.

Question 11. Nutrition during pregnancy is critical for the health of the mother and developing fetus. It is vital that pregnant and nursing women have access to nutrition information that is rooted in science to ensure that they can make healthy decisions for their family. In 2014, FDA and EPA issued draft-updated advice about seafood consumption for pregnant and nursing women. That advice recommended that pregnant women, nursing women, women who may become pregnant and young children should eat more fish that is lower in mercury in order to benefit from important nutrients that can aid growth and development. These recommendations were consistent with the 2010 Dietary Guidelines for Americans. In January 2017, FDA and EPA published revised advice for seafood consumption for these target groups of women and children.

Will you ensure that future nutrition guidance related to seafood consumption for pregnant women, nursing women, women who may become pregnant and young children be based on the most current and relevant nutrition science?

How do you intend to work with EPA to accomplish this?

Answer 11. If confirmed, I will ensure FDA's advice concerning seafood consumption by pregnant and nursing women is based on the most current and relevant nutritional science and appropriately takes into account both the nutritional benefits, and any toxicological risks associated with seafood consumption. I will also work to ensure effective collaboration between FDA and the U.S. Environmental Protection Agency (EPA) on this issue, and a range of other public health matters over which both agencies share regulatory authority.

SENATOR ISAKSON

Question 1. A GAO report in September 2015, requested by this committee, noted that it is illegal under current law to compound animal drugs using bulk active ingredients. While the report noted that a limited amount of compounding from bulk is needed to meet unmet medical needs, some pharmacies are endangering animal health by producing large quantities of near copies of approved animal drugs and mass marketing them essentially acting as manufacturers while skirting the safety and efficacy protections of the FDA approval process.

The GAO strongly urged the Agency to provide clear final guidance outlining conditions under which FDA will generally not take enforcement actions for violations of specific provisions of the Food, Drug and Cosmetic Act with respect to animal drug compounding. FDA released draft guidance to this effect in 2015 and the comment period for that draft ended in November 2015. When will the agency move to protect animal health and issue this final guidance for animal drug compounding?

Answer 1. Ensuring the safety of compounded animal drugs is an important part of FDA's mission to protect and promote public health. If confirmed, I will commit to engaging with FDA's staff to quickly get up to speed on the regulatory history of this issue, and the agency's latest information, thinking, and actions. I would welcome the opportunity to work with Congress on this issue moving forward to make sure the agency is taking timely steps on this matter and implementing the laws and regulations consistent with the intent of Congress.

Question 2. Dr. Gottlieb, as you know, the majority of OTC medicines are regulated under the OTC Monograph system, which is built around notice and comment

rulemaking. These burdensome regulations make changes, such as label warnings or new dosage forms, cumbersome and slow. Shifting these decisions to the drug center within FDA will add efficiency to scientific and medical determinations by removing decisionmaking layers, while continuing to include due process controls. Monograph reform will also allow for greater innovation and offerings for consumers. It is also my hope that this will address the 15-year backlog sunscreen ingredient applications, as well as currently marketed products in the stayed final monograph.

Will you commit to working with Senator Casey and myself on Monograph reform?

Answer 2. OTC products play an important role in our Nation's healthcare system. I believe that the current monograph system for regulating OTC medicines should be evaluated to determine whether certain improvements may benefit public health. I am aware of some of the current proposals for improving on the monograph process. If confirmed, I will commit to working with you, Senator Casey, and members of your staffs on this important issue.

Question 3. I am interested in acceleration of translating scientific research into more effective treatments for cancer and other diseases. The emergence of several notable efforts to conduct observational research of cancer patients and collect large amounts of data—including clinical outcomes, demographic information, and molecular profiles—to create "learning systems" to accelerate research and improve the quality of care.

A notable example of this is a partnership called the Oncology Research Information Exchange Network—or ORIEN for short. ORIEN is a national partnership in which 15 of the Nation's top cancer centers have agreed to use the same protocol to enroll patients and collect and share data on patient outcomes and molecular profiles. As I understand it ORIEN is the largest big-data effort of its kind, with more than 170,000 patients consented. In addition to using this system to work together to tackle major cancer research projects, ORIEN is also partnering with pharmaceutical companies who can use the data to speed up the process of finding the right patients for clinical trials to get new drugs to the market faster.

Another example of a "big data" approach to observational research in cancer is the American Society for Clinical Oncology's "CancerLinQ" program, which is also now aggregating and analyzing large amounts of patient data to support clinical decisions in cancer care.

To what extent could these new health learning systems be of use to the Food and Drug Administration in the evaluation of emerging cancer treatments or related tasks, such as looking at the efficacy of sequences of treatments involving drugs that have already been approved? Would you see any impediment to working in partnership with ORIEN, ASCO and similar organizations to expand the FDA's current capacity for drug evaluation and research in oncology?

Answer 3. As the delivery of cancer care becomes more personalized, and more closely tied to information about the molecular signatures of individual patients, approaches that enable the collection of better, patient-specific data are going to become increasingly important not only in informing the regulatory process, but also the delivery of care and the practice of oncology medicine and personalized medicine. I am committed to finding ways that FDA can more closely partner with, and leverage these opportunities to inform its own work and help fulfill the public health mission of these efforts advance opportunities for improved patient care.

Question 4. Dr. Gottlieb, in 1978 FDA committed to address the overregulation of medical gases, like Oxygen, by creating separate regulations for medical gases as a unique class of drug products. Thirty-nine years later, FDA has not followed through on its commitment to create an appropriate framework specific to medical gases. In 2012, Congress enacted historic and bipartisan reforms at the request of the medical gas industry and pharmacists to require FDA to follow through on its 1978 commitment to address the overregulation of medical gases in the Food and Drug Administration Safety and Innovation Act (FDASIA). In November 2016, FDA issued a final rulemaking that addressed some medical gas labeling issues, however FDA did not, as intended by FDASIA and reiterated to FDA in the fiscal year 2016 Appropriations report language, modify current regulations to address the overregulation regulation of medical gas, such as the medical air labeling, adverse event reporting, expiration dating, calculation of yield and a host of other safety and enforcement issues identified by the medical gas industry as necessary to appropriately regulate medical gases. If confirmed as Commissioner of FDA, would you ensure that FDA fully implements Section 1112 of FDASIA by working with stakeholders to either incorporate by reference industry consensus standards or issue new

final rulemakings on medical gas to address these unique medical gas regulatory issues?

Answer 4. If confirmed, I am committed to implementing all congressional laws, including Section 1112 of FDASIA. I look forward to working with you on this issue.

Question 5. I am interested in bringing more predictability and consistency to the device inspections process. For routine inspections, FDA should be able to give companies advance notice that they will be inspecting, as well as providing regular communications throughout the inspection process. Additionally, should FDA find an issue that needs to be addressed during an inspection, companies have 15 days to submit a remediation plan to FDA but there's no such timeline for FDA to respond to companies to communicate whether the remediation plan meets FDA expectations. I believe it makes sense for FDA inspections to be done in a risk-based system, meaning that FDA should focus its resources on those inspections that will have the most meaningful impact on patient safety. Will you commit to working with me and Senator Bennet on this issue?

Answer 5. I agree that predictability and consistency are very important aspects of the FDA device inspections process. I also agree that across its regulatory portfolio, FDA should be taking a risk-based approach to its work in order to make sure the agency is maximizing its resources in pursuit of its important public health mission to protect and promote public health. If confirmed, I commit to working with you, Senator Bennet, and members of your staff on this issue.

SENATOR FRANKEN

Question 1. The MDUFA agreement includes funding for implementation of NEST and requires a pilot project to test the NEST system to facilitate pre-market approval of medical devices. Will the pilot projects be designed to support the generation and collection of data on devices, even after they come to market? How will this data be used to develop a more active post-market surveillance system?

Answer 1. The reauthorization proposals for PDUFA, MDUFA, GDUFA, and BsUFA were developed and submitted to Congress prior to the end of the previous Administration. I was not involved with the FDA-industry technical negotiations on any of these proposals.

However, I am supportive of data transparency and recognize the importance of collecting valid data that can be used to bring new medical devices to market, expand indications for approved medical devices, and enhance the agency's ability to collect important patient safety information. If confirmed, I will commit to working with staff to quickly get up to speed on this issue and help the agency evaluate whether NEST could be an appropriate tool for post-market surveillance.

Question 2. When I met with you in my office prior to your nomination hearing, you explained that while the industry funding will help develop NEST, the FDA will need to update its tools to fully realize the potential of NEST and other initiatives. What is the FDA's role in this process and does the FDA have the resources it needs to make these updates?

Answer 2. FDA will play an important role in developing NEST but the system will be owned and operated by multiple stakeholders. I support a properly resourced FDA that also has the modern tools it needs in order to use data in pursuing its public health goals and, if confirmed, will work to ensure that FDA is well-positioned to carry out its mission.

Question 3. Rising drug prices continues to be problem in the United States and over 70 percent of Americans think that Congress should address the issue. If appointed as commissioner, will you commit to working with the HELP committee to address skyrocketing drug prices through actions under the FDA's purview? What proposals do you think have the biggest potential to lower costs?

Answer 3. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some innovator products for which traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regu-

latory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 4. In 2001, the FDA withdrew Avastin, a drug approved for breast cancer through an accelerated approval pathway with surrogate endpoint data, due to findings that the drug was not as effective as was indicated by the surrogate endpoint. What did you take away from FDA's experience with Avastin and had you been commissioner in 2011, would you have made a different decision? Would you have overruled your top cancer scientists and drug experts on Avastin?

Answer 4. Insofar as I am not privy to all of the details related to the 2011 withdrawal from the market of Avastin, I do not believe it would be appropriate to opine on all of the things that I hypothetically might, or might not have done differently in that situation. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. If confirmed, I will uphold the Gold Standard by ensuring FDA makes regulatory decisions based on sound science, good regulatory practices, and the support of a strong scientific staff.

Question 5. Based upon the outcome in the case of FDA's withdrawal of Avastin to treat breast cancer and your published criticism of the FDA's decision, what assurances can you give that indicate that you will be willing to take action to protect public safety by removing a product from the market if and when later stage studies show drugs to be ineffective or unsafe?

Answer 5. FDA's ability and obligations to remove a drug from the market, or in this case rescind a specific indication from drug labeling, if a drug fails to meet the required standard in a confirmatory trial, is an important component of the accelerated approval process, as established by Congress. If confirmed, I will follow the science and support the staff in upholding congressional intent in the conduct of the drug review program.

Question 6. Congress passed the Pediatric Device Consortia Program in 2007 to help address the slow rate of innovation in pediatric medical devices but pre-market approvals for pediatric devices still only comprise 5 percent of pre-market approval submissions. What more can the FDA do to foster the development of new pediatric medical devices and improve the number of approvals?

Answer 6. I agree that FDA should support the development of safe and effective pediatric medical devices. I am aware of a number of efforts FDA is undertaking in this area, including data collection on barriers to the development of and the unmet needs for pediatric medical devices. If confirmed, I will continue FDA's work and consider additional efforts in this area.

Question 7. The passage of the Biologics Price Competition and Innovation Act (BPCIA) created a pathway for biosimilar entry. Yet, the FDA is still in the developing stages of developing and implementing this pathway. There are a number of outstanding issues that make it harder for FDA to implement the biosimilar pathway and increase competition to lower prices. What is FDA's role in encouraging more manufacturers to develop biosimilars for the U.S. market?

Answer 7. I fully support the BPCIA. FDA can most effectively support a robust biosimilar marketplace by providing clarity about a consistent, transparent, science-based regulatory process for biosimilars. If confirmed, I will work to ensure the agency has the appropriate policies and processes in place to fully implement the law, as intended by Congress.

Question 8. There are currently 182 drugs on the market that no longer have patent protection but also do not have any generic competition. Further, there are more than 500 drugs with only one marketed generic. In these situations, brand companies are able to price their product however they choose without market competition to drive down prices. What is the FDA's role in monitoring, identifying, and remedying market situations that lead to access barriers for patients or price gouging by manufacturers?

Answer 8. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes don't face effective generic competition even long after the patent expires.

Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some branded drugs for which traditional bio-

equivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

SENATOR PAUL

Question 1. Since passage of the Drug Quality Security Act in 2013, the FDA has implemented and enforced the law in a manner inconsistent with clear congressional intent. The agency has used guidance documents to assert regulatory authority over State-licensed compounding pharmacies and to treat them like drug manufacturers, and overly restricted the geographic limits for compounding in hospital systems. If confirmed as Commissioner, can you can you commit to taking a fresh look at the FDA's interpretation of the DQSA to assure that any regulations or guidance documents issued or related enforcement actions undertaken against pharmacies are consistent with the DQSA as written and in a way that better balances public safety with patient access to critical medications?

Answer 1. If confirmed, I am committed to implementing DQSA, as intended by Congress, to both protect patient safety, and allow the safe and appropriate practice of pharmacy compounding. I will commit to working with your office to make sure we are appropriately pursuing the goals of DQSA, including protecting the role for the safe practice of pharmacy medicine.

Question 2. Currently, FDA has a number of tools at its disposal to allow for innovative clinical trial design and for the consideration of foreign drug data in the drug approval process. Will you consider using or expanding the use of FDA's current authorities to expedite consideration of drugs approved in other countries?

Answer 2. FDA has taken certain steps to bring more harmonization between international regulatory authorities in various aspects of its review programs, and make better use of regulatory data generated from oversees regulatory processes. If confirmed, I would commit to continuing to work with the FDA staff to look at additional ways that the agency can leverage the expertise and experience of its foreign counterparts.

Question 3. OTC medicines are a cost-effective first-line therapy for many conditions, and the Rx-to-OTC switch often has a positive impact on the healthcare system and drives down costs. Since 1976, 106 ingredients have made the Rx-to-OTC switch since 1976. Furthermore, FDA's OTC monograph approval work is far from complete.

What do you believe is the appropriate role of FDA in the Rx-to-OTC process and what can the agency do to improve the process, and ultimately provide greater access to OTC drugs?

There are two older types of insulin available in OTC form. Understanding that that appropriate guidance from a health care professional is important, will FDA continue to consider whether additional formulations of drugs such as insulin can be safely available to patients over-the-counter?

Answer 3. I believe that there may be additional policy steps we can take to leverage opportunities to facilitate more patient access to OTC medicines and that this is an important public health goal. For example, I believe that the current monograph system for regulating over-the-counter drugs should be evaluated to see if improvements can be made. I recognize the potential public health benefit inherent in the increased availability of OTC drugs and, if confirmed, will work to improve this important regulatory pathway.

Question 4. Recently, there have been a number of older, off-patent drugs, such as insulin and tetracycline, that have seen large price increases. Understanding that FDA does not have direct control over drug prices, what role do you believe the agency can play in working to address this problem?

Answer 4. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs, including potentially some insulin products, that sometimes don't face effective generic competition even long after the patent expires. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some branded products for which

traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 5. The FDA's tobacco "deeming rule" threatens to upend the tobacco industry subject to this regulation. In particular, I am concerned that the regulation puts vapor, cigars, and other deemed products at a significant disadvantage to combustible cigarettes, which were allowed to remain on the market when Congress subjected them to FDA review. Furthermore, some of these products may present harm reduction opportunities for tobacco users. Will you commit to working to make this regulation more reasonable, so that it is workable for companies trying to keep products on the market?

