S. HRG. 116–488

NOMINATION OF STEPHEN M. HAHN, 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 SIXTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE NOMINATION OF STEPHEN HAHN, OF TEXAS, TO BE COMMISSIONER OF FOOD AND DRUGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOVEMBER 20, 2019

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C O N T E N T S

STATEMENTS

WEDNESDAY, NOVEMBER 20, 2019

NOMINATION OF STEPHEN M. HAHN, M.D., TO SERVE AS COMMISSIONER OF FOOD AND DRUGS

Wednesday, November 20, 2019

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

The Committee met, pursuant to notice, at 10:04 a.m., in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Isakson, Roberts, Murkowski, Scott, Romney, Braun, Collins, Murray, Casey, Baldwin, Kaine, Hassan, Smith, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor and Pensions will come to order, please. Today we are holding a confirmation hearing on the nomination of Dr. Stephen Hahn to serve as Commissioner of the Food and Drug Administration. Senator Murray and I will each have an opening statement, and then I will introduce Senator John Cornyn of Texas who will introduce Dr. Hahn. After Dr. Hahn's testimony, Senators will each have five minutes for a round of questions. And I will be glad to stay for second round if Senators want to do that. President Trump nominated Dr. Hahn on November 5, 15 days ago. The Committee received his paperwork on November 6.

The Office of Government Ethics paperwork came on November 12, which was eight days ago. So we have all the paperwork. I met with Dr. Hahn on the 6th. I believe he is well qualified to lead the FDA. Dr. Hahn met with all but three Members of the Committee. I thank the Committee Members for making that time available and I thank him as well. And he has offered to meet with every Member. This timeline is consistent with the schedule the Committee followed for the nomination of Dr. Gottlieb to be President Trump's first FDA Commissioner.

The Committee held a hearing for Dr. Gottlieb nine days after he was nominated and five days after we received his final paperwork. This is a critical time for the Food and Drug Administration. There is a lot the FDA needs to do, approve life-saving drugs, regulate tobacco and e-cigarettes, complete the ongoing lung injury investigation having to do with e-cigarettes, and continue addressing the Opioid Crisis, implementing the various provisions of the 21st

Century Cures Act. Dr. Hahn has both the perspective of a physician and the leadership of a well-respected, large healthcare organization with a large employee base and a diverse mission. He is Board certified in both medical oncology and radiation oncology, specializing over the course of his career on prostate, bladder, kidney, testicular, and lung cancers, and sarcoma. He has considerable experience with Federal health agencies.

After graduating with his medical degree from Temple University, he completed a residency in Internal Medicine at the University of California. He was at the National Cancer Institute at the National Institutes of Health between 1988 and 1995. There he completed a residency in radiation oncology, and a fellowship in medical oncology, and was a senior investigator. He also held the rank of Commander in the U.S. Public Health Service Commissioned Corps in 2005. From 1996 to 2014, Dr. Hahn was at the University of Pennsylvania where he was a Professor and Chair of the Department of Radiation Oncology for nine years.

In 2015, he became the Chair and Professor of Radiation Oncology at the University of Texas MD Anderson Cancer Center. Today, Dr. Hahn is the Chief Medical Officer at MD Anderson Cancer Center where he continues to treat patients. Dr. Hahn, you are nominated to lead this agency at a very important time. As an oncologist, you know firsthand the importance of bringing new lifesaving drugs and devices quickly through the regulatory device—the regulatory process, as well as safely.

As a successful Chief Executive, you will bring a guiding hand to an agency tasked with protecting the public's health. MD Anderson is a large organization. You have 21,000 employees there, revenues of $5 billion, the largest number of clinical trials in the United States. That experience should serve you well here. I believe those experiences as well as your experience with the National Institutes of Health and the Public Health Service Commissioned Corps made you well prepared to lead the FDA.

In recent years, this Committee has taken a number of steps to ensure that the FDA can keep up with the rapid pace of new discoveries while continuing to ensure the safety of new drugs and devices. For example, in 2016 Congress passed the 21st Century Cures Act, giving the FDA new hiring authorities to help bring in the right experts and scientists to keep up with biomedical innovation. In 2017, we renewed the FDA's ability to collect user fees from drug companies so FDA can bring drugs and devices through the regulatory process more rapidly.

Last October, we passed legislation to fight the opioids epidemic. That included proposals from 72 different Senators, proposals that would allow the FDA to require prescription opioids to be packaged in set amounts like a three or seven day supply in blister packs, and increased authority to help stem the flow of fentanyl at the border. And in June, Congress reauthorized the Pandemic and All-Hazards Preparedness Act which reauthorized the FDA's ability to help ensure our Nation is prepared for and able to respond to public health emergencies such as pandemic flu or a bioterror or nuclear attack.

Looking ahead, the perspective of a physician and an executive is what the FDA needs to successfully implement the many new

authorities and funding associated with the 21st Century Cures Act, to address the opioids crisis, at the same time to ensure that Americans with chronic pain can receive the medications they need, to protect our Nation's food supply, to appropriately regulate tobacco and e-cigarettes. Dr. Hahn, I enjoyed meeting with you in my office. You have an impressive medical and research background. You are a proven leader in a large health system with complex needs and a dynamic staff.

I believe you are well qualified to lead the FDA. I am not the only one who thinks that. I ask unanimous consent to introduce seven letters of support for Dr. Hahn into the record, which includes a letter of support from five previous Commissioners under Democrat and Republican administrations, as well as letters from physician and research organizations. So ordered.

[The following information can be found on page 42.]

The CHAIRMAN. It is my intent to have the Committee consider your nomination when we return on December 3rd, and I hope that we can report you out on a bipartisan basis so that you can be confirmed by the full Senate before the end of the year. The FDA needs a permanent Senate-confirmed leader. I think you will do an excellent job.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. Thank you, Dr. Hahn, for joining us today. I also want to welcome your wife and family who are with you today. And I want to welcome our colleague, Senator Cornyn. Thank you for being here today to introduce Dr. Hahn to our Committee. Each year $0.20 of every dollar Americans spend goes to products the Food and Drug Administration regulates. Every day people put the well-being of themselves, their families, and even their pets in the FDA's hands. When we sit down for a meal, we count on the FDA's efforts to ensure the safety of 80 percent of our food supply and provide us with the information we need to make healthy choices. When we get our prescriptions filled or turn to medical devices to stay healthy, we count on the FDA's work to uphold the gold standard of safety and effectiveness. We don't have to look hard for reminders of just how enormous the FDA's responsibility is.

A few years ago more than 30 patients at a hospital in Seattle were infected with a superbug by contaminated medical devices and over a third of them died. The FDA eventually recalled the devices after an investigation by my staff found outbreaks linked to the devices worldwide. Over the last two years, several states including Washington State have faced an E. Coli outbreak from romaine lettuce, resulting in over 230 illnesses and five deaths. This year the FDA announced millions of patients were exposed to blood pressure and heartburn medicines with carcinogens, and across the country FDA's failure to meaningfully regulate vaping products has allowed youth tobacco use to skyrocket driven largely by flavored e-cigarette products.

We need to make sure the FDA has strong experienced leadership who will uphold the agency's mission to protect public health, which is why this hearing is so important because President Trump

has an incredibly poor track record when it comes to nominations from his cabinet, to the courts, to critical Government agencies. He has repeatedly put forward nominees with alarming ethical problems and conflicts of interest, nominees without any relevant experience or qualification, and nominees with long track records of putting ideology or partisanship ahead of science, data, and families' best interest. People are counting on us to do this vetting and to do it seriously, especially because the President won't.

Given what I have seen so far, I have some reservations regarding Dr. Hahn's qualifications to lead the Food and Drug Administration. Dr. Hahn has almost no Government experience, no public record on policy issues related to the FDA, and no experience leading an organization anywhere near as complex as the FDA. So I want to be clear what I will be looking for from Dr. Hahn today. First and foremost, I will be looking at his commitment to putting science and data ahead of ideology. This is fundamental to the FDA's work, and when it doesn't happen people are put in harm's way, people are unable to get the care they need.

A good example is emergency contraception known as Plan B. It is now available to people all over the country. But when FDA was considering whether to make Plan B more widely available, I had to fight really hard to make sure science and data would ultimately win out over ideology and political pressure so women across the country could finally get Plan B over the counter. And getting these priorities right is perhaps more important than ever given how much President Trump has let ideology drive policy decisions and putting family's needs first also means quickly following through on strong regulation of e-cigarettes.