Answer 5. If confirmed, I will be committed to implementing the TCA, as intended by Congress, including Section 911 related to modified risk products, which I recognize can provide helpful tools for current tobacco-users to transition off combustible tobacco. As I was not at FDA during the agency's initial TCA implementation activities, I am not fully acquainted with internal processes or specific decisions to-date. If confirmed, I will work with the professional staff to quickly get up-to-speed on this issue, and I will review current FDA policies, including the deeming rule, to ensure FDA treats products appropriately, implements provisions in a timely fashion, and in a manner that is fully consistent with congressional intent under the TCA. I believe that responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

Question 6. A midnight rule proposed by FDA under the Obama administration intends to limit a specific chemical compound's (NNN) presence in smokeless tobacco to presently unachievable levels. Approximately 1,200 Kentucky farm jobs and an additional 600 Kentucky manufacturing jobs are at risk from this proposed rule because nearly all of this dark tobacco is grown within a 50-mile radius of Hopkinsville, KY. If this rule were to be finalized, these jobs would either be eliminated or moved overseas. As commissioner, how will you work to balance regulating chemicals like NNN with the importance of these farming and manufacturing jobs?

Answer 6. I have not been privy to the development of this proposed rule although I understand the comment period has been extended. If confirmed, I will commit to reviewing the scientific evidence and working with you on this issue.

Question 7. Last year, DEA, with FDA's input, decided not to change the controlled substance schedule for cannabis. Also, last year, FDA approved the second cannabis-based drug. I believe continued research in this area is critical to understand the potential medical benefits of cannabis and cannabis-based products. What role can FDA play in continuing to consider the therapeutic benefits and provide access to patients where appropriate?

Answer 7. I am aware that in July 2016, DEA determined, in consultation with HHS, that marijuana continues to meet the criteria for Schedule I control under the Controlled Substances Act. I cannot speak to decisions that the DEA might take in the future, but I do know that FDA is currently involved in supporting scientific research related to medicinal uses of marijuana and its constituents. If confirmed, I am committed to continuing this research.

Question 8. FDA, along with USDA and DEA, published guidance last August on industrial hemp. This guidance went far beyond what Congress had explicitly constructed in statute by narrowing the definition of hemp, restricting commerce from hemp pilot programs, and prohibiting transportation of hemp plants and seeds across State lines. As commissioner, how would FDA work with the industrial hemp industry to ensure it is able to continue thriving?

Answer 8. I have not been involved in this issue so I cannot comment directly. However, I will note that I am committed to implementing congressional laws as they are intended. If confirmed, I will commit to working with you to address this issue.

Question 9. Obamacare authorized the creation of a Federal menu labeling standard. On May 5, 2017, businesses will have to comply with FDA's Federal menu labeling rule. With this rule, businesses could face criminal penalties for violation. To provide context for how difficult this could be, a pizza company based in Kentucky determined there are over 30 million pizza combinations an individual could order at their restaurants. This rule would require them to post calorie counts for all

those possible combinations on a menu in their restaurants, even though it already publicly provide all this information on its Web site. If an employee accidentally puts an extra handful of cheese on the pizza, those calories will inevitably be off—and now they will be subject to criminal penalties. As commissioner, how would you move forward with implementation of this rule and provide flexibility to business owners and their employees?

Answer 9. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the technical specifics. As a general rule, I support providing clear, accurate, and understandable information to American consumers to help inform healthful dietary choices. I believe information about caloric content can be a useful tool. However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with the agency's professional staff to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing unnecessary compliance burden on businesses, particularly small, independent ones.

SENATOR BENNET

Question 1. Antibiotic resistance is a real and growing public health crisis. The Centers for Disease Control and Prevention (CDC) estimates that at least 23,000 people die every year in the United States from resistant infections.

Last year I worked with Senator Hatch on the PATH Act, which creates a new pathway for antibiotics to treat potentially deadly infections for which there are no other treatment options. The legislation was passed in the 21st Century Cures Act. This law allows FDA to approve these drugs on the basis of limited data sets, and also puts important protections in place to ensure these drugs are used only by patients for whom the benefit would outweigh the risk.

If you are confirmed, will you commit to fully implementing this law including the provisions designed to ensure that these drugs go to the patients who actually need them?

Answer 1. The availability and appropriate prescribing of antibiotics are vital to our Nation's public health. Additionally, antibiotic resistance is a significant and growing public health challenge facing our Nation. Within its statutory authorities, FDA should encourage the development of new antibiotics and ensure proper labeling to help address the issue of inappropriate prescribing and/or use. If confirmed, I would commit to fully implementing, in a timely fashion and consistent with congressional intent, the PATH Act for antibiotics.

Question 2. Clinical trials are a necessity to understand the safety and efficacy of new medicine, but participation in trials is remarkably low. One reason for this is the eligibility criteria for potential patients can be quite restrictive. This can result in trials conducted with patients that are not reflective of the people that will ultimately use the drug.

What would be needed for FDA to play a more active role in determining clinical trial eligibility criteria?

What can the FDA do to help trials be more representative of the overall population?

Would efforts to expand eligibility criteria help more patients with rare diseases enroll in clinical trials?

Answer 2. I think it is very important that clinical trials capture the diversity of the population who will likely use the medical product once it is marketed and becomes available. If confirmed, I will work to ensure that FDA policies support the conduct of clinical trials that represent the clinical diversity of the intended patient population, including through the implementation of Section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA). With respect to rare diseases in particular, I would be committed to working with your office and other stakeholders to address ways that FDA can encourage more patients with rare diseases to enroll in clinical trials.

Question 3. Currently, we hear from Coloradans who have a loved one suffering from a severe terminal illness and have no choices in terms of drugs already approved. For those who have no treatment options and are unable to participate in a clinical trial, they understandably seek access to unapproved experimental treatments.

When you previously spoke as the Deputy Commissioner for Medical and Scientific Affairs you stated that "participation in clinical trials is the best way for patients to get access to unapproved drugs."

What else can the FDA do to ensure that these patients can explore all of their options?

Is there a way that FDA can collect safety and efficacy data from expanded access cases in a way that gives companies regulatory clarity while providing another option for patients?

Answer 3. FDA works to inform potential participants on a wide range of issues related to clinical trials. For example, FDA created the Office of Health and Constituent Affairs to serve as a contact for patients. NIH also plays a key role in maintaining *ClinicalTrials.gov*, a data base which anyone, including providers, patients, and family members, can use to search for information about current, ongoing clinical research studies. Nothing prohibits FDA from collecting safety and efficacy data during expanded access cases. However, the conditions and circumstances of expanded access cases do not generally lend themselves to determining the efficacy of a drug. If confirmed, I commit to looking into this issue and working with you on it. I am committed to exploring ways that we might improve expanded access programs to provide patients with terminal diseases more options to get access to promising experimental medicines, and perhaps learn more from these access programs without creating any additional burdens or disincentives for sponsors who are seeking to make drugs available to terminal patients within the scope of the laws and regulations governing these programs.

SENATOR COLLINS

Question 1. FDA's menu-labeling rule, even after an initial stay, will take effect 1 month from today. Grocery stores and other food retailers across America continue to be frustrated with FDA's handling of things, including for local and seasonal food items. Fresh and local food items may be sold at a few stores, under the same name, but the ingredients or recipe can vary, yet they would be considered "standard menu items" and subject to enforcement. The irony is that this will cause stores and restaurants to move away from fresh, local, and seasonal offerings. With just a month before the compliance date, we need FDA to act quickly to further delay, withdraw, or stay the rule so it can be rewritten to give businesses the flexibility to comply. Would you be willing to explore ways to encourage FDA to act before the compliance date to provide this much-needed flexibility for businesses?

Answer 1. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the technical specifics. As a general rule, I support providing clear, accurate, and understandable information to American consumers to help inform healthful dietary choices. I believe information about caloric content can be a useful tool. However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with the agency's staff to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing unnecessary compliance burden on businesses, particularly small, independent ones.

Question 2. The safety of personal care products is an issue of interest to many Americans. The average consumer uses 10 personal care products every day, yet the laws governing the cosmetics and personal care products industry have not been updated since 1938, and States have been acting on their own in the absence of a national safety standard. There is growing support in Congress for modernizing cosmetic safety laws and providing greater transparency for consumers and regulatory certainty for manufacturers. Can you commit to working with us and other Senators to modernize FDA's authority to regulate cosmetic products to better serve public health?

Answer 2. If confirmed, I commit to working with you and others in Congress to explore options to potentially modernize FDA's authorities related to the regulation of cosmetic products.

Question 3. Dr. Gottlieb, in our meeting we discussed the Aging Committee's investigation into the sudden price-spikes of decades old drugs and the report we issued outlining a number of potential bipartisan solutions to help improve access to affordable medications. You spoke about a number of regulatory obstacles to making drugs generic. Would you share with the committee any ideas you have, related to REMS or easing other regulatory obstacles, that could increase generic entry?

We discussed unintended impacts of the FDA risk-evaluation and mitigation strategies (REMS) on generic competition. Some drug companies have used REMS to prevent potential generic competitors from getting access to the drug for the FDA required bioequivalence studies. Two weeks ago, Dr. Janet Woodcock testified that the FDA had reported 150 cases of REMS abuse to the FTC. What can the FDA do to ensure the safe handling of these drugs while still promoting generic entry?

The need for more affordable, complex drugs is also great. Last summer, for example, we saw the Mylan EpiPen price increase by 500 percent. For complex products, such as auto-injectors and metered-dose inhalers, what role can the FDA play in helping sponsors get generic competition approved?

Answer 3. My understanding is FDA has already taken action to instruct manufacturers that they may make samples of products subject to a REMS available to prospective generic competitors for the purpose of bioequivalence studies without running afoul of their legal requirements. It is important to note though, that appropriate safety precautions must be in place under specific circumstances, given the unique patient safety and public health risks associated with certain REMS products. But we need to make sure our policies are striking the right balance between safety and access, and evaluate carefully if regulations meant to improve safety are also becoming an unintended barrier to access and competition. If manufacturers inappropriately refuse to provide their product to prospective generic competitors, this would be a concern to FDA and become a matter for potential enforcement action by the Federal Trade Commission. While drug pricing does not fall directly within FDA's purview, I believe the agency can play a key role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires and other places where there are specific issues that make it hard for generic manufacturers to copy certain products and demonstrate sameness under FDA's existing guidance. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some branded products for which traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 4. Alzheimer's disease is one of the greatest public health threats of our time. More than five million Americans are living with Alzheimer's and other dementias. It is the sixth leading cause of death, and yet there is no cure, treatment, or means of prevention. Researchers are making major advancements in understanding the pathology of Alzheimer's beyond the amyloid beta and tau proteins. Today scientists are finding new genetic links, neuroprotective factors, and brain wide connectivity patterns associated with dementia risk. With the advancements of these biomarkers, we are poised to make progress in cures. How can the FDA support drug development using these biomarkers?

Answer 4. Alzheimer's disease is, indeed, a major public health challenge today, and absent the discovery and development of new medicines that can slow, reverse, and perhaps even prevent the onset of the disease, the future impact Alzheimer's disease is staggering, in terms of human suffering and societal cost. If confirmed, making certain FDA has the right policies and processes in place to effectively encourage the development of safe and effective new medical products for Alzheimer's disease—to prevent its onset, to slow its progression, and one day to cure it—will be one of my highest priorities. I will work to ensure the agency consistently uses sound, rigorous, 21st century regulatory science, tools and approaches to facilitate the discovery and development of drugs for Alzheimer's disease. The use of well-validated biomarkers could be an important component of the future of Alzheimer's research and development. In short, patients with Alzheimer's disease, their families, and our Nation as a whole will benefit from the development of new Alzheimer's treatment options. If confirmed, I look forward to working with Congress, other government agencies like the NIH, industry, academia, and the patient and stakeholder communities to ensure FDA does everything it can to play its important role in tackling this challenging public health issue.

Question 5. This is an exciting time for biologic products and regenerative medicine. In laboratories across America, every day we are learning something new. We

are on the verge of real breakthroughs that may change disease trajectories fundamentally. In this era of discovery in biomedical research, we must promote and incentivize success. Developing biologic products and regenerative therapies is unique compared to traditional targeted drugs. In some cases, different endpoints may be needed. What role do you see for the FDA in facilitating new endpoints?

Answer 5. New areas of biologics and regenerative medicine are some of the most innovative and promising emerging advancements in our scientific approaches to the treatment of human disease. Regenerative medicine, in particular, appears to hold great promise for new therapeutic options for patients and physicians, particularly in areas of unmet or underserved medical need. I believe more generally, FDA should lean forward in defining the regulatory principles on which the safety and effectiveness of these new areas of medicine are going to be judged by the agency, in order to help facilitate their development. This includes the development of appropriate endpoints for evaluating the safety and effectiveness of new areas of biological products and regenerative medicine. If confirmed, I will embrace the responsibility to facilitate important medical innovation, while maintaining the agency's Gold Standard of safety and efficacy.

Question 5. In 2011, FDA issued an Advisory on glass lamellae formation in certain injectable drugs. This action was taken out of concern for the impact of glass contamination on drug quality and patient safety. The Advisory noted at the time that "there is the potential for drugs administered intravenously that contain these fragments to cause embolic, thrombotic and other vascular events." I understand that it has been discovered recently that glass issues, in addition to glass lamellae formations, can increase the presence of glass in injectable drugs beyond the level previously known when the Advisory first was issued. This potential to cause harm to patients presents a public health risk. If confirmed, what action would you plan to take to address these glass issues and when?

Answer 5. I recognize the potential safety concern related to the use of glass vials and, if confirmed, will ensure that FDA is taking every necessary step to address this issue.

Question 6. I mentioned during our meeting the FDA's proposed rule on electronic prescribing information and its implication for rural pharmacists. I continue to be concerned that it would have an adverse effect on patient safety, particularly for Americans who live in areas with limited Internet access, and have serious implications for patients and pharmacists during a power outage or in the wake of a natural disaster or terrorist attack. Given that 96 percent of the public comments were in opposition to the proposal, are you willing to evaluate carefully the concerns and consider withdrawing this ill-conceived proposal?

Answer 6. Ensuring that accurate, science-based information about medical products is readily accessible to patients and providers is an issue that is critically important to public health. Drug labeling is FDA's primary vehicle for communicating risk information to consumers and providers and it needs to be readily accessible to patients. If confirmed, I will commit to engaging with the agency's professional staff to quickly get up to speed on this issue. I would welcome the opportunity to work with you on this issue moving forward.

Question 7. Another area of increasing concern is the overuse of antibiotics in agriculture and the rise of antibiotic-resistant bacteria. Preserving the effectiveness of medically important antibiotics used to treat human and animal bacterial diseases is critical and has been described as the single most important challenge in infectious disease. The CDC estimates that at least 2 million illnesses and 23,000 deaths caused by antibiotic-resistance occur every year in the United States. I have introduced legislation with Senator Feinstein aimed at reducing the overuse of antibiotics in agriculture. Will you continue to support ways that the FDA, in cooperation with other Federal agencies, can address the growing problem of antibiotic-resistant bacteria and the overuse of antibiotics in agriculture?

Answer 7. Antibiotic resistance is a significant and growing public health challenge facing our Nation. In addition to measures FDA should take to address this issue within the context of human use, the agency must effectively collaborate with other government agencies and public health authorities to develop policies and processes to address the issue of antibiotic use in animals intended for human consumption. If confirmed, I will ensure FDA remains engaged on this important public health issue. This includes making sure that animal drug labeling reflects the most up-to-date science, and working closely with the U.S. Department of Agriculture, the Centers for Disease Control, the U.S. Department of Defense, and other appropriate government agencies. FDA should also consider input from other important stakeholders, such as the farmers, the agriculture industry, and veterinarians. FDA's im-

plementation of a voluntary plan with industry to phaseout the use of certain antibiotics is an important step in the right direction.

SENATOR WHITEHOUSE

Question 1. The FDA is currently implementing the 21st Century Cures Act, including its provisions on improving coordination between the relevant centers during the review of a combination product. Though FDA seems to be making progress on improving this review process, I think it is important that we continue to monitor this issue and be ready to make bigger changes to the combination products approval process if they are needed. As Commissioner, will you commit to keeping the HELP Committee updated on FDA's work to improve the combination products review process, and to propose any recommended legislative updates in a timely manner?