Right now we are in the middle of a public health crisis. Millions of children are becoming addicted to tobacco products. The Trump administration's 2017 decision to delay oversight of e-cigarette products was an absolute disaster. Instead of taking strong action to protect children's health, the FDA has instead allowed youth e-cigarette use to more than double among high school students and more than triple among middle students in just the last two years. And now over two months after President Trump promised strong action, he reportedly plans to back away from steps to clear unauthorized flavored e-cigarettes from the market. He has shown he is more swayed by the tobacco industry and politics than by our children's health. We need an FDA Commissioner who will push back hard so children's health comes first, who have finally clear the market of all non-tobacco flavored e-cigarettes, including menthol, nationally instead of offering more delays or half steps, and who will take strong, decisive action to protect our kids from combustible tobacco products as well.

I will also be looking at Dr. Hahn's commitment to putting families' needs ahead of company profits because the FDA absolutely must prioritize making sure drugs and devices are safe and effective. And it should also be doing whatever it can to make sure they are accessible and affordable too. For example, the FDA should do everything it can to facilitate the development and approval of biosimilar insulin, a life-saving drug that many patients struggle to afford, including ensuring a smooth transition of insulin products

to the biologics pathway in March 2020. This is an important step to help cheaper follow-on versions come to market.

Finally, I will be looking at Dr. Hahn's commitment to continue upholding the FDA's gold standard for safety and effectiveness in drugs and medical devices. I am alarmed by changes the Trump administration has proposed to FDA's medical device review program, including a proposal to pre-certify software developers and a decision to apparently break a commitment it made to me to limit a conditional approval pathway to certain animal drugs by expanding it to human medical products as well. I am concerned these proposals are not consistent with the FDA's gold standard and may compromise patient safety, and I expect Dr. Hahn to revisit them if confirmed.

We need an FDA Commissioner who will unquestionably put data and science and families' best interests ahead of ideology or politics or companies' bottom lines. Who will uphold the gold standards that make sure drugs and medical devices are safe and effective, and who has the experience necessary to lead this massive agency and its over 17,000 employees in tackling a wide range of challenges like the ongoing opioid epidemic, drug shortages, the increasing risk of antimicrobial resistance, and much more.

Dr. Hahn, I am going to be listening very closely to your testimony today and asking you about some of the issues I think are particularly important during questioning. And I hope all of our colleagues will continue to work with me to make sure we thoroughly vet your nomination. This role is simply too important for us to do anything less. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. We now welcome Dr. Hahn. We especially welcome his family. There are a large number of you here. We are glad that you are here. Dr. Hahn will be introduced by Senator Cornyn from Dr. Hahn's home State of Texas. Senator Cornyn is completing his third year in the U.S. Senate. He has been elected by his colleagues to the second ranking position on the Republican side of the aisle. We welcome him to the Committee.

STATEMENT OF SENATOR CORNYN

Senator CORNYN. Thank you, Mr. Chairman, Ranking Member Murray, for allowing me to come before the Committee today to introduce Dr. Stephen Hahn, who has been nominated to serve as Commissioner of the Food and Drug Administration. Let me join you in welcoming Dr. Hahn and his family to this hearing.

I am constantly in awe of Americans who are willing to step up and serve our country in important positions like this, people like Dr. Gottlieb, Dr. Hahn, and others, and I am proud to be here with him today. For the past five years, Dr. Hahn has helped lead the University of Texas MD Anderson Cancer Center, the world's leading Cancer Center. He has quickly risen through the ranks of a renowned institution that includes some of the most esteemed faculty in the Nation, including a Nobel laureate and more than a dozen members of the National Academy of Medicine and National Academy of Sciences among others.

He went from Chair of the Department of Radiation Oncology, to Chief Operating Officer and Deputy President, to his current posi-

tion as Chief Medical Officer. He brings both the experience of a talented and dedicated physician as well as that of a leader of a major healthcare and research institution. Like the FDA, MD Anderson is a large organization operating on more than a $5 billion budget. Just to give you a glimpse of the scope of MD Anderson's operations, last Fiscal Year it had more than 20,000 employees, 7,000 trainees, who treated 141,000 patients, and ran 1,200 clinical trials, and logged 1.5 million outpatient visits. I remember visiting MD Anderson with John McCain and Senator McConnell years ago and was astonished to learn that they treat patients from 90 different countries. That was the number at the time.

This is not just a crown jewel of American science and medicine, it is a gift to the world. In 2018, they received the most grants of any entity from the National Cancer Institute and have a proud history of working closely with the FDA to help test leading-edge drugs. If you think running an institution of that size sounds like a lot of work, consider the fact that Dr. Hahn is also a clinician and continues to treat patients.

He is Board certified, as the Chairman noted, in both medical oncology and radiation oncology, and has devoted his career to cancer research and treatment. He has previously served as Chair of the Department of Radiation Oncology at the University of Pennsylvania, where he served for nearly a decade. He is also a Commander in the United States Public Health Service at the National Cancer Institute. I had a chance to meet with Dr. Hahn this last week and we spoke about a number of challenges, many mentioned by the Ranking Member Senator Murray, among them is something I am concerned about, and as she expressed, and I know this Committee has examined last week, the recent increase in tobacco and nicotine product used among children and teens primarily spurred by e-cigarettes.

This combined with varying state laws on marijuana, the rise in CBD, and other hemp derived products and our ongoing efforts to reduce prescription drug prices has only underscored the need for strong leadership at the FDA which I believe Dr. Hahn will provide. The agency needs a commissioner who has experience managing a large organization, which he does, who understands the drug development process, which he does, who is committed to swiftly bring life-saving medications to market, and who prioritizes the health and safety of the American people above all else. I firmly believe Dr. Hahn is the right man for the job.

Throughout his career, he has proven that outstanding patient care is his top priority, as an oncologist providing top-notch care to each patient he saw, as a professor educating our next generation of physicians, and now as the Chief Medical Executive at MD Anderson where he oversees medical practice and patient care. I have no doubt that, if confirmed, Dr. Hahn will bring his patient-centric work ethic to Washington and lead the FDA with the same skill and determination we have seen him display at MD Anderson.

Mr. Chairman, Ranking Member Murray, thank you for allowing me to introduce my constituent and somebody who I have come to admire greatly for his willingness to serve in a very difficult time in a very important position of public trust. So thank you for the opportunity to be here with you today.

The CHAIRMAN. Thank you, Senator Cornyn, and you are welcome to stay as long as you would like but we know you have other hearings and a busy schedule so if you need to excuse yourself, we will understand that. I would say to Senators, we have votes at 11:30 a.m., but we will continue the hearing right through the votes and we will swap the gavel so that everybody can ask their questions, and if necessary, we will have a second round of questions so Senators can ask Dr. Hahn questions. Dr. Hahn, you are now recognized for five minutes of testimony. Welcome.

STATEMENT OF STEPHEN M. HAHN, M.D., TO BE COMMISSIONER OF FOOD AND DRUGS ADMINISTRATION

Dr. HAHN. Thank you, Mr. Chairman. Chairman Alexander, Ranking Member Murray, Members of the Senate HELP Committee, thank you for inviting me to appear before you today. I am humbled to be here and I am very grateful for your consideration of my nomination by President Trump to serve as Commissioner of Food and Drugs. I sincerely appreciate the time that many of you and your professional staff have spent with me over the past several weeks as part of this very important confirmation process.

Before I begin my statement, I would like to introduce my family, my wife Lota, my adult children Chris, Emma, Robert and Caroline, Chris's girlfriend Annie, and our son-in-law Mike, and would also like to point out my first grandchild is on the way. Emma and Mike are expecting. Maybe next week, who knows? It is truly a blessing and a real constant reminder of what is important in life. I am a scientist and a medical doctor. Science and fighting for the best interests of my patients has guided my entire professional career.

I have been a frontline cancer physician, researcher, and leader of complex medical organizations. In my work, I have seen the joys of informing a patient of a successful treatment outcome and I have also seen the sadness in letting a loved one know that there are no further treatment options. Throughout my career, I have depended on and relied on the fact that the Food and Drug Administration had my back. Because of FDA, I had confidence for my patients in the treatments that I prescribed for them. As I reflect on the trust, I placed in FDA, I am now humbled that with your consent I may be in a position to lead that very agency I relied on and trusted for my entire career. If I am fortunate enough to be confirmed by the Senate, I promise to be guided by the core values of integrity and transparency, and I promise to put the interest of the American people first.