Answer 1. I recognize the importance of FDA's combination product review program and, if confirmed, will commit to implementing 21st Century Cures and working with you and the other Senators on the HELP Committee on any related legislative proposals.

Question 2. You have written extensively on your views regarding the regulation of medical software and apps. In a 2014 *Wall Street Journal* commentary titled, "Why Your Phone Isn't as Smart as It Could Be," you wrote "The FDA should exempt the majority of mobile-health apps from premarket review." Last Congress, members of this committee led by Senators Hatch and Bennet worked to define FDA's authority over medical software as part of the 21st Century Cures Act. In that law, we exempted many forms of low-risk software, such as software intended to encourage a healthy lifestyle, from FDA oversight.

Do you believe that there are additional types of medical software that should be exempted from FDA oversight? If so, which ones and why?

Answer 2. I support tools that can help provide consumers with more information about their health. FDA must clearly define when an app is a medical device subject to its regulation, and when it falls outside FDA's framework or is low risk, and therefore appropriate to be exempt from the full scope of FDA's pre-market requirements. For products subject to FDA's pre-market requirements, the agency should use a risk-based approach in regulating consumer apps and other medical software, and, if confirmed, I look forward to helping further refine FDA's approach and implement the related provisions of 21st Century Cures in a timely fashion and consistent with congressional intent.

Question 3. In the 21st Century Cures Act, Congress established an administrative process that FDA can use to bring medical software that is exempted from regulation back under FDA oversight if it is reasonably likely to have "serious adverse health consequences."

How would you determine whether a piece of medical software or an app poses an adverse health threat?

Under what circumstances would you conclude that this administrative process should not be used if medical software is determined to have a risk of serious adverse health consequences?

Answer 3. If confirmed, I look forward to working with the FDA's professional staff to properly implement this framework, consistent with congressional intent. I would also commit to working with you and your colleagues in Congress, to keep you informed about FDA's implementation efforts.

Question 4. In the same *Wall Street Journal* commentary referenced in question 2, you suggested that FDA should employ "post-market controls" to make sure mobile health apps are meeting expectations. What types of post-market controls should FDA use to make sure such software—as you wrote—"meets expectations"?

Answer 4. Controls should be used to ensure, among other things, that mobile health apps are providing consumers with data that is accurate and reliable. If confirmed, I would work with Agency staff to develop appropriate post-market controls that ensure the safety of consumers but continue to allow for innovation in product development.

Question 5. The Centers for Disease Control and Prevention estimates that 2 million people develop antibiotic-resistant infections in the United States each year, resulting in at least 23,000 deaths. The World Health Organization has concluded that antibiotic resistance . . . "is one of the biggest threats to global health" . . . One area in which CDC, FDA, and the agriculture sector has made strides in recent years is the judicious use of medically important antimicrobial drugs in food-pro-

ducing animals. Do you believe FDA should have a role in improving antimicrobial stewardship? What is that role?

Answer 5. Antibiotic resistance is a significant and growing public health challenge facing our Nation. In addition to measures FDA should take to address this issue within the context of human use, the agency must effectively collaborate with other government agencies and public health authorities to develop policies and processes to address the issue of antibiotic use in animals intended for human consumption. If confirmed, I will ensure FDA remains engaged on this important public health issue, making sure that animal drug labeling reflects the most up-to-date science, and working closely with the U.S. Department of Agriculture, the Centers for Disease Control, the U.S. Department of Defense, and other appropriate government agencies, among other steps. I believe it is a priority for FDA to continue to play an important role in improving antimicrobial stewardship.

Question 6. Stakeholders within the animal health sector acknowledge the need for better data and more timely information about the use of antibiotics in production agriculture and its role in antibiotic resistance. As you may know, the National Antimicrobial Resistance Monitoring System (NARMS), jointly coordinated by CDC, FDA, and the USDA, analyzes trends in antibiotic resistance by collecting bacteria samples from animal and meat products as well as cases of human foodborne illness. This allows the aforementioned Federal agencies to accelerate their response to emerging public health threats. Do you support the NARMS initiative and intra-agency efforts to conduct surveillance of antibiotic resistance across the food chain?

Answer 6. I fully support efforts that will help facilitate the collection of more and better information about foodborne illness and emerging and resistant infections.

Question 7. As you know, earlier this year President Trump signed an Executive order instituting a hiring freeze for the executive branch. The order did not state how the freeze would affect many agencies, including the FDA. The 21st Century Cures Act recently provided the FDA with new hiring authorities, and a significant portion of user fee dollars goes toward supporting the hiring of FDA review staff in the drug and device centers.

Do you agree that FDA's approval process would benefit if it could promise higher salaries to attract scientific expertise? If so, what steps will you take to advocate for an exemption for FDA from the hiring freeze?

Do you believe the FDA will be able to fulfill its mission if the freeze prevents you from hiring new staff?

Answer 7. I was not involved with the development of the Administration's Federal workforce proposals, including the hiring freeze Executive order. FDA's ability to fulfill its mission to protect and promote public health depends on its world-class workforce of talented and dedicated public servants. If confirmed, I will commit to working with my colleagues in the Administration, as well as Congress, to ensure FDA is appropriately resourced and staffed.

Question 8. Regulatory capture has been a concern within regulated industries since Woodrow Wilson. In the case of FDA, industry is not only regulated by the agency, but is also its funder.

According to the Congressional Research Service, when the prescription drug user fee agreement was first authorized, user fees funded 10 percent of the Human Drug Program's activities. In 2016, it was nearly 65 percent. The medical device user fees covered 16 percent of the device center's costs in 2006, compared with 35 percent in 2015. As Commissioner, what specific steps will you take to ensure the FDA is able to maintain its independence so it can continue to put public health and safety first when reviewing drug and device applications?

Answer 8. As you note, user fees have grown to provide a significant portion of FDA's funding. At the same time, I have confidence that these fees are structured in a way that does not allow regulated industry to exert inappropriate influence on the agency. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. If confirmed, I will uphold the Gold Standard and the independence of FDA's review process by ensuring FDA makes regulatory decisions based on sound science, good regulatory practices, and the support of a strong scientific staff.

Question 9. Many of my Senate colleagues and I have called on the FDA to issue advice to pregnant women about the safe consumption of seafood that is based on the latest nutrition science. FDA research shows that maternal seafood consumption offers significant neurodevelopmental benefits for children. FDA committed to completing the seafood advice in 2011, but only did so on January 18, 2017. While I was pleased to see the advice finalized, it is now inconsistent with the Dietary

Guidelines issued by the Department of Health and Human Services and the Department of Agriculture.

Have you reviewed FDA's advice on safe seafood consumption for pregnant women?

Do you believe Federal guidance in this area should be based on the best available science?

If you are confirmed, will you work with the relevant Federal agencies to ensure the guidance about seafood consumption for pregnant women is consistent?

Answer 9. If confirmed, I will ensure FDA's advice concerning seafood consumption by pregnant and nursing women is based on the most current and relevant nutritional science and appropriately takes into account both the nutritional benefits, and any toxicological risks associated with seafood consumption. I will also work to ensure effective collaboration between FDA and the U.S. Environmental Protection Agency (EPA) on this issue, and a range of other public health matters over which both agencies share regulatory authority.

Question 10. 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, not less, which is why last Congress I cosponsored the Tobacco to 21 Act, which would have raised 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 FDA Commissioner, you would be charged with working to enhance the health and well-being of Americans, and there is clear evidence that access to tobacco products does nothing but detract from it.

Do you believe FDA should have a role in regulating tobacco products?

As Commissioner, will you support efforts to restrict the sale of tobacco to young Americans?

Answer 10. Through the Tobacco Control Act (TCA), Congress gave FDA regulatory responsibility over tobacco products. If confirmed, I will be committed to implementing the TCA, as intended by Congress. I fully support efforts to restrict the illegal sale of tobacco products to minors and reduce smoking rates in this country. I believe responsibly implementing the TCA is an integral part of FDA's core mission to protect and promote public health.

Question 11. 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?

Answer 11. Yes. Ensuring compliance and educating the public are important public health responsibilities for FDA, and an important component of the goals of the TCA.

Question 12. In May 2016, the FDA announced changes to the Nutrition Facts label for packaged foods in 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 by the current compliance date of July 2018?

Answer 12. I believe consumers should have access to standard, understandable, and accurate information that they can use to make educated decisions about a healthful diet. If confirmed, I will commit to engaging with the agency's professional staff to quickly get up to speed on this issue. I would welcome the opportunity to work with you on this issue moving forward.

Question 13. It has been reported that President Trump, who has publicly questioned the safety of vaccines and perpetuated the myth that vaccines cause autism, will convene a Commission on Vaccine Safety. The scientific community has overwhelmingly concluded vaccines are safe and have saved countless lives. As FDA Commissioner under President Trump, you may be charged with implementing an anti-vaccine agenda.

Do you commit to protecting access to life-saving vaccinations?

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?

Answer 13. As I stated during my confirmation hearing before the committee, this scientific question pertaining to vaccine safety and autism is perhaps one of the

most rigorously and exhaustively studied public health questions in modern times. I believe the science with respect to the question of there being any causal link between childhood vaccines and autism is clear and settled. Vaccines are safe and effective, and they are among the most impactful tools we have at our disposal to protect and promote public health. If confirmed, I will advise my colleagues and superiors within the Administration about the scientific validity and public health value of vaccines and will promote sound vaccination public policies.

Question 14. I have heard from medical device companies in Rhode Island who are pleased with the medical device user fee agreement that has been negotiated between FDA and industry, and would like to see it enacted by Congress as negotiated. Yet, with only a few months left before the agreements expire, President Trump has proposed doubling the amount of user fees collected by the FDA. Have you reviewed the MDUFA IV agreement, and do you support its enactment as negotiated?

Answer 14. The reauthorization proposals for PDUFA, MDUFA, GDUFA, and BsUFA were developed and submitted to Congress prior to the end of the previous Administration. I was not involved with the FDA-industry technical negotiations on any of these proposals. I was also not involved in the development of the President's Blueprint Budget. I recognize these user fee programs are critically important to FDA, and the patients the agency serves, as they provide significant resources to support FDA's regulatory activities related to innovative and generic medicines, biosimilars, and medical technologies. In order to ensure FDA is adequately resourced to facilitate the discovery, development, and regulatory review of safe and effective medical products to help American patients, if confirmed, I will work with my colleagues in the Administration, Congress, industry, and stakeholders to reauthorize these critical user fee programs in a timely manner.

Question 15. In addition to challenges obtaining FDA approval, innovative technologies can face additional hurdles getting authorized for reimbursement once they are approved. There have been efforts to make these two processes move on a parallel path, instead of one after the other. In your role as FDA Commissioner, would you support efforts to make these two approval processes work in tandem instead of separately?

Answer 15. I have been supportive of the concept of parallel review. If undertaken appropriately, it could facilitate more timely patient access to safe and effective new FDA-approved medical products. If confirmed, I would look forward to working with my colleagues at CMS on this issue.

Question 16. 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 obtain samples of their drugs—samples they need to be able to prove substantial equivalence and get approval from the FDA. Or they refuse to agree on a shared safety protocol for the drug, another FDA requirement. Last Congress, I cosponsored the CREATES Act, which would have allowed 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?

Answer 16. My understanding is FDA has already taken action to instruct manufacturers that they may make samples of products that are subject to REMS available to prospective generic competitors for the purpose of bioequivalence studies without running afoul of their legal requirements. It is important to note though, that appropriate safety precautions must be in place under specific circumstances, given the unique patient safety and public health risks associated with certain REMS products. We need to make sure our policies are striking the right balance between safety and access, and evaluate carefully if regulations meant to improve safety are also becoming an unintended barrier to access and competition. If manufacturers inappropriately refuse to provide their product to prospective generic competitors, this would be a concern to FDA and become a matter for potential enforcement action by the Federal Trade Commission. While drug pricing does not fall directly within FDA's purview, I believe the agency can play a key role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires and other places where there are specific issues that make it hard for generic

manufacturers to copy certain products and demonstrate sameness under FDA's existing guidance. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some branded products for which traditional BE/BA testing alone are sometimes insufficient for proving sameness.

Question 17. Increasing generic competition is one way the FDA can support efforts to lower prescription drug prices. One issue in the generic drug program has been deficient applications, requiring FDA and the sponsor to go through multiple review cycles before a product can be approved. The GDUFA II agreement includes changes that would give sponsors more opportunities to address deficiencies in their applications before FDA decides it does not have enough information to proceed with its review.

Do you support efforts like those in GDUFA II to reduce the number of review cycles for generic drug applications?

How else can the FDA work with sponsors to reduce the number of review cycles needed and get products to market faster?

Answer 17. The reauthorization proposals for PDUFA, MDUFA, GDUFA, and BsUFA were developed and submitted to Congress prior to the end of the previous Administration. I was not involved with the FDA-industry technical negotiations on any of these proposals. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 18. While much of the conversation about high drug prices has focused on innovative blockbuster drugs, like treatments for hepatitis C, the prices of many older drugs are rising too. I heard from the medical director of a health center in Providence that some of her patients can no longer afford insulin, a drug that has been around in some form for nearly a century. An insulin biosimilar was finally brought to market at the end of 2016, and more products are in development now, but Americans should not have to wait nearly 100 years to be able to purchase a lower cost version of a drug.

What will you do to ensure drug companies can not abuse their patent protections to keep generic competitors out of the market?

What steps will you take to incentivize potential competitors to use the generic and biosimilar approval pathways to improve competition, even for decades-old drugs?

Answer 18. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition, especially for complex drugs that sometimes do not face effective generic competition even long after the patent expires. This could include certain insulin products. I am also committed to working with the FDA professional staff to make sure the agency has appropriate standards and guidance in place that help balance the mandate to ensure with the safety and effectiveness of biosimilars while creating efficient pathways for inclusion of the sort of labeling claims on these products that will help facilitate their broader adoption and product competition that can enhance patient access.

Question 19. Last year, the FDA announced it would prioritize the review of generic products that would compete with "sole-source" products, or drugs that have only one manufacturer. However, other uncompetitive markets that have supply shortages or limited competition could also be improved by approving competitors more quickly. Should the FDA prioritize generic applications for market deficiencies caused by factors other than there being a single manufacturer?

Answer 19. If confirmed, I am fully committed to looking at additional ways that FDA can take steps, under the agency's existing legal authorities, to facilitate more product competition and generic market entry as a way to enhance patient access to medicines.

Question 20. Many agencies responsible for the approval of prescription drugs in other countries take cost-benefit analyses and comparative-effectiveness research into account during the approval process. Although the FDA does not make deci-

sions about the prices of drugs or whether health insurance programs will cover them, could the consideration of comparative-effectiveness research help inform the FDA's decisionmaking?

Answer 20. The legal standard for FDA drug approval is whether a drug is safe and effective for its intended use. I am committed to working with Congress to consider additional ways that FDA could potentially improve the quality of data used to inform the agency's decisionmaking while maintaining its Gold Standard of safety and efficacy.

Question 21. Both the PDUFA and GDUFA fee structures include mechanisms to reduce the financial burden for small companies. Do you support efforts like these to make the new drug and abbreviated new drug application processes more accessible to small, innovator companies? What else would you do to ensure small companies are not priced out of the FDA review process?

Answer 21. I support policies that appropriately take into consideration the unique challenges posed by small companies. Among the many steps that we can take to ensure small and sometimes undercapitalized companies are not priced out of the FDA review process is to make sure the regulatory requirements are consistent, transparent, efficient and based on the most modern science. FDA must also take a risk-based approach to regulation, so that we are not imposing unnecessary regulatory costs that are not achieving their intended public health purpose.

SENATOR CASSIDY

Question 1. The literature often speaks of the activated patient—one engaged in their own health care. Ideally, each patient would be engaged in their own health care decisions, and would choose the most efficient expenditure of their health care dollar. However, in health care, a given patient may have a plethora of options from which to choose—this can be very true in the device space.

Patients are seeing an increasingly crowded field of devices. However, it is very difficult for a typical patient to find the device that would produce the best value for somebody with similar health status. As a provider for 30 years, I can tell you that providers are in the same boat—data on outcomes for medical products and services certainly exist, but are not readily consumable.

Currently, the FDA regulatory structure incentivizes device makers to make their products as similar to each other as possible, in order to avoid lengthy and expensive premarket approvals. Dr. Gottlieb, do we reduce incentives for patient-focused innovation in the device industry this way?

For drugs, the FDA uses a rating system to differentiate between drugs that provide a substantial improvement over current standards of care—priority-rated drugs—and those that bat par with existing options. While there is little reward for those more substantive improvements today, this priority rating system has been well-developed between patient groups, clinical experts, industry, and the FDA—and serves as a clear signal to the health care system and to patients.

Dr. Gottlieb, could a parallel effort by the FDA in the device space help us identify those devices which show big steps forward in patient outcomes? Could this be done some time after market introduction, based upon real world evidence?

Answer 1. If confirmed, I would be committed to working with you to explore additional ways we might modernize the medical device review process to ensure a proper balance between the need to ensure the safety and effectiveness of these products, and appropriate steps to facilitate innovation. Medical devices are important tools in the hands of physicians, and much of the impactful innovation in devices have been through successive improvements made over periods of time, often based on the real world experience of providers. From a public health perspective, we should support a regulatory process that helps facilitate this sort of continuous innovation that can improve the safety and effectiveness of products.

Question 2. It seems as though some drugs attain orphan drug status for treating a subset of a condition, but go on to gain additional approvals for treating the condition more broadly. Orphan products may face a different set of standards for approval, and earn a different amount of market exclusivity, compared with non-orphan products. Dr. Gottlieb, what are your thoughts on our incentive structure for orphan drugs, and how these incentives interact with those drugs indicated for populations larger than orphan size?

Answer 2. The Orphan Drug Act has played an important role in incentivizing manufacturers to develop treatments for rare diseases. Given the small patient populations and inherent challenges associated with clinical trials for rare diseases, I believe we must protect these incentives and assess whether additional incentives may be necessary to spur the development of safe and effective new treatments for

patients with rare diseases. We must also make sure that the Orphan Drug Act isn't being used in ways that Congress did not intend. If confirmed, I pledge to work with Congress, patients, industry, and other stakeholders to make sure the Orphan Drug Act continues to achieve its important public health goals.

SENATOR BALDWIN

Question 1. Wisconsin has been a leader in advancing new technologies to better diagnose and screen for disease. An innovative company in Madison was the first to receive FDA approval for a new stool-based DNA test for colorectal cancer. But, in recent years, we have seen significant growth of the laboratory-developed test (LDT) industry, which are not approved by FDA. I am concerned with this uneven oversight of critical diagnostics, and believe that FDA oversight of LDTs must be appropriately updated and modernized. You have stated that "the regulation of lab tests is best left to a more robust CLIA [or framework through CMS], and not FDA."[42] If confirmed, would you support FDA as the primary regulator of diagnostics, including LDTs?

Answer 1. Defining an appropriate regulatory framework for Laboratory Developed Tests (LDTs) is important to FDA's mission to protect and promote public health. In order to both protect patient safety and encourage innovation and patient access, I believe we must strike the right balance between Clinical Laboratory Improvement Amendments (CLIA) and FDA regulation and regulatory requirements. If confirmed, I would commit to working with Congress and stakeholders to develop appropriate LDT regulatory policies.

Question 2. As we discussed when we met, dairy farmers in Wisconsin pride themselves on producing high quality milk that meets very specific requirements. In fact, many of those requirements are set by the FDA's standards of identity regulations. Despite the constant work farmers do to meet these standards, there are many imitation products on the market today that get away with using dairy terms without meeting the standard of identity for that product. This is unfair and I, along with thousands of farmers across America, am very frustrated that FDA has not enforced its own regulations. If confirmed, how will you enforce FDA regulations against all plant-based imitation products that use dairy terms?

Answer 2. While I am not personally familiar with the current discussion inside FDA related to this specific issue, I strongly support accurate product labeling and consistent and effective implementation of laws Congress passes and the rules FDA promulgates. If confirmed, I will commit to engaging with the agency's professional staff to quickly get up to speed on this issue. I would welcome the opportunity to work with you on this issue moving forward.

Question 3. Dairy farmers have been waiting for FDA to address this for years without action, and they are tired of waiting. That is why I introduced the DAIRY PRIDE Act earlier this year—my bill would require FDA to enforce its own regulations within 60 days. But the agency should be doing this already. If confirmed, will you commit to beginning enforcement within 60 days?

Answer 3. If confirmed, I commit to implementing congressional laws according to the timelines prescribed by the law and to working with your office on this issue.

Question 4. According to the Institute of Medicine, nearly 50 percent of all cancer patients experience distress. Further, studies suggest that distress in cancer patients leads to higher healthcare costs, less compliance with treatment pathways and poorer health outcomes. While we have seen significant advancements in biomedical treatments, there remain barriers to more effective development of therapies. I am encouraged by FDA's enhanced focus on considering patient experience data when assessing treatments. I believe that FDA should explore mechanisms to capture data beyond just disease symptoms and physical functioning to include psychosocial health measures, including distress screening (*e.g.*, concerns related to disruption of work/family life [due to the regimen], concerns related to nutrition, financial impact and others). This would provide meaningful patient feedback about issues that may not be identified through the current measures being used in the clinical trial process. How would you work to enhance FDA's patient-reported outcomes work to include comprehensive and reliable measures on patient experiences that capture physical and psychosocial symptoms?

Answer 4. I strongly agree that patient experiences, preferences, and perspectives should play an important and appropriate role in FDA's regulatory policymaking

[42] *http://www.aei.org/publication/theranos-woes-offer-lesson-in-how-labs-should-be-regulated/*.

and decisionmaking. Among other approaches, I have advocated that we continue to advance well-validated, scientific tools for incorporating Patient Reported Outcomes (PROs) as endpoints in clinical trials. I support these and other measures that would allow meaningful patient feedback to be incorporated into regulatory decisionmaking to better define patient-experience data that may not be identified through the current measures being used in the clinical trial process. If confirmed, I look forward to working with you on this issue.

Question 5. You have argued that the FDA should allow drug companies to promote uses for drugs that have not yet been FDA approved—a position the drug industry shares—because FDA labels, are "slow to incorporate important medical results about the effectiveness of medical products."[43] The agency has been working to improve the accuracy of labels. For instance, FDA proposed a rule to ensure that labels for generics drugs were rapidly updated to include the latest safety information. However you, along with the generic drug industry, opposed FDA finalizing this rule. You have said this is because it would "expose the generic-drug industry to the same kind of costly product liability suits that plague branded-drug makers"[44] I am concerned with these seemingly contradictory positions that suggest—at least when it comes to drug labels—a potential bias in favor of positions supported by the biggest industry stakeholder. As FDA Commissioner, responsible for guaranteeing that patients have the most up-to-date and accurate information about drugs, what principles would you use to determine the best communication and labeling standards?

Answer 5. I believe it is important that generic drug labels be kept up-to-date and generic manufacturers engage in appropriate post-market safety surveillance. The FDA proposed rule would alter the legal responsibilities of generic firms. If confirmed, I will work with agency's staff as we consider future regulatory actions. As a general matter, I am philosophically in favor of approaches to enable providers to get more and timelier truthful, non-misleading information about the medical products they prescribe, in a non-promotional context.

Question 6. Among its many roles, FDA plays a key part in helping ensure that U.S. companies that export foods such as dairy products are able to keep tapping into those foreign markets and thereby support American jobs. Can you assure me FDA will prioritize working with its interagency partners to swiftly resolve export certification issues in order to keep those foreign markets open to U.S. products?

Answer 6. I will commit to working with our interagency partners on this issue. I recognize the importance of maintaining access to these foreign markets for our U.S. companies.

SENATOR HATCH

Question 1. Dr. Gottlieb, one issue that was not really addressed by the 21st Century Cures law as enacted is how reimbursement and coding issues can affect the availability of needed treatments. While we recognize that reimbursement is not directly within the purview of FDA, your mission in speeding safe and effective treatments and cures to patients has a direct relationship to how quickly patients can benefit from medical products FDA approves. This is particularly important for new and innovative products, both drugs and devices. It strikes us that your background at both CMS and FDA puts you in a unique position to make a valuable contribution toward addressing this issue. Our question is simple: When confirmed, will you take steps to partner with CMS to work on ways to make certain that new therapies in the critical areas you mentioned at your hearing are made available to patients as early as possible?

Answer 1. I believe my prior experiences at both FDA and CMS will help guide my work as Commissioner, if confirmed. As you mentioned, reimbursement and coding issues are outside the purview of FDA, but I agree that there are areas where CMS and FDA could work more closely together to increase the availability of innovative therapies. I commit to working with my colleagues at CMS and you on this issue.

Question 2. Since its inception, the Orphan Drug Act has fueled treatment discoveries, and even cures, for rare diseases that would probably remain untreated to this day without the Orphan Drug Act's incentives. We still have about 95 percent of the over 7,000 identified rare diseases remaining with no FDA-approved treat-

[43] *http://healthaffairs.org/blog/2008/04/23/from-fda-a-good-framework-for-distributing-information-on-off-label-uses/*.

[44] *https://www.aei.org/publication/how-obamas-fda-keeps-generic-drugs-off-the-market/*.

ment option. Many of these disorders have prevalence rates of several hundred to several thousand patients, leaving little commercial incentive for investment. As such, what do you anticipate doing to ensure that patients with these extremely rare conditions, and innovators, see FDA as an effective partner toward approving new treatments and cures?

Answer 2. The Orphan Drug Act has played an important role in incentivizing innovators to develop treatments for rare diseases. Given the small patient populations and inherent challenges associated with clinical trials for rare diseases, I believe we must protect these incentives and assess whether additional incentives may be necessary to spur the development of safe and effective new treatments for patients with rare diseases. If confirmed, I pledge to work Congress, patients, industry, and other stakeholders to make sure the Orphan Drug Act continues to achieve its important public health goals. Given the unique challenges to developing drugs for extremely rare conditions, we also must continue to make sure that we are using the most modern regulatory science in order to make the process for developing safe and effective drugs targeted to extremely rare diseases as efficient as possible.

Question 3. Every day, millions of Americans safely take one or more dietary supplements. As consumers continue to take greater control of their health, it is important that they have access to safe products that fit their needs. The FDA currently has the oversight authority to remove any product it finds is unsafe and to take enforcement action to remove the product from the market. Dr. Gottlieb, do you believe the FDA's current regulatory framework under DSHEA provides for adequate enforcement tools to remove unsafe dietary supplements from the market?

Answer 3. As someone who uses dietary supplements every day, I believe they serve an important role in health promotion for millions of Americans and I support consumer access to these products. I believe the regulatory framework established under DSHEA is the right one, and if confirmed, I would commit to enforcing DSHEA, as intended by Congress.

Question 4. One of the world's most pressing health problems is the emergence of bacterial infections that are resistant to antibiotics. According to the Centers for Disease Control and Prevention (CDC), every year at least 2 million Americans get sick with antibiotic-resistant infections. Sadly, an estimated 23,000 people die as a result. As bacterial strains consistently evolve and adapt to current drug therapies, providers struggle to improve upon documented over-prescription of antibiotics. Moreover, the Nation faces a lack of new antibiotics in the development pipeline, leading researchers to estimate that 10 million people annually could die from drug resistant infections by the year 2050.

While reducing the inappropriate and unnecessary use of antibiotics can slow how quickly bacteria become resistant to currently utilized drug therapies, this alone is unlikely to solve the problem. Manufacturers must develop new antibiotics. Yet reduced antibiotic discovery, gaps in scientific research, and poor return on investment pose significant barriers to developing new, novel antibiotics. Congress has responded with a number of initiatives to respond to this crisis. Specifically, in 2012, legislation I authored called the Generating Antibiotic Incentives Now (GAIN) Act was signed into law. This law gave companies enhanced tools that encourage development of new antibiotics and allowed an expedited FDA approval process for antibiotics that treat life-threatening infections. Last Congress, I also authored legislation that was included in the 21st Century Cures Act to speed the research and development of new antibiotics that would address an unmet medical need by establishing a limited population antibiotic approval pathway that allowed smaller, faster clinical trials. These laws have had an impact, but more action is needed to increase development of novel therapies.

Dr. Gottlieb, in 2013, you co-authored an article printed in The RPM Report titled "Paying for New Drugs for New Bugs: Regulation is Only One Side of the Coin". In that article you assert that, while the FDA and Congress are making headway to improve the regulatory environment for antibiotic development, that these changes are not sufficient without adjustments to reimbursement. What do you believe Congress should be doing, in consultation with the Administration, to spur innovation in the antibiotic class of prescription drugs?

Answer 4. As the nominee to be the next Commissioner of Food and Drugs, I do not believe it would be appropriate to comment on questions about issues that are outside the jurisdiction of FDA. With regard to FDA's role in this important issue, I believe the availability and appropriate prescribing of antibiotics are vital to our Nation's public health. Additionally, antibiotic resistance is a significant and growing public health challenge facing our Nation. Within its statutory authorities, FDA should encourage the development of new antibiotics and ensure proper labeling to

help address the issue of inappropriate prescribing and/or use. If confirmed, I would commit to fully implementing the law as it relates to these issues, and in particular, the Limited Population Approval Pathway for antibiotics.

Question 5. The 21st Century Cures Act requires FDA to update guidance and regulations for regenerative therapeutic products and to hold a public meeting to encourage innovation. This is a great first step, and we are hopeful that you will prioritize the potential of these products as the new Commissioner of the FDA. If you are confirmed, how do you envision FDA's regulatory framework for these cutting-edge treatments and therapies now and in the future?

Answer 5. Regenerative medicine is one of the most innovative and promising emerging advancements in our scientific approaches to the treatment of human disease. Regenerative medicine appears to hold great promise for new therapeutic options for patients and physicians, particularly in areas of unmet or underserved medical need. However, as with all products FDA regulates, the agency must have the appropriate policies and processes in place to assess and ensure the safety and efficacy of regenerative medical products before they are approved for use by American patients. FDA must ensure patients and providers are appropriately educated about the potential risks and benefits of regenerative medicine therapies that fall within the scope of FDA's oversight, and that these products meet the agency's standard for safety and effectiveness. If confirmed, I will embrace the responsibility to facilitate important medical innovation in the regenerative medicine space, while maintaining the Gold Standard of safety and efficacy.

Question 6. There has been much discussion on the use of biomarkers in the context of rare disease drug development and the FDA has a formal procedure to qualify such biomarkers. To your knowledge, has the FDA ever qualified a biomarker as a surrogate efficacy outcome measure to expedite the full approval of therapeutics for rare diseases? How would you seek to balance discussions on the utility of biomarkers between fast and slow adopters at the agency?

Answer 6. I am not aware of whether the FDA has ever qualified a biomarker as a surrogate efficacy outcome measure to expedite the full approval of therapeutics for rare diseases. If confirmed, I will ensure that FDA is using the most current science to maximize the potential of biomarkers to advance drug development and that we bring consistency across the agency with respect to the application of modern and well-validated scientific and regulatory principles.

Question 7. Dr. Gottlieb, 21st Century Cures contained provisions that specifically exempt certain low-risk software functions from FDA pre- and post-market regulatory requirements. However, the law provides a mechanism for the FDA to pull a product back under FDA jurisdiction if there is a determination that a product "would be reasonably likely to have serious adverse health consequences." How do you plan to operationalize this provision in a way that provides as much clarity to innovators as possible?

Answer 7. I support tools that can help provide consumers with more information about their health. FDA must clearly define when an app is a medical device subject to its regulation, and when it falls outside FDA's framework or is low risk, and therefore appropriate to be exempt from the full scope of FDA's pre-market requirements. For products subject to FDA's pre-market requirements, the agency should use a risk-based approach in regulating consumer apps and other medical software, and, if confirmed, I look forward to helping further refine FDA's approach and implement the related provisions of 21st Century Cures.