As a front-line cancer physician, researcher, and executive at an academic medical center, I am profoundly aware of the importance of the FDA's role in the health and welfare of the American people. The FDA represents the gold standard for protecting the public health, is trusted by Americans, and admired around the world for its mission in ensuring the safety, security, effectiveness of medical products and ensuring the safety of our Nation's food supply.

The professionals at the FDA have remarkable expertise and a deep commitment to the agency's mission. I believe strongly in the importance of science, data, and the law that have guided and should continue to guide FDA with their decision-making. I also

want to emphasize that I have deep respect for Congress, and its role in writing the laws that the FDA must enforce. If confirmed, I faithfully pledge to execute the laws written by Congress and be responsive to your questions regarding the agency. I believe strongly, very much, in collaborating with the Legislative branch to protect the public health.

The role of the FDA is as vital today as it was when the Food, Drug and Cosmetic Act was first approved and became law in 1938. We are at a crucial and exciting time in American medicine and science, one in which the discoveries are dramatic and the translation of science into better medical products for patients is occurring at an ever more rapid pace. We are also approaching a time when new and improved ways of evaluating data will allow us to expedite innovation, better evaluate new products and ensure food safety, all with even greater accuracy and certainty.

All of this, however, requires that the FDA have the appropriate talent, expertise, and infrastructure to keep up with progress in science and technology. It is crucial that the FDA encourage innovation and competition so that Americans have access to a continuously improving universe of treatments. The American people depend on a strong FDA, and if confirmed, I will work with Congress, the Administration, and stakeholders to ensure fulfillment of that vision as its leader.

There are many issues that will likely come before the Commissioner that are perplexing and engender honest disagreement. When that occurs, I pledge to listen, study, and assess all viewpoints. It is true that the challenges are many and complicated, but it is also true that there are remarkable, and I mean remarkable solutions on the horizon and these solutions are within our grasp. As I have spent time meeting with each of you, I am increasingly optimistic and energized about the prospects of working toward data-driven and balanced solutions that are congruent with the law. It is my belief that regardless of our differences of opinion on any one issue or another, we all want what is best for the American people.

The mission of the FDA is too important and the stakes are too high not to make the absolute best decisions, guided by science, data, and the law. Chairman Alexander, Ranking Member Murray, Members of the Senate HELP Committee, sitting behind me are my wife and our children. I want them, their children, and all of the American people to live in a world where they can trust in the safety and security of their food supply and where they have access to the most innovative, effective, and safe medical products in the world.

If I have the honor of being confirmed by the Senate, I will uphold myself to the highest standards of integrity, transparency, communication, and teamwork at the FDA. I will collaborate closely with you in a bipartisan way, communicate about the FDA's programs, and will rely on your counsel to faithfully serve the American people. Thank you for your consideration of my nomination. I look forward to answering your questions.

[The prepared statement of Dr. Hahn follows:]

PREPARED STATEMENT OF STEPHEN HAHN

Chairman Alexander, Ranking Member Murray, Members of the Senate HELP Committee, thank you for inviting me to appear before you today. I am humbled to be here and am very grateful for your consideration of my nomination by President Trump to serve as Commissioner of Food and Drugs. I sincerely appreciate the time many of you and your professional staff have taken to meet with me over the past several weeks as part of this very important confirmation process.

Before I begin my statement, I would like to introduce my family who are here today. I am joined here by my wife Lota; our four children, Chris, Emma, Robert and Caroline; and our son-in-law, Mike. As you can probably see from your seats, Emma and Mike are expecting our first grandchild any day. This is a true blessing for our family and a constant reminder of what is important in life.

I am a scientist and a medical doctor. Science and fighting for the best interests of my patients has guided my entire professional life. I have been a front-line cancer physician, researcher, and leader of complex medical organizations. In my work I have seen the joys of informing a patient of a successful treatment and the sadness in letting a loved one know that there are no further options. Throughout my entire career—I have depended on and relied on the fact that the Food and Drug Administration (FDA) had my back. Because of the FDA, I had confidence for my patients in the treatments I administered. As I reflect on the trust I placed in the FDA, I am now humbled that, with your consent, I may be in a position to lead that very agency I have relied on and trusted for my entire career.

If I am fortunate enough to be confirmed by the Senate, I promise to be guided by the core values of integrity and transparency, and I promise to put the interests of the American people first. As a front-line cancer physician, researcher, and executive at an academic medical center, I am profoundly aware of the importance of the FDA's role in the health and welfare of the American people. The FDA represents the gold standard for protecting the public health, is trusted by Americans and admired around the world for its mission ensuring the safety, efficacy, and security of medical products and the safety of the Nation's food supply. The professionals at the FDA have remarkable expertise and a deep commitment to the agency's mission. I believe strongly in the importance of science, data, and the law that have guided and should continue to guide the decision-making at the FDA.

I also want to emphasize that I have deep respect for Congress, and its role in writing the laws that the FDA must enforce. If confirmed, I pledge to faithfully execute the laws written by Congress, and be responsive to your questions regarding the agency. I look forward to collaborating with the legislative branch to protect the public health.

The role of the FDA is as vital today as it was when the Food, Drug, and Cosmetic Act became law in 1938. We are at a crucial and exciting time in American medicine and science, one in which the discoveries are dramatic and the translation of science into better medical products for patients is occurring at an ever more rapid pace. We are also approaching a time when new and improved ways of evaluating data will allow us to expedite innovation, better evaluate new products and ensure food safety, all with even greater accuracy and certainty. All of this, however, requires that the FDA have the appropriate talent, expertise, and infrastructure to keep up with progress in science and technology. It is crucial that the FDA encourage innovation and competition so that Americans have access to a continuously improving universe of treatments. The American people depend on a strong FDA and, if confirmed, I will work with Congress, the administration, and stakeholders to ensure fulfillment of that vision as its leader.

There are many issues that will likely come before the Commissioner that are perplexing and engender honest disagreement. When that occurs, I pledge to listen, study and assess all viewpoints.

It is true that the challenges are many and complicated, but it is also true that there are remarkable solutions on the horizon and these solutions are within our grasp. As I have spent time meeting with each of you, I am increasingly optimistic and energized about the prospects of working toward data-driven and balanced solutions that are congruent with the law. It is my belief that regardless of our differences of opinion on any one issue or another, we all want what is best for the public health. The mission of the FDA is too important for the American people and the stakes are too high not to make the absolute best decisions, guided by science, data, and the law.

Chairman Alexander, Ranking Member Murray, Members of the Senate HELP Committee, sitting behind me are my wife and our children. I want them, their chil-

dren, and all of the American people to live in a world where they can trust in the safety and security of their food supply and where they have access to the most innovative, effective and safe medical products in the world. If I have the honor of being confirmed by the Senate, I will uphold myself to the highest standards of integrity, transparency, communication, and teamwork at the FDA. I will collaborate closely with you in a bipartisan way, communicate about the FDA's programs, and will rely on your counsel to faithfully serve the American people.

Thank you for your consideration of my nomination, I look forward to answering your questions.

The CHAIRMAN. Thank you, Dr. Hahn. And we will now begin five-minute rounds of questions by Senators.

Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman, Ranking Member. And thank you Dr. Hahn for being here today and especially thank you for spending the time yesterday. We had a good conversation about the importance of the generic market. So often we hear a lot of conversation about the prices of drugs, but we fail to appreciate the positive impact that generic drugs are having around the country. Speaking specifically of that, in 2019, Fiscal Year 2019, we saw a record-breaking 1,171 drugs, generic drugs, come to market.

2018 was a record-breaking year. 2017 was a record-breaking year. So we are moving in the right direction. 90 percent of the prescriptions filled, of course, are generics, 90 percent of which have a copay of less than $20. This is all good news, especially when you compared to 1990 when fewer than a third of the drugs were generics. That being said, I have real concerns that we could see this trend slow down or even reverse. Earlier this year we voted in this Committee to report out the Lower Health Care Costs Act which contains dozens of good targeted policies that will benefit Americans.

Unfortunately, one provision, Section 205 of the bill, could have an unintended consequence of deterring generic drug development and discouraging manufacturers for filing early. This would mean less competition and certainly higher prices for consumers. I filed an amendment that would have targeted Section 205 so as to deter the so-called exclusivity parking that it was strapped to combat, but without punishing good faith manufacturers who are actively pursuing final approval.