SENATOR MURKOWSKI

Question 1. FDA's menu-labeling rule, even after an initial stay, will take effect 1 month from today. Grocery stores and other food retailers across America continue to be frustrated with FDA's handling of things, including for local and seasonal food items. Fresh and local food items may be sold at a few stores, under the same name, but the ingredients or recipe can vary, yet they would be considered "standard menu items" and subject to enforcement. The irony is that this will cause stores and restaurants to move away from fresh, local, and seasonal offerings. With just a month before the compliance date, we need FDA to act quickly to further delay, withdraw, or stay the rule so it can be rewritten to give businesses the flexibility to comply. Would you be willing to explore ways to encourage FDA to act before the compliance date to provide this much-needed flexibility for businesses?

Answer 1. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the technical specifics. As a general rule, I support providing clear, accurate, and understandable information to American consumers

to help inform healthful dietary choices. I believe information about caloric content can be a useful tool. However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with the agency's staff to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing unnecessary compliance burden on businesses, particularly small, independent ones.

Question 2. Dr. Gottlieb, one issue that was not really addressed by the 21st Century Cures law as enacted is how reimbursement and coding issues can affect the availability of needed treatments. While we recognize that reimbursement is not directly within the purview of FDA, your mission in speeding safe and effective treatments and cures to patients has a direct relationship to how quickly patients can benefit from medical products FDA approves. This is particularly important for new and innovative products, both drugs and devices. It strikes us that your background at both CMS and FDA puts you in a unique position to make a valuable contribution toward addressing this issue. Our question is simple: When confirmed, will you take steps to partner with CMS to work on ways to make certain that new therapies in the critical areas you mentioned at your hearing are made available to patients as early as possible?

Answer 2. I believe my prior experiences at both FDA and CMS will help guide my work as Commissioner, if confirmed. As you mentioned, reimbursement and coding issues are outside the purview of FDA, but I agree that there are areas where CMS and FDA could work more closely together to increase the availability of innovative therapies. I commit to working with my colleagues at CMS and you on this issue.

SENATOR MURPHY

Question 1. Dr. Gottlieb, in 1978 FDA committed to address the overregulation of medical gases, like Oxygen, by creating separate regulations for medical gases as a unique class of drug products. Thirty-nine years later, FDA has not followed through on its commitment to create an appropriate framework specific to medical gases. In 2012, Congress enacted historic and bipartisan reforms at the request of the medical gas industry and pharmacists to require FDA to follow through on its 1978 commitment to address the overregulation of medical gases in the Food and Drug Administration Safety and Innovation Act (FDASIA).

In November 2016, FDA issued a final rulemaking that addressed some medical gas labeling issues, however FDA did not, as intended by FDASIA and reiterated to FDA in the fiscal year 2016 Appropriations report language, modify current regulations to address other aspects that are unique to medical gases. For example, the November 2016 rule did not address medical air labeling, adverse event reporting, expiration dating, calculation of yield and a host of other safety and enforcement issues identified by the industry as necessary to appropriately regulate medical gases.

If confirmed as Commissioner of FDA, would you ensure that FDA fully implements Section 1112 of FDASIA by working with stakeholders to either incorporate by reference industry consensus standards or issue new final rulemakings on medical gas to address these unique medical gas regulatory issues?

Answer 1. If confirmed, I am committed to implementing all congressional laws, including Section 1112 of FDASIA. I look forward to working with you on this issue.

Question 2. In April 2016, the FDA proposed to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior because they present an unreasonable and substantial risk to public health and they have been used on children with intellectual and developmental disabilities as young as 9 years old. This step was the result of deliberative discussion and consideration about the harmful nature of these devices. The proposed rule stated that the FDA determined that ESDs presented a number of psychological and physical risks, including depression, fear, panic, aggression, pain, burns and errant shocks from device misapplication or failure. Moreover, ESDs have been associated with additional risks such as suicidality, chronic stress, acute stress disorder and hypervigilance. It is not surprising that this is the case because as Dr. Margaret Nygren from the American Association of Intellectual and Developmental Disabilities noted during the April 2014 advisory committee meeting,

"These devices are explicitly intended to inflict pain. The pain is not an unfortunate risk or byproduct of the intervention. With these devices, the pain is the intervention."

I, along with a number of my colleagues, wrote to then Commissioner Califf to support this proposed ban. In that letter, we stated, "The use of these electric shock devices as aversive therapy for individuals with developmental disabilities is inhumane, especially since many of these individuals have difficulty communicating and alternative effective treatment options are available. Put simply, it is outrageous that this practice is allowed in the United States for this vulnerable population and it should be stopped immediately. As such, we urge you to finalize the proposed rule as quickly as possible."

Leading disability organizations and advocates also support finalizing the proposed ban. A letter from two dozen of these groups from July 25, 2016, stated,

> "We applaud the FDA for taking this critically important step, which we believe is long overdue. For too many decades, children with disabilities have been subjected to physical and psychological abuse through the use of these devices, and have experienced pain, trauma, suffering and long-term harms."

If confirmed, would you ensure that the FDA moves forward with the proposed ban of electrical stimulation devices used to treat self-injurious or aggressive behavior?

Answer 2. While I am not personally familiar with the specific details of this issue, if confirmed, I commit to engaging with the agency's professional staff to get up to speed on this issue and reviewing the agency's scientific opinions and input from stakeholders, including Congress.

Question 3. The CDC estimates that 23,000 Americans die each year from drug-resistant infections. The World Health Organization predicts that without urgent action, we are headed toward a "post-antibiotic" future where common infections and minor injuries will once again kill.

The over-use of broad-spectrum antibiotics is a major contributor to the rise of these super bugs. Antibiotic stewardship—more judicious use of antibiotics in medical practice—is therefore an important public health initiative. One way we can reduce the prescribing of broad-spectrum antibiotics is to make better use of penicillins, which are less costly, have fewer side effects and are not known to give rise to some of the most worrying resistant bugs, like *C. difficile*.

More than 30 million people in the United States self-report as penicillin allergic. Most of these patients are prescribed a broad-spectrum antibiotic in place of penicillin or amoxicillin. Yet, the American Academy of Allergy, Asthma and Immunology has said that less than 10 percent of those people actually have the allergy, and with improved penicillin allergy testing, we could make much better use of penicillins.

The CDC and other public health organizations have been educating the community on the need for penicillin allergy testing to confirm current allergy, before resorting to non-penicillin broad spectrum antibiotics.

Do you agree that penicillin allergy testing could help us be better stewards of the antibiotic drug supply and do you agree that it is important for public health that FDA work with sponsors to approve tests for penicillin allergy testing?

Answer 3. Yes, I believe penicillin allergy testing could be an important piece of addressing antibiotic drug resistance, and that we should advance technologies that can help widen such testing and make sure that the testing that is done is safe and reliable. I look forward to working with CDC and other public health organizations on this issue.

Question 4. How can the FDA promote research transparency and clinical data sharing so that patients, healthcare providers, and independent researchers have access to information about the risks and benefits of medical products? How can the FDA be more transparent with key decisions in its own review process for medical products?

Answer 4. I am a strong proponent of data transparency—for patients, physicians, and manufacturers. I have long advocated that the FDA release more information related to its own review process that could be used to better inform consumers and product developers alike. If confirmed, I will be committed to working with Congress, patients, industry, and stakeholders on the issue of data transparency and new ways that FDA could potentially make the importance of its own information and deliberations more readily available to the public.

Question 5. New innovations in wearable wellness technology are empowering consumers by providing access to health data, including steps taken, hours slept,

and heart rate. It is my understanding the FDA's current policy is that these devices do not require FDA approval as long as the information is not used by a medical professional to make a diagnosis.

As wearable technology continues to advance, such as warning consumers about an abnormal heart rate reading, where do you see the line between a medical device and a consumer application?

Answer 5. I support tools that can help provide consumers with more information about their health. FDA must clearly define when an app is a medical device subject to its regulation, and when it falls outside FDA's framework or is low risk, and therefore appropriate to be exempt from the full scope of FDA's pre-market requirements. For products subject to FDA's pre-market requirements, the agency should use a risk-based approach in regulating consumer apps and other medical software, and, if confirmed, I look forward to helping further refine FDA's approach and fully implement the related provisions of 21st Century Cures.

Question 6. Connecticut is a State with a growing number of small farms. These small farmers face unique challenges when adapting to new food safety regulations. I have led my colleagues in letters urging the FDA to expedite implementation of Sec. 209 of the Food Safety Modernization Act (FSMA), which includes a provision that provides technical assistance and training for small farmers, small producers, and fruit and vegetable merchant wholesalers in order to reduce confusion surrounding new regulations and promote effective implementation.

Can you commit to ensuring FSMA implementation will continue to have a focus on the unique challenges faced by small farmers?

Answer 6. The Food Safety Modernization Act (FSMA) provides FDA with important tools and authorities to support its responsibility to ensure the safety of our Nation's food supply. If confirmed, I will work to ensure FDA has the appropriate policies, processes, and resources in place to implement FSMA, as intended by Congress. I agree that FDA should implement FSMA in a way that protects and promotes public health by enhancing food safety, while also collaborating with the U.S. Department of Agriculture, State officials, and other Federal and State Government agencies to conduct regulatory activities in a manner that takes into account the unique challenges faced by small farmers and small businesses.

Question 7. Sesame is now one of the most prevalent, and most dangerous, food allergies in the United States. I have heard from many Connecticut constituents about the need for the FDA to require that sesame seeds and sesame products be labeled as such, in a manner similar to the other eight major allergens. Sesame allergies are particularly severe and, for some, sesame exposure can trigger fatal anaphylaxis. Allergists estimated 300,000 to 500,000 people in the United States have sesame allergies.

Given the severity and number of sesame allergies, what is the FDA doing to address this problem? What more can the FDA do under its current authority in the Food Allergen Labeling and Consumer Protection Action to require sesame labeling?

Answer 7. I am not aware of what FDA has reviewed or done to date with respect to sesame and labeling. If confirmed, I look forward to reviewing the Food Allergen Labeling and Consumer Protection Act to understand what authority FDA may have under the current law with regard to this issue.

Question 8. Nationally, the production value of farmed oysters and clams is growing at a rate of 8 percent a year, with some areas of the country like the Northeast growing at a much higher rate of 31 percent. With this surge in production, producers in my home State of Connecticut are anxiously looking to expand to new markets. The EU and United States have been in trade negotiations to open up trade between two U.S. States—Massachusetts and Washington—and two EU countries—Spain and the Netherlands. Negotiators finally arrived at a compromise that is designed to resolve the issue and technical audits were performed in 2015 that satisfied the health concerns of the respective health agencies. Connecticut producers are anxious for this agreement to be finalized so trade can begin and agencies can start discussions to further expand trade to new U.S. States and EU countries.

What progress has the FDA made toward finalizing an equivalence determination with the European Union? What more can the FDA do to accelerate the process of finalizing this agreement and publish a notice in the Federal Register? What can we do to ensure that the other interested States gain access in a timely fashion?

Answer 8. I am not aware of where FDA is in the process of finalizing an equivalence determination with the EU. I commit to reviewing this issue, and working with your office on this matter, if confirmed. If FDA is able to finalize the agree-

ment, then I would work to ensure that other States interested in participating do not face lengthy waits.

Question 9. Connecticut shade tobacco, which is used as a wrapper for premium cigars, has been grown in Connecticut for centuries and is sought after for its unique flavor profile. I recently wrote to the FDA about an issue Connecticut tobacco farmers face regarding potential misbranding of foreign tobacco products.

Will you commit to working with me going forward to address this issue and assist Connecticut's small tobacco farmers?

Answer 9. Yes, I commit to working with you on this issue, if confirmed.

SENATOR ROBERTS

Question 1. FDA's menu-labeling rule, even after an initial stay, will take effect 1 month from today. Grocery stores and other food retailers across America continue to be frustrated with FDA's handling of things, including for local and seasonal food items. Fresh and local food items may be sold at a few stores, under the same name, but the ingredients or recipe can vary, yet they would be considered "standard menu items" and subject to enforcement. The irony is that this will cause stores and restaurants to move away from fresh, local, and seasonal offerings. With just a month before the compliance date, we need FDA to act quickly to further delay, withdraw, or stay the rule so it can be rewritten to give businesses the flexibility to comply. Would you be willing to explore ways to encourage FDA to act before the compliance date to provide this much-needed flexibility for businesses?

Answer 1. While I am broadly aware of the menu labeling issue, this is not a matter on which I am familiar with the technical specifics. As a general rule, I support providing clear, accurate, and understandable information to American consumers to help inform healthful dietary choices. I believe information about caloric content can be a useful tool. However, I am mindful of the unique challenges that developing and communicating such information can pose, particularly on small, independent businesses. If confirmed, I will commit to working with the agency's staff to quickly get up to speed on the regulatory history related to menu labeling, as well as FDA's latest thinking and actions. I would welcome the opportunity to work with Congress and stakeholders to ensure any regulatory requirements would promote public health by providing helpful information to consumers, while not placing unnecessary compliance burden on businesses, particularly small, independent ones.

Question 2. There has been much discussion recently about how FDA restricts what drug makers and medical device manufacturers can say about their products. Legislation has been introduced in the House of Representatives and there have been high profile lawsuits surrounding FDA's actions and the First Amendment. There are many treatments that have additional uses that are medically accepted, that doctors can prescribe for their patients, and that the Federal Government will even pay for—but FDA prohibits the manufacturers, who know the most about their products, from discussing those uses under most circumstances.

Do you have ideas on how to modernize or improve how FDA regulates communication between doctors, patients and payers, while making sure information is truthful and not misleading? How do we strike the right balance to allow more communication while maintaining incentives to get additional indications for therapies approved?

Answer 2. Medical product labels are one of the primary tools FDA uses to promote the appropriate use medicines and technologies and communicate risk information. It is important that information on product labels is accurate, clear, and scientifically based; and be the result of a sound regulatory process. Further, it is crucial that manufacturers continue to develop and submit to the agency clinical data demonstrating the safety and efficacy of medical products for new indications they seek to include on labeling and in their marketing communications with patients, payers, and providers. I also believe that patients and physicians make the best decisions when they have access to as much truthful, non-misleading, scientifically based information as possible. So, I believe and FDA has similarly maintained that there is some public health benefit in certain contexts of allowing non-promotional communication about truthful, non-misleading, clinical data that is not already incorporated into FDA-approved product labeling. If confirmed, I will commit to working with FDA's staff to get up to speed on the agency's latest thinking and actions on these matters, and providing clarity to manufacturers, payers, providers, and patients about acceptable, truthful and non-misleading communications related to clinical data not already incorporated in a label.

Question 3. Various U.S. agencies, including the FDA, are tasked with implementing laws and furthering policies that are science-based regarding food and beverages. We expect the same from other countries and our partners abroad. Decisions based on science provide predictability and certainty for the value chain, as well as a level playing field for all countries. In late 2015, the World Health Organization International Agency for Research on Cancer (IARC) classified the consumption of red and processed meat as probably carcinogenic and carcinogenic to humans, respectively. While then USDA Secretary Tom Vilsack did publically state that U.S. dietary guidelines rely on science regarding healthful meat consumption, in December 2016, the Food Safety and Inspection Service was petitioned to inform the public about the "risk" of cancer from processed meat. This request relied strongly upon the IARC classification. In addition, when issuing draft guidance on sodium reduction in June 2016, FDA relied in part on a recommendation of the Dietary Guidelines Advisory Committee—which has specifically come under intense criticism for cherry-picking its science.