Former Commissioner Gottlieb tweeted in support of the amendment and wrote an article suggesting that we should consider finding ways to strengthen rather than cheapen the 180-day exclusivity period. Dr. Hahn, given that discussions with the FDA are still ongoing as to how we might better target Section 205, can you commit to engaging with my office on this issue as we seek to ensure strong and sustainable market competition?

Dr. HAHN. Senator, nothing is more important than getting innovative products onto the market for the American people and providers. I think the generic pathway is an incredible way to do that and to introduce competition, and there are many virtuous effects of the generic pathway. As you mentioned, FDA has done a remarkable job over the last several years and I am very supportive of continuing that work and accelerating the approval and safe approval of generics. And pledge to work with your office, sir, and I look forward to doing that.

Senator SCOTT. Thank you very much. When we talk about the importance of innovation, there is maybe no area where the conversation is more meaningful than the issue of rare and ultra-rare diseases. As you are familiar, I think we talked about it yesterday, there are like 7,000 rare diseases and only about 5 percent are set differently. 350 of those rare diseases have an FDA-approved treatment, which I think is challenging and certainly a real opportunity for the FDA to work on.

Looking at the FDA, some review divisions seem to have much more experience than others with applications for rare and especially ultra-rare conditions. How can we work with you to create some transparency on which divisions these are, and how to support them as they evaluate drugs for what are often times the first in class treatments or treatments for conditions that have nothing—for patients?

Dr. HAHN. Senator, I share your concern about the rare conditions. I think nothing is more important than that we don't forget any Americans who have serious illnesses, and I very much would, if I am fortunate enough to be confirmed, look into the issue that you described. I do know that the Oncology Center of Excellence has done a really terrific job in the area of rare tumors. It is something we specialize at MD Anderson, and I look forward to seeing how best practices can be spread across the agency.

Senator SCOTT. Thank you, Dr. Hahn. We look forward to your successful vote and look forward to working with you on a number of these issues. I can't think of an area that is more important to the American community, our citizens than healthcare and frankly drug prices. We have so much negative news on drug prices that so often we forget the benefits that we are getting from the generic market. And the importance of stabilizing the generic market to me is in critical need and thank you very much for your commitment to do so. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Scott.

Senator Murray.

Senator MURRAY. Thank you. Mr. Chairman. Dr. Hahn, the FDA's gold standard for product review ensures the safety, efficacy, and quality of our medical products. And patients and families place their trust every day in the FDA to make sure the products that they use meet that high standard. Yet, the Trump administration has repeatedly undermined the gold standard by prioritizing ideology over science. If you are confirmed, your duty as Commissioner would be to uphold that gold standard. Do you commit to upholding and protecting the gold standard for all medical products including drugs and devices?

Dr. HAHN. Senator, as I mentioned in my opening statement, as a frontline physician who has come to depend upon the FDA, I very much commit to that gold standard. I believe that is very important in terms of assessing the safety and efficacy, and you are absolutely, right both patients, all of the American people, and the providers in this country very much depend upon that.

Senator MURRAY. Thank you. Do you commit to making decisions based on science and not ideology and not bowing to political pressure from President Trump or the administration?

Dr. HAHN. Senator, throughout my career whether it was at a patient's bedside or as a medical executive, I have made decisions based upon data and science congruent with the law. Nothing is more important for a patient than for them to trust that you are making a decision that is in their best interest and no one else's interest. And I commit to you that science, data, and the law will guide decisions that I would make if I am fortunate enough to be confirmed by this Senate as Commissioner of Food and Drugs.

Senator MURRAY. Okay. Thank you very much. In September, as you know, the Trump administration announced plans to ban the sale of unauthorized, non-tobacco flavored e-cigarettes. I was really hopeful that the administration was finally taking the youth vaping epidemic seriously. And since then, as we all know now the President has reversed course all together choosing politics over children's health.

A week ago, Mitch Zeller was here. He is the head of the FDA's Tobacco Center and I asked him if he is committed to finalizing that flavor ban that was announced, and he could not give me an answer. Instead, he referred questions to the White House. The President has chosen you now to run the FDA. So I am now asking you, are you committed to finalizing the flavors compliance policy that the administration announced on September 11th, yes or no?

Dr. HAHN. Senator, thank you for your question. I am going to preface this Senator by emphasizing the point that I am a lung cancer doctor and I have seen the ravages of tobacco-related cancers. It is all too real to me. I also know youngsters who are very close to me who use e-cigarette products. I am aware of the youth tobacco survey data, and I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine, and I believe that we need to take aggressive action to stop that.

Senator MURRAY. Is that a yes or no that you will work on finalizing that compliance policy?

Dr. HAHN. I understand that the final compliance policies is under consideration by the administration. I look forward to their decision. I am not privy to those decision making processes, but I very much agree and support that aggressive action needs to be taken to protect our children.

Senator MURRAY. Well, have you told the President that you disagree with his decision to back away from those actions.

Dr. HAHN. I have not had a conversation with the President.

Mr. MURRAY. Is failing to implement a flavor ban and ignoring the millions of children who are getting addicted to e-cigarettes consistent with your focus on science and data?

Dr. HAHN. Senator, I look forward to hearing all of the data associated with this. As a scientist and a researcher and a doctor, seeing all the data and the complete set of data is important for making a decision. What I can promise you, Senator, is I will absolutely do that if I am fortunate enough to be confirmed as Commissioner of Food and Drugs. Nothing is more important than protecting our youth.

Senator MURRAY. Are you willing to say to the President what you believe the science and data is on banning this or will you just take what the President tells you to do and implement it?

Dr. HAHN. Senator, throughout my career using data, science, and the law, I have had conversations with people about what I think is best and I do look forward and will have those conversations.

Senator MURRAY. Okay, let me ask you quickly about opioids because President Trump's commission on combating the opioid crisis identified the FDA's, "inadequate oversight as one of the causes of that crisis and the commission found that for years the FDA accepted the pharmaceuticals industry's outrageous claims that newly formulated opioids were not addictive and failed to take action to mitigate that really critical public health crisis."

There is a lot more to be done to address the safety of opioids and the FDA plays a very critical role in monitoring and ensuring the appropriate use of prescription painkillers. If you are confirmed, can you tell us quickly what three steps you would take to make sure the FDA is doing what it can?

Dr. HAHN. Thank you, Senator. Yes, I think continuing the great work that the Congress—the laws Congress passed with respect to packaging and labeling is important. I look forward very much to approaching this in a holistic way with accelerated approval or increased approval of non-opioid products as well as looking into potentially even medical devices to help.

I believe based upon my experience at MD Anderson that a comprehensive holistic approach often without opioids can be very helpful in the treatment of pain including cancer pain. This is a significant problem and what we have to do is balance the relief of suffering with making sure that we prevent as much as possible misuse and addiction.

Senator MURRAY. Thank you very much.

The CHAIRMAN. Thank you, Senator Murray.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman, and Ranking Member. And thank you, Dr. Hahn. It was good to meet with you. I am impressed by your credentials and experience. Your comment a moment ago that you have respect for Congress calls into question your judgment——

[Laughter.]

Senator ROMNEY. But nonetheless, the great balance that you will have is to fulfill your responsibilities at the FDA where public health is of the ultimate significance versus the strength of politics and political donations, which have an enormous impact on the decisions that sometimes are made in Washington. And the stress that can come from politics and people who are driven by politics or political donations is wholly different than anything you have ever experienced in life and I can attest to that myself.

This issue of vaping as it relates to this question is to whether you will put science and public health ahead of politics and political contributions? And they don't come to you directly, but they are the kind of people who will be telling you what to do. The question is how you will balance those things in which you put forward? For me, vaping is, if you will, the canary in the coal mine or better the child in the vaping room, and so how you will deal with this issue is a pretty good test case for how you would deal with this issue on an ongoing basis on matters not just relating to vaping.

I mean, in September President Trump and Secretary Azar said they would regulate flavored e-cigarettes. We now know that over 5 million high schoolers are addicted to nicotine through vaping products. The Members of this body have been waiting for more than two months for the FDA to release a flavor ban. And while we have been waiting, 35 more people have died from lung injury, and I understand these death may be from adulterated products, but you can't decouple this and the fact that the flavors are what is luring kids in.

Just three days after this Committee heard from the FDA and CDC officials that flavored e-cigarettes are driving youth vaping rates, we learned from news reports that the administration may no longer act on banning flavors. A number of us have bills that relate to banning these products, banning flavors, some include menthol some don't, some have a sunset provision some don't, but this is a really critical issue.

The first question I would ask you is, is the FDA and your leadership able and willing to take action which will protect our kids whether or not the White House wants you to take that action?

Dr. HAHN. Senator, thank you for the question. As a physician I took a pledge many years ago to uphold the ethics of medical practice, to always put the patient first. Senator, I take that pledge very seriously and I think if you ask anyone who has worked with me, they will tell you that I have upheld that pledge every time I have seen a patient but also as a medical executive and a leader of academic medicine. I take that incredibly seriously, patients need to come first, and the decisions that we make need to be guided by science and data congruent with the law.

Senator ROMNEY. There are many people who rely upon that oath and I have as a patient. And I certainly hope that will be foremost in your mind because this is a place where sometimes an oath of that nature takes a backseat. I would note that Dr. Schuchat last week in her testimony indicated that flavors are the key driver in leading us into this youth vaping epidemic where we have millions, millions of high schoolers and middle schoolers that are now addicted to nicotine and will be battling with that throughout the rest of their life. I can't imagine a reason for holding off on immediately banning these kinds of flavors. Do you see a reason for holding off on that?

Dr. HAHN. Senator, I have also seen the data that you described suggesting the flavors are a significant positive effect—not positive but an effect for children using e-cigarettes and I am alarmed by those data, completely alarmed. I think it is a serious issue and I think it requires bold action to keep these out of the hands of kids. I do not want to see another generation of children become addicted to tobacco and nicotine.

Senator ROMNEY. You recognize of course that there will be very strong lobbying efforts on the part of tobacco producers, tobacco companies, vaping shop owners, vaping shop employees, a lot of jobs on the line. There will be enormous political pressure which will say keep these products out there, and there is not a lot of money coming in the other side.

From a political standpoint, there is no one coming to us and saying, hey, we are going to contribute to you all if you will make

sure and ban these flavors. No, it is just moms and dads and millions of kids that need—basically it is going to be on your shoulders. As I understand it, you are the decider here. President Bush used to say, you are the decider. Are you willing and is there anything that is keeping you from making that decision to ban these flavored products?

Dr. HAHN. Senator, as I mentioned to Senator Murray, I understand the final compliance policy is under consideration. I don't want to prejudge that and I don't have all the facts that they might have but I can tell you this for sure, sir. I will use science and data to guide the decisions if I am fortunate enough to be confirmed and I won't back away from that. I am a lung cancer doctor, I am a researcher, I am a father, and soon to be a grandfather and I take that incredibly seriously.

Senator ROMNEY. Thank you.

The CHAIRMAN. Thank you, Senator Romney.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. I want to follow-up on this line of questioning of Ranking Member Murray and Senator Romney. It strikes me that there are many areas in which the FDA could be active in this issue of vaping and e-cigarettes and the lung injuries that we are seeing. We focused on some. I just came from a hearing where there was an exploration of other ways to be engaged.

Let me just say that without decisive action from the FDA and the administration, we can bet that there is going to be more kids who will take up vaping. This leads to another problem that has been mentioned, nicotine addicted children. As you know, there are no FDA-approved cessation therapies for those under age 18. There are divisions other than the Center for Tobacco, there is the Drug Center that looks at—within the FDA—that looks at the potential development of effective treatments for things like nicotine addiction in children.

If confirmed, how would you tackle this problem and ensure that the FDA is prepared to address the challenge of nicotine addiction among our Nation's young people?

Dr. HAHN. Senator, thank you for your question. First, I would like to say Senator that I hope we have less and less nicotine addicted children in this country and hopefully zero in the future. And I am alarmed by the situation and what we are facing right now. Tobacco cessation and nicotine addiction are serious problems. I see that because many of my patients want to stop. Fortunately, there is great research, much of which has been funded by Congress, at NIH that has allowed us to look at this intersection between nicotine addiction, tobacco use, and what we might be able to do in the future.

I am very supportive of taking measures and expediting those measures to try to find out what novel products we can use to help with the tobacco cessation problem that we have. The more that we can accelerate those products onto the market to help people, I think the less of a public health issue this will be and look very much forward to working with Congress and researchers around this country to help expedite that.

Senator BALDWIN. Right. This next question is on the food end of the FDA. 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 standards of identity regulations. Despite the hard work that farmers do every day to meet these standards, there are many imitation products on the market today that get away with using dairy terms without meeting the same standards of identity for their products.

Your predecessor was working on this issue and held a comment period for farmers, consumers, and food companies to provide input on the mislabeling that is going on in the marketplace. Now that the FDA has received that information, the FDA needs to finish the job. How will you enforce FDA regulations against all plant based imitation products that use dairy terms?

Dr. HAHN. Senator, thanks for the question. I did very much enjoy hearing or having the conversation with you and hearing about this particular topic. I am in favor of clear, transparent, and understandable labeling for the American people. The American people need this so that they can make the appropriate decisions for their health and for their nutrition. I very much want to look at this issue when I get to the FDA if I am fortunate enough to be confirmed and I will work with you and your office to assess that.

I would like to point out that this is consistent with what I said around science, data, and congruent with the law. It is a really important part of what FDA does.

Senator BALDWIN. I thank you for that. The agency should be enforcing this already. If confirmed, can you commit to me to begin enforcement within 60 days?

Dr. HAHN. Senator, what I can commit to is that I will look at this as soon as I am confirmed, if I am fortunate enough to be confirmed, and then to get back to you as quickly as I possibly can.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Welcome, Dr. Hahn. I first want to associate myself with my colleagues' comments on the vaping epidemic. You and I had a discussion about this problem in my office and I believe, as they do, that it is absolutely essential that the FDA act to ban the flavors, but I believe take a number of other actions as well.

In that regard, I would commend to you an op-ed that was written by your predecessor, Dr. Gottlieb, on other actions that the FDA should take such as banning cartridges on e-cigarettes that kids can use or others can use to refill with dangerous substances, which have led to this outbreak of serious lung diseases. Since you have discussed those issues at length, let me turn to two others. One is the issue of drug shortages and the other is the issue of drug pricing.

Patients, pharmacists, physicians, and hospitals in my state are struggling with shortages of vital drugs. Maine Health, our largest healthcare organization is currently managing 40 such shortages. Northern Light Health Care in Bangor has had to hire four additional staff to manage ongoing shortages. We have had surgeries

from patients in rural hospitals transferred to larger hospitals because of a shortage of injectable morphine.

Cancer survivors are being denied additional preventive immunotherapy treatments, and now we are hearing about shortages of vincristine, which treats many childhood cancers as if cancer diagnosis weren't frightening enough to those children and their parents. Senator Tina Smith and I have introduced a bill to help lessen these drug shortages and that bill has the support of more than 50 healthcare organizations showing how widespread this problem is.

You shared your personal experience as a physician with drug shortages. Today, will you commit publicly to all those patients who are affected by drug shortages and to this Committee that you will work with us on legislation and explore other ways to mitigate this very serious problem?

Dr. HAHN. Yes, Senator. I very much enjoyed our meeting and the discussion regarding this very important topic. And yes, I commit certainly to working with Congress on this issue. As I mentioned to you, this is something that is very significant, telling parents and a child that you don't have enough vincristine to treat their cancer, something that no provider, no physician wants to be in that position. And so this is an incredibly serious issue and I look forward to working with Congress on this as there are things that I think we can do to help.

Senator COLLINS. Thank you. I hope we can get our legislation through with your help. I wanted to turn to the issue of drug pricing. Dr. Gottlieb, your predecessor, has observed that if all the biosimilars that have been approved by the FDA were successfully marketed in this country in a timely fashion, Americans would have saved more than $4.5 billion in 2017.

Let me give you an example. Humira, the world's best-selling drug is really a textbook example. The biosimilar version has been available in the European Union for more than a year but American consumers must wait until 2023 because of gaming of the patent system by the brand name manufacturer. Senator Kaine and I have sponsored legislation that would provide earlier and greater disclosure of patents surrounding biologics so that biosimilars can come to the market sooner and a version of our bill has been included in this Committee's Lower Health Care Costs Act.

What role do you see the FDA playing in coordination with the FTC and the patent office to prevent the gaming of the patent system when we are dealing with biosimilars, and are you willing to have FDA play an aggressive role in using the purple book to publicize patents?