Under your leadership, what efforts would the FDA undertake to ensure that the U.S. Government inquires and responds to these types of findings and data in a science-based manner? Individual countries also pass food and beverage safety labeling laws that are not grounded in sound science. How will the FDA support a strong U.S. Government signal to such countries regarding the need for science-based laws and regulations for food and beverages? How will FDA ensure that its own guidance and other decisions will be thoroughly science-based?

Answer 3. I agree that FDA should base its regulatory decisions on sound and rigorous science. If confirmed, I will work to ensure that FDA possesses the scientific expertise necessary to inform these decisions.

Question 4. Recently, FDA has been pursuing considerable regulatory change as it relates to the use of antibiotics in agriculture, specifically their use in animals. You will certainly get pressure to "do more" and to limit certain uses of antibiotics, something the FDA has requested comment on regarding how to apply judicious use policies. Much scientific evidence has proven that healthy animals produce healthy food. Keeping animals from getting sick and preventing disease outbreaks should be a top priority. Allowing veterinarians and others in agriculture the flexibility to prevent disease outbreaks is critical for FDA to consider.

Will you work with, and be responsive to, the concerns of the agriculture and veterinary industries on this issue?

Answer 4. Antibiotic resistance is a significant and growing public health challenge facing our Nation. In addition to measures FDA should take to address this issue within the context of human use, the agency must effectively collaborate with other government agencies and public health authorities to develop policies and processes to address the issue of antibiotic use in animals intended for human consumption. If confirmed, I will ensure FDA remains engaged on this important public health issue, making sure that animal drug labeling reflects the most up-to-date science, and working closely with the U.S. Department of Agriculture, the Centers for Disease Control, the U.S. Department of Defense, and other appropriate government agencies. FDA should also consider input from, and be responsive to, other important stakeholders, such as the farmers, the agriculture industry, and veterinarians. If confirmed, I would commit to working closely with these important stakeholders.

SENATOR WARREN

Question 1. Approximately 48 million Americans experience age-related hearing loss, including over half of adults between the ages 70–79.[45] 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.[46] 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.[47] Senators Grassley, Isakson, Hassan, and I recently introduced bipartisan

[45] Frank R. Lin, John K. Niparko, and Luigi Ferrucci. 2011. "Hearing Loss Prevalence in the United States," Archives of Internal Medicine 171: 1851–53 (online at: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/*).

[46] 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*).

[47] President's Council of Advisors on Science and Technology, *Aging America and Hearing Loss: Imperative of Improved Hearing Technologies* (October 2015) (online at: *https://*

legislation that would make certain types of hearing aids available over the counter (OTC).[48] In December 2016, the FDA announced a commitment to examining OTC hearing aids and said it will no longer enforce the medical waiver requirement associated with hearing aids. In making this announcement, FDA Commissioner Califf stated that the guidance would support consumer access, "while the FDA takes the steps necessary to propose to modify our regulations to create a category of OTC hearing aids that could help many Americans improve their quality of life through better hearing."[49]

Do you agree that over the counter hearing aids would expand access to hearing aids to millions of Americans with hearing loss who struggle to afford these devices?

If confirmed, will you commit to work toward making safe and innovative hearing aids intended to be used by adults to compensate for mild to moderate hearing impairment available over the counter?

If confirmed, what steps will you take to implement the FDA's stated commitment to creating a category of OTC hearing aids?

Do you agree that a key step in improving access to OTC hearing aids will be pre-empting the many State requirements that now regulate access to hearing aids?

If confirmed, what steps will you take to develop a clear OTC access standard by pre-empting these State requirements?

Answer 1. I have not been privy to the discussions that FDA has had related to this matter, although I am aware the agency announced a commitment to examining OTC hearing aids. If confirmed, I commit to reviewing the scientific evidence and to working with you, Senators Grassley, Isakson, and Hassan, and other Members of Congress on this issue.

Question 2. The Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently released preliminary results of an ongoing review, finding that procedures associated with fixing seven faulty cardiac implants cost Medicare $1.5 billion and resulted in an additional $140 million in out-of-pocket costs to Medicare beneficiaries.[50] The OIG recommended that the Center for Medicare and Medicaid Services (CMS) collaborate with the Accredited Standards Committee X12 (ASC X12) to include medical devices' unique device identifier (UDI) on health insurance claim forms. In October 2016, ASC X12 voted in favor of a technical solution to this issue.[51]

In a July 2016 joint letter to X12, the FDA and CMS identified several benefits to collecting device identifiers on medical claims form, including: Strengthening capacities to evaluate product performance and safety concerns for specific models of medical devices, improving surveillance efforts, helping support device innovation, allowing providers and payers to compare costs and outcomes by device model, and supporting program integrity efforts.[52] Inclusion of UDIs in claims is also supported

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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. 21–2. 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%20bstacles%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/*).

[48] S. 670 (115th Congress)—Over the Counter Hearing Aid Act of 2017 (online at: *https://www.warren.senate.gov/files/documents/3_21_17_Hearing_Aids_Bill_Text.pdf*).

[49] FDA, "Immediately in Effect Guidance Document: Conditions for sale for air-conduction hearing aids—Guidance for industry and FDA staff" (Dec. 12, 2016) (online at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf*); FDA News Release, "FDA takes steps to improve hearing aid accessibility" (online at: *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm*).

[50] Letter from HHS Inspector General, Daniel Levinson, to Andrew Slavitt, Acting Administrator, Centers for Medicare and Medicaid—"Early Alert: Incorporating Medical Device-Specific Information on Claim Forms (A–01–16–00510)" (September 30, 2016) (online at: *https://oig.hhs.gov/oas/reports/region1/11600510.pdf*).

[51] American Hospital Association, "Standards organization approves UDI changes" *AHA News Now* (September 20, 2016) (online at: *http://news.aha.org/article/160920-standards-organization-approves-udi-changes*).

[52] Letter from CMS Acting Administrator Andrew M. Slavitt and FDA Commissioner Robert M. Califf to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online

Continued

by clinical societies like the American Academy of Orthopedic Surgeons (AAOS),[53] and by members of both parties in Congress.[54] FDA has agreed to develop a list of specific, high-risk implantable devices for which reporting on claims will be recommended.[55]

The AAOS stated in a 2015 letter to then-Acting FDA Commissioner Stephen Ostroff that UDIs "will significantly enhance post-market surveillance activities by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries."[56] Do you agree that including device identifier information in medical claims could support the evaluation of medical devices after approval?

If confirmed, 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?

How will you direct FDA to work with CMS to ensure that device identifiers can be effectively used to monitor threats to Medicare program integrity, as well as to patient health?

What steps will you take to develop a list of high-risk implantable devices and support the inclusion of device identifiers for these devices on claims forms? More specifically:

- What criteria should be used to determine whether a device should be included on the list?
- What factors should FDA consider in deciding what these criteria should be?
- How will FDA support providers and insurers who wish to exchange device identifier information, even for devices not included on the FDA's high-risk list?

Answer 2. I am committed to reviewing the work done to date by staff at CMS and FDA on this issue. Policies that can help us identify problems with devices are important, and if confirmed, I look forward to working with my colleagues at CMS and the X12 Committee to explore these policies. These considerations should also include achieving interoperable electronic health records with UDIs—a goal that is consistent with the health information technology provisions in 21st Century Cures.

Question 3. Once relatively simple, well-understood pathology tests used for diagnostic purposes, lab-developed tests (LDTs) have become more advanced and a staple of clinical decisionmaking. They are often now used to diagnose high-risk, but relatively common, diseases. Increased understanding of genetics and the role particular genes play in disease has led to the creation of new, more complex, medical diagnostic technology. LDTs hold great promise to customize healthcare to be more efficient and targeted for an individual patient. However, because of their increasing prevalence in the clinic, it is imperative that they perform reliably and accurately. Incorrect results mean that patients either will not seek out the care and therapy that is needed, or will be subject to treatments that do not work or are harmful.[57] FDA, which has authority under the Food, Drug and Cosmetic Act to regulate LDTs, released draft guidance in October 2014 after years of delay.[58] However, in November 2016, FDA stated that it would not release final guidance during the Obama administration. If you are confirmed Commissioner—

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at: *http://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg__uploaded/LETTER__FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf*).

[53] American Academy of Orthopedic Surgeons letter to FDA Commissioner Margaret A. Hamburg (Nov. 7, 2012) (online at: *http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/FDA/UDI%20Proposed%20Rule%20Comment%20Draft__final.pdf*); Multi-organization letter to CMS (December 15, 2015) (online at: *https://s3.amazonaws.com/assets.fiercemarkets.net/public/004Healthcare/external/Public+health%2C+clinician+and+stakeholder+comments+in+support+of+UDI+in+EHRs+12-15+FINAL.pdf*).

[54] Letter from Senator Warren and Senator Grassley to Gary Beatty, Chair of ASC X12 (Aug. 29, 2016) (online at: *http://www.warren.senate.gov/files/documents/2016-8-29__UDI__letter__to__ASC__X12.pdf*).

[55] American Hospital Association, "Standards organization approves UDI changes" *AHA News Now* (September 20, 2016) (online at: *http://news.aha.org/article/160920-standards-organization-approves-udi-changes*).

[56] American Academy of Orthopedic Surgeons letter to Acting FDA Commissioner Stephen Ostroff (Oct. 26, 2015) (*http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/FDA/AAOS__FDA%20Comment%20Letter%20on%20MDEpiNet%20Report__FINAL%20%20.pdf*).

[57] 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*).

[58] 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*).

- What role do you believe that FDA 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?
- Do you agree that high-risk LDTs that inform clinical diagnoses should be clinically validated?
- How will you ensure patient safety by implementing risk-based oversight and regulation of LDTs?
- How will you direct FDA to ensure reliability of LDTs, particularly those that are moderate- or high-risk?
- What steps should FDA take to improve reporting by clinicians and patients of faulty or unreliable LDTs?
- What steps should be taken when such LDTs are identified?

Answer 3. Defining an appropriate regulatory framework for Laboratory Developed Tests (LDTs) is important to FDA's mission to protect and promote public health. In order to both protect patient safety and encourage innovation and patient access, I believe we must strike the right balance between Clinical Laboratory Improvement Amendments (CLIA) and FDA regulation and regulatory requirements. If confirmed, I would commit to working with Congress and stakeholders to develop appropriate LDT regulatory policies.

Question 4. 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.[59] 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.[60] Building on these steps will require leadership from the next FDA Commissioner.

If you are confirmed as Commissioner—

Are you committed to implementing a risk-based blood donation deferral policy for all donors?

As FDA Commissioner, how would you support the FDA's efforts to move to a risk-based referral policy for all blood donors?

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:

- Will you commit to developing a risk-based onsite questionnaire to be used at blood donation clinics?
- When can we expect FDA to release a draft of a risk-based questionnaire?
- Will you commit to gathering stakeholder input on the questionnaire?
- Over what time period will you test the questionnaire and gather input?
- Will you commit to integrating stakeholder input into the questionnaire? How will you perform that integration?

What specific steps will you take to engage with impacted groups, which may be newly eligible for blood donation, to encourage blood donation in line with new policies?

Answer 4. Ensuring the safety and adequacy of our Nation's donated blood supply is critically important to public health. If confirmed, I will work with FDA staff to closely develop, implement, and monitor the impact of policies to promote blood safety. I will also commit to continuing to work with FDA staff to review its donor deferral policies to ensure they reflect the most up-to-date scientific knowledge.

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[59] 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*).

[60] 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*).

Question 5. 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 percent from 2009 through 2015, and increased by 2 percent from 2014 through 2015."[61]

The 2014 National Strategy for combating 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."[62]

This initiative has enabled significant progress in establishing policies that better protect lifesaving antibiotics. FDA policies (Guidance for Industry (GFI) #209 and #213 and the Veterinary Feed Directive Final Rule) now make the use of antibiotics to promote animal growth illegal and subject all remaining uses of antibiotics to veterinary oversight. However, more work could be done to strengthen FDA policies aimed at preventing bacterial drug resistance.

As FDA Commissioner, will you commit to continuing this important collaborative work with the Secretaries of Agriculture and Defense to combat antibiotic-resistant bacteria?

Will you ensure that FDA staff time is dedicated to continuing the relationship with USDA and DOD in service of the important goal of reducing antibiotic overuse and misuse in animals?

Using low doses of antibiotics for long periods of time—as called for by many growth promotion indications—can lead to resistance, yet many commonly used antibiotics do not come with instructions regarding treatment time limits. Without instructions on the label, there is no mechanism for enforcement. The FDA recently sought comments on a plan to establish treatment time limits for medically important antimicrobial drugs when administered to animals.[63] This comment period closed on March 13, 2017.

Will you commit to ensuring that this process for establishing treatment time limits continues in a timely manner once the comment period closes? When can we expect a proposed regulation?

GFI #213 describes principles that veterinarians should consider when determining the appropriateness of antibiotic use for disease prevention. While the FDA "intends to work with veterinary and animal producer organizations to reinforce the importance of these principals,"[64] not all stakeholders agree on the need to reduce antibiotic use or on the impact that the FDA's policies will have on the amount of drugs used. Given the documented disagreements among stakeholders, and given that veterinary adherence to appropriate antibiotic prescribing guidelines is a critical part of FDA's policies, FDA oversight is particularly important. Will you commit to putting in place a protocol to monitor and report on veterinary compliance with GFI#213's appropriate antibiotic prescribing guidelines?

GFI #213 was released in 2012, but only just fully implemented on January 3, 2017. If confirmed, your agency will have the responsibility for measuring whether or not this policy successfully reduces antibiotic resistance in humans and taking additional action if it does not. What metrics would you use to evaluate whether the FDA's policies (Guidance for Industry (GFI) #209 and #213 and the Veterinary Feed Directive Final Rule) have been successful or unsuccessful at reducing the misuse and over-use of antibiotics in animal agriculture?

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[61] 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*).

[62] "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.

[63] Food and Drug Administration, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Establishing Appropriate Durations of Therapeutic Administration; Extension of Comment Period" (Nov. 29, 2016) (online at: *https://www.federalregister.gov/documents/2016/11/29/2016-28660/the-judicious-use-of-medically-important-antimicrobial-drugs-in-food-producing-animals-establishing*).

[64] Kraus, Thomas A., Associate Commissioner for Legislation, FDA to Senators Warren, Feinstein and Gillibrand, Sept. 8, 2014; FDA, *Guidance for Industry #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* (December 2013), p. 7.

If FDA's guidance documents succeed in reducing the use of dangerous antibiotics, what changes should we expect to see in sales data and in the Veterinary Feed Directive? When do you expect to see those changes?

The FDA and USDA have both acknowledged that collecting data that shows how antibiotics are used on farms is vital to enhanced monitoring, however they have not yet enacted a joint plan. The Antimicrobial Resistance Action Plan, released by the USDA's Animal and Plant Health Inspection Service (APHIS) National Animal Health Monitoring System (NAHMS), proposed initiatives include on-farm studies.[65] Will you commit to working with USDA to prioritize the collection of on-farm data on antibiotic use?

A report published in October 2016 by the European Medicines Agency shows that sales of antimicrobials used in animals in Europe fell between 2011 and 2014.[66]

- What policies in selected countries in the European Union do you believe have led to that reduction?
- As FDA Commissioner, which of these policies will you look to as an example of how we can better manage the use of antibiotics in food animals in the United States?

Answer 5. Antibiotic resistance is a significant and growing public health challenge facing our Nation. In addition to measures FDA should take to address this issue within the context of human use, the agency must effectively collaborate with other Federal and State government agencies and public health authorities to develop policies and processes to address the issue of antibiotic use in animals intended for human consumption. If confirmed, I will ensure FDA remains engaged on this important public health issue, making sure that animal drug labeling reflects the most up-to-date science, and working closely with the U.S. Department of Agriculture, the Centers for Disease Control, the U.S. Department of Defense, and other appropriate government agencies. While I am familiar with the EMA report, I have not reviewed it in detail. If confirmed, I would commit to reviewing it further and sharing my views on any lessons we could learn from that experience. FDA should also consider input from other important stakeholders, such as the farmers, the agriculture industry, and veterinarians. FDA's implementation of a voluntary plan with industry to phaseout the use of certain antibiotics is an important step in the right direction.