Dr. HAHN. Senator, I really appreciated this conversation with you. We are all very fortunate that your passion is behind this because it is a significant problem across the country. As we have discussed, biologics represent an important treatment source for cancer patients, and their availability and also the upward pressure that they are causing on prices are substantial.

The biosimilar pathway is crucial and very much in favor of transparency. And anti-competitive practices should be eliminated. So I pledge to work with you, Senator and the Congress, on those particular issues.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Hassan.

Senator HASSAN. Well, thank you Chairman Alexander and Ranking Member Murray, and welcome to our nominee——

The CHAIRMAN. Senator Hassan, I made mistake. I should have called on Senator Murphy.

Senator HASSAN. It is all good. So I will yield to Senator—or we are going to follow——

The CHAIRMAN. But having put him on the spot, he is a gentleman as always.

Senator Hassan.

Senator HASSAN. Thank you. And thank you for your courtesy, Senator Murphy, and again, welcome doctor. Welcome to your family. Service is a family affair and we very much appreciate your family's support not only in this endeavor but on all the work you have already done. We can't overstate the importance of the FDA Commissioner as an advocate for public health, and as you have heard from all of us, fact-based decision making particularly at a time when we continue to grapple with the devastating impact of the opioid epidemic and the surge in youth e-cigarette use.

Dr. Hahn, as we discussed in my office last week, eight months ago, Senator Markey and I sent a letter to the FDA asking basic questions about the approval and labeling of opioids, including the influence that drug manufacturers had on these decisions. We also asked in that letter about a problematic clinical trial design that FDA allows for opioid approvals. It is called the enriched enrollment randomized withdrawal study design, which is a mouthful, and some non-experts like me think skew the results.

As you know, FDA has not responded to our letter. This Committee has a track record of working on a bipartisan basis to address the devastating opioid crisis, and we need FDA to be a partner in those efforts. That includes being responsive to and transparent with Members of this Committee. I heard what you said in your opening statement and responses to other Senators here about working with Congress.

My question to you is asking for the same commitment from you today that you gave to me in my office last week. If confirmed, will you respond to our letter within the first 30 days of your tenure?

Dr. HAHN. Senator, as I said in your office and I commit to this, within 30 days I will look into this issue and get back to you regarding your letter. I also want to emphasize that I very much appreciate your approach here. And that is always important to have a look back to see what happened, to see if you can have continuous improvement. I think that is a really strong effort.

Senator HASSAN. Well, I appreciate that and I take it from your answer that your update on the response will include specifics on where the response is held up and why, if you can't get me a full response.

Dr. HAHN. Yes, Senator.

Senator HASSAN. Because a look back isn't particularly helpful if it takes too long to do, right?

Dr. HAHN. Yes, Senator.

Senator HASSAN. Okay. I also appreciated our discussion in my office about balancing access to opioids for those who need them with policies that keep these highly addictive drugs from being overprescribed. Can you talk about how your views on opioids have evolved since medical school and how marketing efforts by opioid manufacturers may have influenced physicians and patients' initial understanding of the dangers of opioids?

Dr. HAHN. Senator, yes. Thank you for the question. And it is a really interesting time in medicine regarding this issue. And congratulations to Congress for their excellent work as well as the administration on this because provider education has gone a long way to addressing the problems that we have seen.

I mentioned in your office that when I first went to medical school and started taking care of cancer patients, the teaching was that cancer patients should be treated liberally with opioids and that they don't become addicted to pain medications. And we found out that wasn't the case, and in some instances with tragic consequences. We have totally changed based upon new information and education how we provide relief of pain for cancer patients. And as you can imagine as a cancer doctor in the front lines, this balance between relieving suffering but also making sure there is not misuse or abuse is critically important.

A multidisciplinary approach has been instituted at MD Anderson as we talked about with certainly opioid therapy, but also non-opioid therapies, behavioral therapies, even potentially medical devices to help with pain. I am very much a supporter of the multidisciplinary approach to treating pain. I think it is something that we need to do more of and if I am fortunate enough to be confirmed as Commissioner or Food and Drugs, I look forward to furthering the education efforts for providers and patients.

Senator HASSAN. Alright. Well, thank you for that and I appreciated that conversation. And I look forward to you continuing to take that hard look at that risk-benefit analysis of these kinds of drugs and what they should be used for and what they shouldn't be. You have heard a lot of concern up here about fact-based decision making, about the influence of outside interests, whether their special interests or ideological ones on decision making at the FDA. Right now we are dealing with reports that the administration caved to special interest in reversing the e-cigarette flavor band and that is incredibly disturbing. You have talked a little bit about your concerns about the ban.

But if you are confirmed you are going to be overseeing the FDA premarket tobacco application process for e-cigarettes. A whole lot of people are counting on the FDA to put public health first. Will you commit to public disclosure of all meetings between FDA and Juul that take place before and during the pre-market tobacco application process, including who attended and what was discussed?

Will you commit to providing this Committee with any data you receive from companies like Juul that relate to youth e-cigarette use including data on flavors and diversion?

Dr. HAHN. Senator, so I am aware of the pathways that you are describing. I think they are important and I do think they need to be supported by science and data and congruent with the law. What I can promise you Senator because I am not at the FDA, I

don't know the rules and regulation around disclosure, that I will look into that, understand what those rules are, and follow the law.

Senator HASSAN. Well, and just for the record here, Juul made a commitment that they weren't going to lobby on this and then their representatives come to my office and mention all the meetings they have had at the FDA and when I asked the FDA about what meetings they had, they said nothing to do with policy. They are either lobbying or they are not and the American public has a right to know how decisions that affect their children and our public health are made, and so I am very hopeful that we will get full disclosure from the FDA about their meetings with Juul and the information Juul has brought forward. It was an issue with opioid approval as well. And I thank you, Mr. Chairman, for letting me go over.

The CHAIRMAN. We will have time for second round of questions if Senators wish. Dr. Hahn, several Senators have mentioned e-cigarettes and our hearing last week and the appearance of the Director of the Center for Tobacco Products. Just as a matter of record, there was some disagreement here about tobacco among Senators.

We have got 23 Members, a lot of different points of view, libertarian, whole variety of points of view. But there was no disagreement on two issues, among the whole crowd that I heard. One was we are very concerned about the 2,000 Americans who have lung disease. You are a lung doctor. That is not completely explained and is related to e-cigarettes.

What do we do about that? And very concerned about the 1 in 4 high school students who apparently are using e-cigarettes. I didn't hear anybody on this Committee of any point of view advocate for that. And Mr. Zeller made it clear that the FDA has plenty of authority to deal with all of those things. Sometimes we tie the hands of the administration, but just for example, as Senator Romney and Senator Collins mentioned, requiring tamper-proof cartridges that couldn't be—so you couldn't insert a vitamin E or THC, for example, I believe you have the authority to do that now if you are the FDA Commissioner.

Lowering the level of nicotine, FDA could do that now. Putting labels on the actual products, FDA could do that now. Regulating flavors, the FDA could do that now. Improving age verification methods, developing better standards for retailers, spending more the $5 plus billion you have collected from tobacco companies over the last several years, on a more effective way persuading young people not to use e-cigarettes, they have that authority now so I don't need an answer to the question from you today because you are not yet the commissioner.

But my point is you have plenty of authority if you are the Commissioner to deal with the issues that almost everybody on this Committee is worried about concerning e-cigarettes. When we were working on the 21st Century Cures Act, I asked Dr. Caleb who was then Commissioner, what is your top priority? I said, this is a train that is likely to get to the station, meaning our bill, so what is the single most important thing we could do for the FDA? And he said it was having the flexibility to hire the right people and pay them enough to keep them working at the FDA yet late in 2017 Commis-

sioner Gottlieb said that FDA's hiring process can take anywhere from 150 to 550 days.

What can you do to implement this new authority FDA has to make sure you have the right people at FDA to deal with speeding up approval of safe treatments and cures?

Dr. HAHN. Senator it is striking—thank you for the question—on how much the similarities between MD Anderson and FDA exist. Both are large——

The CHAIRMAN. How many employees do you have at FDA?

Dr. HAHN. At FDA?

The CHAIRMAN. Well at both.

Dr. HAHN. MD Anderson is 21,700.

The CHAIRMAN. At FDA?

Dr. HAHN. 17,000 is my understanding, sir. Big complex, public health driven, research driven organizations. In the case of the University of Texas at MD Anderson is a state bureaucracy associated with hiring and obviously FDA with the Federal Government. I applaud Congress has inclusion in the 21st Century Cures Act.

The CHAIRMAN. What can you do about it? What can you do about hiring more talented people?

Dr. HAHN. I think one of the first things, and I said this to many of you in meetings, that I believe it will be a top priority for me to make sure that all of the new authorities that were given to FDA through 21st Century Cures Act are in fact implemented. Nothing is more important than getting the right expertise in the agency to help adjudicate these decisions on these incredible new treatments that are coming down to help the American people. So I think there is that. I think also the experience I have had at MD Anderson with respect to recruiting and retaining the best and brightest to help with the mission will help with FDA.

The CHAIRMAN. Well, this was a bipartisan priority and it was a top priority of FDA. It would seem to me that given our goals that would be a top priority of yours. I just have a few seconds left but regenerative medicine. On the one hand, FDA has taking enforcement action, which it should, against stem cell clinics and manufacturers that may be misleading people. On the other hand, we have diabetes advocates who come to me and say regenerative medicine may restore pancreas or put out of business a heart transplant surgeon by restoring a heart, or I had a friend from Tennessee who came and whose eyesight was restored by stem cell therapy.

We gave new authority to the FDA to move ahead with real treatments and cures in regenerative medicine and new money to Dr. Collins at NIH to work with you on that. Will you commit to taking seriously the promise of regenerative medicine and stem cell therapy?

Dr. HAHN. Senator, I certainly commit to that. I have had a chance to speak to Dr. Collins and I think the work that they are doing, particularly in the all of us project is so important and I absolutely commit to trying to accelerate that work.

The CHAIRMAN. Thank you, Dr. Hahn. Now, Senator Murphy—excuse me for skipping over.

Senator MURPHY. No problem at all. Thank you very much, Mr. Chairman. Good to see you again, doctor. A handful of questions.

First, we had the chance to talk privately about two priorities of mine and I want to get your commitment on the record to continuing to work on them if you are confirmed for this post.

The first is an FDA current proposed rule to ban electrical stimulation devices. These are devices that have been used in many cases on children with little efficacy and many long-term negative side effects. The second is the increasing propensity of children to show allergy to sesame and there is a conversation happening about labeling sesame as one of the regulated allergens through FDA. Can you just commit to me again in public to continue to work with us on both of these issues?

Dr. HAHN. Senator, if I am fortunate enough to be confirmed, I commit certainly to working with you on both of those issues.

Senator MURPHY. Second, we have had a problem in other areas of the administration where information is often readily shared with Republicans but is withheld intentionally from Democrats. That was not the case with your predecessor. Scott Gottlieb was I think very good about making sure that both Republicans and Democrats were informed, a little bit easier on the FDA because there is not a lot of politics. That plays into the decisions that you make but I just want to make sure that you commit to this Committee to work with all Members, Republicans and Democrats, to share updates and to gather input without regard for party.

Dr. HAHN. Senator, I commit to that. As you and I discussed in your office, many of these issues are not party based, they are bipartisan and I certainly commit to that, sir.

Senator MURPHY. Lastly, I certainly agree with your testimony, this is a really exciting time for American medicine and science but we have a drug and device manufacturing system that is rewarded really solely for bringing to market products that can lead to strong profits. And often we talk about this in the context of rare diseases that go unmet by drug discoveries. But, frankly the real scandal is that even in many common disease states, we have had very little innovation, and as someone who works a lot on mental health, it is remarkable how little innovation we have seen over the last 50 years when it comes to drugs that treat depression, for instance, which is a common disease state inflicted upon millions and millions of Americans.

In fact, this year was the first time in decades that the FDA approved any new major depression drugs. And so you are in a really unique position as a physician to bring together clinicians and patients and other stakeholders to hear about how these gaps impact patient care. So if you are confirmed, what kind of things do you think you can do at the FDA to identify those areas of medicine where we just haven't seen advancements in treatment options, especially when it comes to mental health where people are crying out for additional treatments and drugs?

Dr. HAHN. Senator, thank you for the question, and you are right, mental health, we have lagged behind in terms of innovations. I think the other area are the neurodegenerative disorders, ALS, etc., Parkinson's disease, and these are areas where there is fantastic research going on. I don't understand completely why there is this gap between that research and product development. I know that there are best practices at the agency with respect to

some areas and I look very much forward to working with you and Congress finding how we can spread those best practices across all of the different units of the agency.

Senator MURPHY. I had one of the few major pharmaceutical companies that is investing some major money in mental health drug development pathways, and they identified patient and human testing as an area that they really saw opportunity for reform. And once you got a drug into those tests, it was much harder to prove efficacy than it was for other disease states. And that is certainly something that you at FDA can work with these companies on trying to reform and perfect.

Dr. HAHN. Senator, this is an area of particular interest to me. As you know, I am a clinical trialist and what endpoints we use in clinical trials, which is exactly what you are getting, could help actually expedite some of this medical product development. We have to be pragmatic but we also have to make sure that they are validated endpoints. I am very interested in working with all stakeholders on this.

Senator MURPHY. I hope you will allocate sufficient time and attention to it. It could really use some leadership from the top. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy. And I would say Dr. Hahn, Senator Murphy and Senator Cassidy for example, and their work on mental health are an example of the opportunities we have to work in a bipartisan way on this Committee. So as you work with Congress, just because we make a lot of noise sometimes about politics, doesn't mean there are not plenty of opportunities for substantive progress. I would encourage you to work with the Members of this Committee on both sides of the aisle to try to—because that is usually the way we get a result.

Senator Braun.

Senator BRAUN. Thank you. Mr. Chairman. I enjoyed our meeting in our office. You are entering into an area of the economy, Warren Buffett calls it the tapeworm on the economy. I am recently a CEO and biggest challenge was how to control healthcare costs. And I know you don't get involved in that but I think part of what I am looking for with science and fact based is like taking a risk and changing the paradigm. So often I see the FDA, I see the HHS, have been a stodgy part of the problem.

We have evolved to where the healthcare system is broken and every opportunity, I get to say it publicly I blame it on the industry. So in your own way when it comes to the other sectors, hospitals, insurance, practitioners, pharma will be what you focus on and I look at a particular issue of methodology. And I want to focus in and Senator Murphy mentioned it a moment ago, on diseases like ALS, DMD, where no real good remedies, narrow windows of survival once you are diagnosed, why would we be sticking with the old ways of doing things?

Are you going to feel like any CEO would in running a business where you actually excel and do well when you take risks and stick your neck out, and in this case why wouldn't you want to change the process to advance drugs and therapies and treatments for diseases that have nothing going on for them?

Dr. HAHN. Senator, I really appreciate our conversation, and you with your business background presented me with incredible pragmatic and interesting observations about the way the world works with respect to insurance and medical care. So I appreciate that very much. My experience at MD Anderson is with a large bureaucratic organization. I understand what you are saying about risk aversion.

It is always a balance between making sure we ensure the safety of our patients and get the best treatments to them while at the same time making advances. My colleagues at MD Anderson say that the most risk-free clinical trial is one that doesn't happen and of course that is a really bad thing for patients because we don't actually—aren't able to figure out what is the right treatment for them. So sir, I do believe this is a balance.

I do believe that we have to accelerate innovation and get those products into the hands of patients and the American people and the providers. And I very much appreciate your perspective and look forward to working with you on the subject.

Senator BRAUN. That is good. Next week I am introducing a conditional approval bill where drugs can be provisionally approved after receiving promising early stage data. Could be transformational in my mind to address some of these diseases that, have no cures, nothing really working well.

The FDA could grant limited marketing authorization to new drugs after successful phase 1 and phase 2 clinical trials establishing safety and a reasonable expectation of effectiveness, allowing patients in need of a treatment to benefit while allowing companies to generate a modest amount of revenue to help fund phase 3 trials. Does that sound like something that would be in your entrepreneurial framework heading this agency? Is that something that you think makes sense?

Dr. HAHN. Senator, I am always willing to hear about science and data and new approaches. My career has been in clinical trials and clinical trial design, and understanding the novel approaches that we can use. I think it is important to expedite and to have innovation reach patients as quickly as possible. I do want to make sure that these approaches are validated so that we don't make huge mistakes that hurt patients, but I am open to conversation about all of those.

Senator BRAUN. Rest assured after your confirmation I will be getting with you. Drug importation. Of all of the things you can do at the FDA, pharma is probably the most focused in place because everybody is involved with it. I know as representing the only financial stakeholder in healthcare, that would be the private insurance sector and the employers who pay all the bills that subsidize low prices across the rest of the world, I would hope that you will look at anything that, even though I know you can't get in the pricing but you can control some of the structure and processes.