Question 6. Compounding pharmacies serve individual patients who need specialized drugs. Without these customized products, some of the most vulnerable patients would not be able to get the precisely formulated medications they need. While intending to provide special services for individual patients, the lack of regulation and oversight of compounding pharmacies led to tragedy in 2012, when a widespread fungal meningitis outbreak caused by contaminated compounded drugs from New England Compounding Center (NECC) impacted over 20 States. The outbreak resulted in over 750 people falling ill, including 64 deaths.[67] The following year, Congress passed the bipartisan Drug Quality and Security Act (DQSA), which clarified and enhanced FDA's authority to regulate drug compounding.[68] Since then, the FDA has issued a number of draft and final guidances and rules, performed over 300 inspections of drug compounders, and found numerous violations, causing some facilities to close and recall their products.[69] The FDA Commissioner oversees the

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[65] "Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan," APHIS, April 2015 (Online at: *https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf*).

[66] European Medicines Agency, "Sales of veterinary antimicrobial agents in 29 European countries in 2014," Oct. 14, 2016. (Online at: *http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/10/WC500214217.pdf*).

[67] Centers for Disease Control and Prevention, "Multistate outbreak of fungal meningitis and other infections—Case count" (Oct. 30, 2015) (*https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html*). Accessed Jan. 17, 2017.

[68] H.R. 3204, Drug Quality and Security Act (113th Congress) (*https://www.congress.gov/bill/113th-congress/house-bill/3204*).

[69] *See for example*, Christine Blank, *Drug Topics*, "FDA temporarily shutters 'filthy' compounding pharmacy" (May 12, 2016) (*http://drugtopics.modernmedicine.com/drug-topics/news/fda-temporarily-shutters-filthy-compounding-pharmacy); Food and Drug Administration, "Well Care Compounding Pharmacy issues voluntary statewide recall of all sterile compounded products due to lack of assurance of sterility concerns" (May 17, 2016) (http://www.fda.gov/Safety/Recalls/ucm501543.htm*); Mintz Levin Cohn Ferris Glovsky and Popeo PC, *Lexology*, "Health care enforcement review and 2017 outlook: FDA's wide-ranging activities" (Jan. 4, 2017) (*http://www.lexology.com/library/detail.aspx?g=efefdb42-b573–4193–990a–2f903cb866f0*). Accessed Jan. 17, 2017. "Drug Compounding: FDA has Taken Steps to Implement Compounding Law, but

Continued

agency's activities regarding implementation of DQSA and ensures the safety and health of the American people by regulating the safety and efficacy of domestic and imported pharmaceutical products, including compounded drugs. If you are confirmed Commissioner—

Will you agree that effective Federal oversight of compounding facilities is essential in preventing disease outbreak and danger to patients?

Will you commit to protect patients through strong enforcement of the DQSA?

Will you commit to supporting FDA's efforts in carrying out inspections of compounding facilities?

What specific steps will you take to ensure patient health and safety for patients who need compounded drugs?

Answer 6. Congress clarified FDA's regulatory authorities related to compounding by passing the Drug Quality and Security Act (DQSA). If confirmed, I am committed to implementing DQSA, as intended by Congress, to both protect patient safety, and allow for safe and appropriate practice of pharmacy compounding. The practice of pharmacy compounding can serve an important role, allowing providers to develop individualized formulations of certain medicines for specific patients with unique needs. However, I know that there are examples of actors operating as manufacturers of unapproved new drugs under the guise of a pharmacy license, violating the careful framework created by Congress, circumventing the FDA oversight that Congress intended for certain products, and putting patient safety at risk.

Question 7. On January 18, 2017, the FDA and the Environmental Protection Agency (EPA) released final advice on fish consumption, clarifying appropriate amounts of fish consumption for pregnant and breast feeding women, and parents with young children.[70] Many pregnant and breast feeding women rely on Federal nutrition advice, and so over the past few years, my colleagues and I have pushed for the FDA to finalize updated advice on fish consumption for pregnant women that reflects the most up-to-date, scientific information.

As a doctor, do you agree that pregnant women should have access to the latest science-based nutrition advice so that they can make healthy nutrition decisions before and after pregnancy?

If confirmed Commissioner, what additional steps will you take to ensure that this final advice is consistent with the latest nutritional science?

If this advice is confirmed to be consistent with the latest nutritional science, what steps will you take to work with appropriate stakeholders to ensure that this final advice is clearly communicated to pregnant women?

Answer 7. As a doctor, I do agree that pregnant women should have access to the latest science-based nutrition advice so that they can make healthy nutrition decisions before and after pregnancy. If confirmed, I will ensure FDA's advice concerning seafood consumption by pregnant and nursing women is based on the most current and relevant nutritional science and appropriately takes into account both the nutritional benefits, and any toxicological risks associated with seafood consumption. I will also work to ensure effective collaboration between FDA and the U.S. Environmental Protection Agency (EPA) on this issue, and a range of other public health matters over which both agencies share regulatory authority.

Question 8. In March 2016, the FDA issued a request for comment entitled, "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third Party Entities and Original Equipment Manufacturers."[71] In October 2016, the agency held a public workshop, in which they heard from a variety of stakeholders, including OEMs, third party vendors, healthcare technology management professionals, and trade associations. This action was taken because of concerns over "quality, safety, and continued effectiveness of medical devices" that have been subject to third-party repair and servicing.[72] As

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Some States and Stakeholders Reported Challenges," *GAO* (November 2016) (online at: *http://www.gao.gov/assets/690/681096.pdf*). Accessed April 5, 2017.

[70] FDA News Release, "FDA and EPA issue final fish consumption advice" (Jan. 18, 2017) (*http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537362.htm*).

[71] "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third Party Entities and Original Equipment Manufacturers; Request for Comments," [Docket No. FDA-2016-N-0436] *Federal Register* (March 4, 2016) (online at: *https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04700.pdf*).

[72] "Public Workshop—Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers," *FDA* (October 27–28, 2016) (online at: *https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM525760.pdf*).

you know, determining industry best practices and appropriate regulation of third-party repair of medical devices is an important part of ensuring patient safety.

If confirmed FDA Commissioner, do you agree that it is important to ensure the safety and efficacy of medical devices that are repaired and serviced by third-party entities?

How will you continue to engage with stakeholders, such as patient groups, healthcare technology managers, and the medical device industry, in responding to the comments received through the FDA's Request for Comment and public workshop?

What specific steps would you recommend the FDA take to address the comments received by the agency?

- What would the timeframe for those actions be?
- How would the actions you propose be impacted by the regulatory freeze initiated by President Trump?

Answer 8. An important part of FDA's responsibility to protect and promote public health is upholding the Gold Standard of safety and efficacy for medical products American patients use. With regard to the issue of medical devices that are serviced by 3d parties, if confirmed, I will commit to quickly engaging with FDA's professional staff to get up to speed on this issue, including a review of the public comments received by the agency. I look forward to working with FDA's staff, Congress, and stakeholders to ensure that the agency has in place the right policies and processes to ensure the safety and efficacy of medical devices.

Question 9. The Food, Drug, and Cosmetic Act prohibits the marketing of medical products for uses not approved by the FDA. In January 2017, FDA issued two draft guidance documents on off-label communications to promote medical products, and the 21st Century Cures Act made changes to the safe harbor requirements for the communication of health care economic information (HCEI) between medical product companies and payers.[73] I am concerned that, should you be confirmed FDA Commissioner, you would aim to loosen restrictions on off-label promotion even further. Even though physicians can already use their expert judgment to prescribe drugs for off-label use, you have advocated allowing companies to actively promote their products for non-FDA-approved indications.[74]

Do you believe that medical product companies should be given greater latitude to promote their products for non-FDA-approved indications?

If confirmed Commissioner, would you commit to not loosening restrictions on off-label communications to physicians and payers?

Answer 9. Medical product labels are one of the primary tools FDA uses to promote the appropriate use of medicines and technologies and communicate risk information. It is important that information on product labels is accurate, clear, and scientifically based; and be the result of a sound regulatory process. Further, it is crucial that manufacturers continue to develop and submit to the agency clinical data demonstrating the safety and efficacy of medical products for new indications they seek to include on labeling and in their marketing communications with patients, payers, and providers. I also believe that patients and physicians make the best decisions when they have access to as much truthful, non-misleading, scientifically based information as possible. Toward these same ends, FDA has consistently acknowledged that there is some public health benefit of allowing certain non-promotional communication about truthful, non-misleading, clinical data that is not already incorporated into FDA-approved product labeling. Indeed, FDA has carved out certain "safe harbors" for such communications. If confirmed, I will commit to working with FDA's staff to get up to speed on the agency's latest thinking and actions on these matters.

Question 10. America is in the midst of an opioid epidemic, which is devastating communities in every State. According to the Centers for Disease Control, 33,000 Americans died of an opioid overdose in 2015—that's an average of 91 people every day. Nearly half of all opioid overdose deaths involved a prescription opioid and three out of four new heroin users abused prescription opioids before moving to heroin. We must take action to address this epidemic.

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[73] *See for example*, David C. Gibbons, Dara Katcher Levy, "Slower than Molasses in January, FDA Moves to Provide Guidance on Product Communications by Pharmaceutical and Device Manufacturers," *FDA Law Blog* (March 2, 2017) (online at: *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2017/03/slower-than-molasses-in-january-fda-moves-to-provide-guidance-on-product-communications-by-pharmaceu.html*).

[74] *See for example*, Bronwyn Mixter, "Trump's FDA Nominee Spurs Concerns About Drug Approvals, Off-Label Promotion," *Bloomberg BNA* (March 14, 2017) (online at: *https://www.bna.com/trumps-fda-nominee-n57982085167/*).

What role do you believe the FDA has in combating this epidemic?

If you are confirmed as Commissioner, what FDA authorities could you use to help address the opioid crisis?

Both the FDA's Opioid Action Plan and the Comprehensive Addiction and Recovery Act emphasize the role that the FDA's advisory committees should play in the decision to approve opioid medications. If you are confirmed as Commissioner, would you pledge to respect the advice of the FDA's advisory committees in their recommendations with regard to the safety and public health risks of dangerous and addictive opioids?

If you are confirmed, what will you do to improve physician education on the safe prescribing of opioid medications?

If you are confirmed, what will you do to improve physician education on the safe prescribing of benzodiazepines to patients who may already be prescribed opioid medications?

Answer 10. Opioid abuse, misuse, and addiction constitute one of the most urgent and immediate public health threats facing our Nation. It is the biggest public health crisis facing the FDA. The human and economic toll of this crisis is staggering. If confirmed, this will be my highest immediate priority. I will make sure FDA is aggressive, forward leaning, and fully engaged in combating this epidemic. I will work with FDA's staff to ensure FDA has the right policies and processes in place to:

- Facilitate the developments of new approaches and technologies to reduce the abuse/addictive potential of painkillers American patients use;
- Support the development of non-opioid analgesic alternatives for physicians and patients;
- Assess whether FDA's current approach to opioid regulatory decisions, including labeling, REMS, and physician/patient education are appropriate, robust, and fully effective;
- Encourage the development of new pharmacological tools for physicians and patients to both prevent opioid misuse and abuse, and support treatment and recovery for patients struggling to overcome opioid addiction;
- Enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools to better target this information;
- Taking steps to make sure that providers are appropriately educated on identifying, and helping to property intervene with, abuse-prone patients;
- Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
- Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign imported narcotics;
- Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
- Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA on the two agencies shared goals.

Question 11. Nearly 2,000 opioid-related deaths occurred in Massachusetts during 2016.[75] HHS data also shows that the State had the highest rate of opioid-related emergency room visits among the 30 States analyzed in a recent Federal report.[76] Access to the prescription drug naloxone, a medication that can arrest or reverse an opioid overdose, saves lives in Massachusetts. 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

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[75] Massachusetts Department of Public Health, "Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents" (February 2017) (online at: *www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-february–2017.pdf*).

[76] Matt Rocheleau, "Mass. Had Highest Rate of Opioid-Related ER Visits," *The Boston Globe* (April 3, 2017) (online at: *https://www.bostonglobe.com/metro/2017/04/02/mass-had-highest-rate-opioid-related-visits/6vJ4kwtO1dvQGf7TGuXueN/story.html*).

label that would be required for such a product."[77] 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.

Do you agree that expanding access to naloxone, including by making it safely available over the counter, is an important part of FDA efforts to address the opioid epidemic?

What is the current status of FDA efforts to develop and test a package label for an OTC naloxone product?

What efforts does the FDA have underway to encourage physicians to co-prescribe naloxone with opioid medications?

What additional steps could the FDA take to safely facilitate increased rates of co-prescribing of naloxone with opioid medications?

What additional steps can the FDA take to work with interested manufacturers to continue expanding access to naloxone?

Answer 11. I support increased access to drugs like naloxone, which can arrest or reverse opioid overdoses. I am not aware of the current status of FDA efforts to develop and test a package label for an OTC naloxone product or closely familiar with the FDA efforts currently underway to encourage physicians to co-prescribe naloxone with opioid medications. If confirmed, I will commit to working with FDA staff to quickly get up to speed on this specific issue. More broadly, opioid abuse, misuse, and addiction constitute the most urgent and immediate public health threat facing our Nation. It is the biggest public health crisis facing our Nation, and it will be my highest immediate priority if confirmed to lead FDA.

Question 12. Increased sharing of clinical trial data could strengthen academic research, improve the practice of medicine, and protect the integrity of the clinical trials system.[78] I have supported the proposal advanced by the International Committee of Medical Journal Editors to require that researchers share data as a condition of publication in major medical journals,[79] but there are a variety of approaches to expanding data sharing and transparency that could improve medical research.

Unfortunately, some efforts to improve data sharing have been hampered by incomplete compliance with Federal requirements. A 2015 study published in the British Medical Journal, found that several major drug companies have not met the standards for clinical trial results reporting under the Food and Drug Administration Amendments Act (FDAAA) of 2007.[80] FDAAA established civil monetary penalties of up to $10,000 per day for non-compliance, and yet the FDA has never imposed such penalties. In September 2016, the FDA removed a major barrier to enforcement of the FDAA penalties by issuing a final rule detailing the requirements for submitting clinical trial results to Clinicaltrials.gov.[81]

What do you believe the impact of greater transparency of clinical trial data and results would be on—

1. Clinical trial efficiency
2. The cost of drug development
3. Drug safety
4. Biomedical innovation

If you are confirmed Commission, what specific steps would you take to increase sharing of clinical trial data?

You have supported making FDA's complete response letters publicly available to improve information about why the agency has rejected a company's application.

- What would be the impact of making complete response letters publicly available on:
  1. Clinical trial efficiency

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[77] 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/fdavoice/index.php/2016/08/fda-supports-greater-access-to-naloxone-to-help-reduce-opioid-overdose-deaths/*).

[78] Elizabeth Warren, "Strengthening Research through Data Sharing," *New England Journal of Medicine* 2016; 375:401–3 (online at: *http://www.nejm.org/doi/full/10.1056/NEJMp1607282*).

[79] Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data—a proposal from the International Committee of Medical Journal Editors. *N Engl J Med* 2016;374:384–6.

[80] Jennifer E. Miller, David Korn, and Joseph S. Ross, "Clinical trial registration, reporting, publication and FDAAA compliance: A cross-sectional analysis and ranking of new drugs approved by the FDA in 2012," *BMJ Open* 2015;5:e009758. doi: 10.1136/bmjopen-2015-009758.

[81] Department of Health and Human Services, "Clinical Trials Registration and Results Information Submission: Final Rule," 42 CFR Part 11, *Federal Register* 81:183 (online at: *https://www.gpo.gov/fdsys/pkg/FR–2016-09-21/pdf/2016–22129.pdf*).

2. The cost of drug development
3. Drug safety
4. Biomedical innovation

- If you are confirmed as Commissioner, will you commit to making complete response letters publicly available?
- What specific steps would you take to make complete response letters publicly available?

If you are confirmed Commissioner—

- How will you ensure compliance to the disclosure policy implemented by FDAAA?
- Will you enforce the law using civil monetary penalties or by other means?

Answer 12. I am a strong proponent of data transparency—for patients, physicians, and manufacturers. I have long advocated that the FDA release more information related to its review process that could be used to better inform consumers and product developers alike. This includes the complete response letters, after proper redaction of commercial confidential information. If confirmed, I will be committed to working with Congress, patients, industry, and stakeholders on the issue of data transparency and new ways that FDA could potentially make important information more readily available to the public.

Question 13. Recent news reports have discussed,

> "a surge in human infections of a deadly bird flu in China [that] is prompting increasing concern among health officials around the world . . . [and that] poses the greatest risk of a pandemic threat if it evolves to spread readily from human to human."[82] I recently sent a letter with Senator Patty Murray and Representatives Pallone, DeGette, and Green expressing my concern over the impact of a series of actions taken by President Trump on the Nation's preparedness for a pandemic flu outbreak.[83]

I am also concerned that, during your previous tenure at the FDA, you had to recuse yourself from pandemic planning efforts inside the agency, due to your conflicts of interest with companies that manufactured flu vaccines.[84] You have indicated to the Office of Government Ethics that—if confirmed as Commissioner—you will recuse yourself from participating personally or substantially in any particular matter involving specific parties in which New Enterprise Associates, American Pathology Partners, or Collective Health is a party or represents a party, or in which a former client is a party or represents a party.

What role does the FDA play in preparing for a pandemic flu outbreak?

Are New Enterprise Associates, American Pathology Partners, Collective Health parties, or do they represent any parties, that has any involvement with flu vaccines, flu preparedness, or flu response?

Are any of your former clients a party, or do they represent any party, that has any involvement with flu vaccines, flu preparedness, or flu response?

Will this commitment to recuse yourself from participating personally or substantially in any particular matter involving these specific parties affect your ability to engage in pandemic planning efforts as FDA Commissioner, should you be confirmed in this role?

Answer 13. The FDA's medical product centers play an important role in preparing for pandemics by assisting in and fostering the development and approval of safe and effective medical products, such as vaccines, drugs, diagnostic tests, masks and gloves, to help respond to emerging public health threats. Career officials, without the involvement of the Commissioner, typically handle this work. The Commissioner has broad leadership, policy and advocacy roles but is rarely involved in individual product development and approval matters. To my knowledge, New Enterprise Associates is not invested in entities that have a direct interest in flu vaccines, flu preparedness, or flu response. I do not believe Collective Health and American Pathology Partners are engaged in such efforts as they are healthcare services companies. I believe GlaxoSmithKline, a former client, develops flu vaccines

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[82] Lena H. Sun, "Surge in Human Cases of Deadly Bird Flu is Prompting Alarm," *Washington Post* (March 3, 2017) (online at: *https://www.washingtonpost.com/news/to-your-health/wp/2017/03/03/surge-in-human-cases-of-deadly_bird-flu-is-prompting-alarm/?postshare=8471488556990075&tid=ss_tw&utm_term=.40b2cf15e3cb*).

[83] Letter from Senators Warren and Murray and Representatives Pallone, DeGette, and Green to HHS Secretary Tom Price and Acting CDC Director Anne Schuchat (March 17, 2017) (online at: *https://www.warren.senate.gov/files/documents/2017_3_13_Letter_to_CDC.pdf*).

[84] Diedtra Henderson, "FDA Official Recused in Flu Fight," *Boston Globe* (November 12, 2002) (online at: *http://archive.boston.com/business/healthcare/articles/2005/11/12/fda_official_recused_in_flu_fight/*).

and other products for flu response but I do not know whether it or any other entity may become involved with flu response efforts during my public service. For all of these reasons, I do not believe that the recusals set forth in my ethics agreement would impair my ability to fully perform my duties with respect to pandemic response. Moreover, should a circumstance arise that requires my recusal, my deputy or another senior FDA official will handle that matter. I am and will remain committed to pandemic preparedness and have every confidence that my team at FDA will ensure that the FDA's mission with respect to this important public health concern is fulfilled. Finally, I would like to clarify that contrary to certain erroneous press reports, I was not recused from pandemic planning efforts during my prior tenure at the FDA. Rather, I was only recused from certain matters related to particular individual companies that manufactured vaccines.

Question 14. FDA's work is supported by highly skilled, professional employees who uphold the agency's mission and protect public health in the United States.

If you are confirmed as Commissioner, will you work cooperatively with employees and employees' representatives, including unions?

Should you be confirmed, will you meet with national leadership of employees' union representatives soon after you begin your duties?

Answer 14. FDA's ability to fulfill its mission to protect and promote public health depends almost entirely on its world-class workforce of talented, dedicated public servants. If confirmed, I look forward to building strong and trusting relationships with the agency's career employees, and their representatives.

SENATOR KAINE

Question 1. During the hearing, I appreciated your interest in addressing the opioid epidemic. According to the CDC, opioid-related overdose deaths in the United States have quadrupled in the last decade. During this same time period, prescriptions for opioids have also increased. Do you agree voluntary opioid prescribing guidelines can be a useful tool to help inform physicians in treating pain and in opioid prescribing?

Answer 1. I agree that better information about appropriate prescribing can be an important tool in combating this epidemic by helping ensure physicians are properly informed about the risks and benefits of opioid prescribing, and in particular, in educating providers about identifying and prescribing opioids in patients at risk for abuse. We need to enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools.

Question 2. Do you agree that a focus on abuse deterrent formulations by FDA, while important, are not the only steps the Agency can help reduce opioid addiction?

Answer 2. Given the tragic scope and urgency of this crisis, FDA has to take an all of the above approach to addressing this epidemic. The opioid crisis is a human tragedy of enormous scope and should be the FDA's highest public health priority. It is the biggest crisis facing the agency. ADFs are just one tool in addressing this crisis. Among other steps that, I believe, FDA can take to address the opioid epidemic, I am committed to helping:

- Facilitate the developments of new approaches and technologies to reduce the abuse/addictive potential of painkillers American patients use;
- Support the development of non-opioid analgesic alternatives for physicians and patients;
- Assess whether FDA's current approach to opioid regulatory decisions, including labeling, REMS, and physician/patient education are appropriate, robust, and fully effective;
- Encourage the development of new pharmacological tools for physicians and patients to both prevent opioid misuse and abuse, and support treatment and recovery for patients struggling to overcome opioid addiction;
- Enhance physician and patient educational materials to strengthen public awareness of the risks of opioids, as well as the FDA-approved resources available to them, using the full range of FDA's risk communication tools to better target this information;
- Taking steps to make sure that providers are appropriately educated on identifying, and helping to property intervene with, abuse-prone patients;
- Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
- Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign imported narcotics;

• Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
• Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA on the two agencies shared goals.

Question 3. As we discussed when we met, I was extremely concerned about the action the Agency took with regards to Zohydro and the approval of Oxycontin for children despite the recommendations from an Advisory Committee. Can you address under what circumstances the Agency should override recommendations from an advisory committee?

Answer 3. I believe FDA should have the benefit of independent advice from the outside experts who serve on Advisory Committees. I understand that this advice is often critical to FDA as they consider challenging regulatory decisions. However, I also recognize that FDA retains the ultimate responsibility to consider the totality of evidence in making a final agency determination.

Question 4. You also discussed abuse-deterrent formulations for opioids. Do you agree that a focus on abuse deterrent formulations by FDA, while needed, fall well short of how the Agency can help reduce opioid dependence?

Answer 4. Please see my response to this question in your question No. 2.

Question 5. You have argued that drug manufacturing standards to assure safe products are a cause of price spikes and drug shortages. Specifically, you said in Forbes In August 2016 when discussing the application of regulations to generic manufacturers:

> "In a push to reduce the risk of contamination, the agency in 2009 forced generic-drug makers to retool their sterile manufacturing plants and make production lines less intricate. The abruptness of the change caused many facilities to be shut down, creating drug shortages and driving up prices."

Do you believe that the regulation is not the only cause of spiking drug prices? What are other causes of drug price spikes and how would you use your role as Commissioner to address this issue?

Answer 5. Regulatory factors relating to manufacturing are only one factor causing price spikes for certain drugs. In many cases, the issues causing specific drugs to experience sharp increases in price are different. While drug pricing does not fall directly within FDA's purview, I believe the agency can play an important role on this important issue by taking steps to improve product competition. If confirmed, I will work to ensure FDA has the appropriate policies and processes in place to effectively facilitate generic market entry and competition. Reforming the regulatory pathway for complex generic products would address one key policy deficiency that results in unnecessary barriers to the development and review of generic competitors for some innovator products for which traditional bioequivalence and bioavailability testing alone are sometimes insufficient for proving sameness. FDA should also explore options to improve the efficiency and consistency of ANDA review processes and timelines, so that financial speculators cannot engage in a regulatory arbitrage, by dramatically hiking the price of some very old generic drugs because they know it can take years for new generic competitors to enter the market.

Question 6. You have acknowledged that high drug prices are a problem for consumers, and said in an FDA speech on 9/20/2005,

> "Many people are rightly concerned about the high prices on many drugs, especially people who can least afford to pay for medicines because they lack good health insurance, or have no health insurance at all."

But you are also an opponent of the Affordable Care Act. You have referred to the ACA's Essential Health Benefits as "politically crafted." [Forbes, 2/19/2016] Do you consider the inclusion of prescription drug coverage as an essential health benefit to be politically crafted? Do you think more people will have access to prescription drugs if we repeal the ACA?

Answer 6. As the nominee to be the next Commissioner of Food and Drugs, I do not believe it would be appropriate to comment on questions about issues that are outside the jurisdiction of FDA.

SENATOR HASSAN

Question 1. As you know, the recommendations of FDA physicians and scientist reviewers about safety and efficacy, approval, and labeling of products—including those related to women's reproductive health—should be based solely on scientific evidence. Do you commit to allowing FDA physicians and scientist reviewers to make decisions on safety and efficacy, approval, and labeling of products related to women's reproductive health, including new and existing drugs and devices, without political interference or interference from you, should you be confirmed as FDA Commissioner?

Answer 1. Maintaining the Gold Standard of safety and efficacy for medical products is fundamental to FDA's mission to protect and promote public health. If confirmed, I will uphold the Gold Standard by ensuring FDA makes independent regulatory decisions based on sound science, good regulatory practices, and the support of a strong scientific staff. This applies to all clinical areas, including products related to women's reproductive health.

Question 2. In a 2012 op-ed published in the *Wall Street Journal*, you questioned the role of the Drug Enforcement Agency (DEA) in regulating opioid use and abuse. You said that the DEA may be the "wrong enforcer" and that their tactics are "imprudent."

Since you penned that piece, the number of opioid deaths in the country has exploded, surpassing 33,000 in 2015. We know that prescription opioids have contributed to our current epidemic. Further, we know that the DEA is authorized through the Controlled Substances Act to play a law enforcement role in the opioid crisis and to set limits on overall active ingredient allowed in the marketplace.

In light of our current opioid epidemic, have your views on the DEA's regulation of opioids changed?

At the time that you wrote this article, were you being paid by or representing pharmaceutical distributors or any entity in the opioid industry? If so, which ones?

Did any individual or organization connected to or hired by an opioid manufacturer or distributor assist in the drafting of this op-ed? If so, who helped you and in what capacity?

Answer 2. I believe now, as I did at the time that I wrote the op ed, that there needs to be closer coordination and collaboration between the law enforcement and public health entities charged with combating this tragic human crisis. This is especially true when it comes to DEA and FDA. I believe the two agencies need to be working closely together to combat this crisis, and such coordination would be a top priority of mine if I were confirmed into this role. I also believe that the tools and approaches for achieving that purpose have evolved as the crises has grown larger and more intractable since the time I wrote that op ed. I was the author of the op ed article and was representing my personal views on this policy matter. As is customary, I do research and communicate with sources in advance of writing articles. I was paid by the *Wall Street Journal* in connection with this op-ed.

Question 3. In the aforementioned article, you advocate for having some of DEA's current authorities transferred to the Department of Health and Human Services (HHS), including having HHS take on the "responsibility for apportioning active ingredients to manufacturers of narcotics," commonly referred to as "quotas."

In your capacity as an FDA official, did you ever advocate for the DEA to increase, or directly or indirectly ask the DEA to increase, any opioid quota, including any quotas for active opioid ingredients? If so, why?

If the above answer is yes, were your activities advocating for the DEA to increase, or asking the DEA to increase, any opioid quota, including any quotas for active opioid ingredients, undertaken on behalf of or intended to benefit a particular person or company? If so, please identify that person or company and explain the rationale for your involvement.

Answer 3. At various times, DEA has advocated that the quota for active pharmaceutical ingredients used to manufacture opioid drugs be limited, while FDA has, at the same time, maintained that such limits could contribute to a drug shortage for appropriate patients. This engagement is a matter of public record. These discussions are a reflection of the careful balancing that must occur between the need to maintain access to important medicines for appropriate patients, while taking the necessary steps to address the tragic and rampant abuse and diversion of opioid drugs. Drug shortages are an issue of critical concern for FDA. I recall the issue of quotas being raised to me by FDA career staff and some interactions between FDA and DEA on this subject. My involvement in these matters was to support the science-based positions of the FDA's professional staff. None of my actions were undertaken on behalf of, or intended to benefit, a particular person or company. Rath-

er, my role was to represent the agency's public health positions. FDA's positions in these matters were taken in consideration of issues related to abuse and diversion, consistent with the FDA's regulatory and public health mandates. However, since my tenure at FDA more than a decade ago, the scientific and public health consensus about the proper ways to combat the opioid health crisis have evolved sharply as this epidemic has grown in scope and severity and become our Nation's most urgent public health crisis and a tragedy of enormous proportion. I also believe, based on this collected experience, that it is even more critically important that FDA and DEA collaborate very closely in order to properly confront this human tragedy. Seeking such collaboration would be one of my highest priorities, if confirmed.

Question 4. In your article, you said that other public health agencies within HHS would be better able to judge "distinctions between illicit diversion and the legitimate practice of medicine."

Effectively, you suggest transferring the regulatory and enforcement components from an agency equipped for those roles to an agency that has little capacity to execute them. With its current authority and resources, it is unlikely HHS would be able to effectively take on this role.

Describe how agencies within HHS—which President Trump wants to cut by $15 billion in 2018—would be able to effectively absorb the DEA's roles in regulating overprescribing from pharmacies and providers?

Answer 4. Given the tragic scope and urgency of this crisis, FDA has to take an all-of-the-above approach to addressing this epidemic. The opioid crisis is a human tragedy of enormous scope and should be the FDA's highest public health priority. It is the biggest crisis facing the agency. Among other steps that, I believe, FDA can take to address the opioid epidemic, I am committed to helping:

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- Taking steps to make sure that providers are appropriately educated on identifying, and helping to properly intervene with, abuse-prone patients;
- Re-assess whether FDA has the appropriate framework and authorities for evaluating the risk of abuse and diversion as a component of its review and approval process for opioids;
- Undertake a comprehensive effort to evaluate the full scope of the sources and threats from foreign-imported narcotics;
- Evaluate whether FDA should bring more alignment between the review and approval of different medical product platforms used in the treatment of pain to make sure the agency is adopting the best public health standard in assessing these products; and
- Collaborate effectively with other government agencies and external stakeholders to develop and execute comprehensive and effective strategies to win the battle against opioid abuse, misuse, and addiction. This includes steps for FDA to more closely collaborate and coordinate with DEA on the two agencies' shared goals.

[Whereupon, at 12:37 p.m., the hearing was adjourned.]

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