Drug prices and the fact that I listened to Senator Merkley a couple Thursdays ago highlighting an insulin drug, sales for $343 here, in average it is about $50 bucks across six other countries. I know you can't do anything about the mechanics that have evolved in such a way to give us such poor results but what about using the agency to speed up the process of getting drugs that are

being produced elsewhere into this country and change the paradigm that is made so clumsy and then calling out the drug companies that in many cases do everything they can to restrict the process, including biologics.

Dr. HAHN. Senator, as you point out, there are indirect things that FDA can do in this really important issue. Not a week goes by when I see a patient that doesn't comment on the stress, financial toxicities, how people refer to it, of high prescription drug prices. And the American people want urgent action and I support moving forward with action that makes sense. With respect to drug importation, as you know, the Secretary has the power under Section 804 to certify to Congress that importation will reduce costs for the American people and that it is safe and does not introduce additional risks. FDA's role in that is to actually to certify the safety and security of the Nation's drug supply which is the safest and most secure in the world. And that would be our job to look at the data and——

Senator BRAUN. Keep the gold standard there but be entrepreneurial and push and hold the industry accountable. Thank you.

Dr. HAHN. Thank you, sir.

The CHAIRMAN. Thank you, Senator, Braun. The votes will begin 11:30 a.m. I am going to go vote quickly on the first vote. Senator Murray will preside. I will get back. We will continue the questioning as we go along.

Senator Rosen.

Senator ROSEN. Thank you. And thank you for your willingness to serve and for what you have done throughout your career to support patients and their families through some of the most difficult times in any family's life. I really appreciate your dedication to your medical practice. And we talked a little bit about palliative care. As an oncologist, medical oncologist, a lot about that, especially a radiation oncologist. And so I want to make sure that patients with serious illnesses are treated in a comprehensive way that includes focusing on reducing stress and alleviating pain.

I was glad to launch the bipartisan Senate comprehensive care caucus with Senators Barrasso, Baldwin, and Fisher, as my co-chairs. We are using this as a way to improve access to palliative care and care coordination and address issues impacting caregivers. And I know the importance of this firsthand. For example, near the end of her life, my mother suffered from a tumor on her spine and needed palliative radiation therapy. Not a curative. She was terminal but it was going to help reduce her pain for the rest of her life, and it was really important for the quality of life. So I have two questions for you.

What else could the FDA be doing to advance options for palliative care? And how can we balance the variety of patient needs including that of palliative care when we look at how the FDA evaluates drugs and devices for safety and efficacy?

Dr. HAHN. Thank you, Senator, for this question. As you know, I expressed in our meeting a very special, feeling toward the supportive care and palliative of our patients. As a cancer doctor, that is incredibly important and some of the best things that you can do for people as they end their life. So it is a really interesting

question, Senator, particularly when you think about what are the end points that can be used in clinical trials for drug approvals.

There is a lot of great work going around in this country looking at what those endpoints are, what endpoints matter to patients, and what are the most important in the palliative setting. And I think there is great opportunity for us to look at those endpoints and see how that can be incorporated in the drug and the device pathways to actually help in the palliative care setting. So I look very much forward to working with your caucus on that if I am fortunate enough to be confirmed.

Senator ROSEN. Thank you. I want to move on to a little bit more to the research area too. We all are aware of this successful research that led to cannabidiol, and I am probably not saying that right. It is used to treat seizures in children who suffer from a severe form of epilepsy. So we want to find new treatments that have fewer side effects or more effective. And so I have researchers at the University of Nevada Las Vegas. They are stymied and their scientific efforts because of the challenges to gain access to study marijuana legally, developed different strains like this one for epilepsy.

Even in states like Nevada where marijuana is legal. And so given the great needs for alternatives, again, whether it is palliative care, pain management, we hear talk about opioids, depression, anxiety. What can we do to make it easier for the researchers not to take that one or two years to get Schedule 1 license approval?

Dr. HAHN. Senator, thank you for the question. The top line answer to that is clarity and transparency about what the rules of the road are. That is really important for all innovators as they try to bring new medical products to patients across America. The issue of CBD that you described, in fact, it is an active ingredient in this drug that was approved for a very serious childhood seizure disorder. I think that tells us that there is a pathway for medical products. There are also some indications cancer, palliative care setting where CBD might be of benefit, but there are some open and unanswered questions that have to be filled by research exactly as you described, Senator. What is the appropriate dosage and for what medication? What are the implications of long-term use Unsubstantiated claims like we see in the marketplace are of concern in terms of things like curing Alzheimer's or cancer. It needs to be supported by data.

Senator ROSEN. Can you help us speed up that process for researchers just to even get you this data so we can do what we need to do if you are lucky enough to be confirmed?

Dr. HAHN. Senator, huge supporter of research and getting clarity and transparency around the processes to allow us to get the medical products to patients.

Senator ROSEN. Thank you.

Dr. HAHN. Thank you.

Senator MURRAY. [presiding] Thank you.

Senator Isakson.

Senator ISAKSON. Thank you, Senator Murray. I have been listening to everybody and decided I am not going to ask a question then probably make a 15 minute speech. I am not going to make

a speech but I am going to tell you, what Ms. Rosen was just talking about and what has been talked about by other Members and a concern that I have as well and that is there seems to be almost an inhibitor to get drugs to market place because we get new developments take place, new drugs are found. We can't get enough time to approve them. We can't get enough authority over them. We don't get enough transparency to get things we need and it has been going on and on, and finally we don't solve a problem and then get another problem. But the people are sick and are not getting help. I want to talk about two or three things that happened to me while I have been a Senator and the specific thing that happened and ask you a little bit about it, one was on September 12, 2001.

We all remember what happened the day before. It was the most tragic attack on the United States in America history. And in New York City we had more people affected by bad and debilitating burns than any place we had in history. And I had a phone call on my cell phone that ended up leading me to the FDA, that ended up leading me to Salve Pharmaceutical, which is now in Austria, but it was here in the United States, at time in my district, who had developed a drug called flamazine. Flamazine was used in burn cases. It was a salve of some type. It was not approved in the United States, it was approved in Europe.

On September 11, 2001, 2002 when they called me up, they wanted to give it to us in the United States, give it to doctors and United States hospitals but they couldn't because they weren't approved to be used. I think that was an FDA decision if I am not mistaken. So I called FDA and one day, the next day, flamazine was on the way to the Northeast in New York and around for use in cases where they run out of every other preparatory salve type—and I don't know, I am not using the right terms—but medicine that there was. And I thought to myself, gosh, that we had all these things but we took so long to get to the patients because we never could get through all—so before we got someone that was really bad, we got through in one day. And that shows you what you can do.

I bragged about the FDA so many times for that because we would never get that done but we got it done in one day when the whole world was scared about what had happened. We need to improve—we don't need to get down to one day approvals. I don't think one day of rules on pharmaceuticals would be popular or possible, but we ought to get to a situation where it doesn't take an absolute emergency or death-defying circumstance to cause somebody to move. What can we do to get a more agile FDA in terms of getting those things to the marketplace and get them approved and through the process?

Dr. HAHN. Senator, I share your enthusiasm from modernizing and making more efficient all of the approval processes. I am cognizant that as a physician I rely upon FDA to protect the public health and the standards can't be compromised. However, I believe in the new era where science is moving so quickly, the agency should be more efficient, and we should have more agility to actually do those approvals.

Part of that is in fact getting the right people in place to help make the assessments that are needed to uphold the gold standard. But part of that is the possibility of using data, new ways of using data, data analytics to help us come to more accurate and precise conclusions about products. And those are two very important things to me that I would like to see, if fortunate enough to be confirmed, pushed forward at the agency.

Senator ISAKSON. How much difficulty is getting things to the marketplace, do you find, from the trial but actually scaring off the development new drugs because it is getting approved without them. Just some of the manufacturers are fierce and they just don't do it. How much did you fear the try bar and cause you to get people to say well, we are not going to develop a drug. That would be too expensive, too big a risk. We are just not going to do it. So they don't do it because the fear of being sued or having a liability they couldn't afford.

Dr. HAHN. Senator, it is a concern. I am not sure that it is a primary concern that I have seen from my perspective and very much be interested to hear what stakeholders say about that and address the problems to the extent that FDA could.

Senator ISAKSON. I think you said the magic word on that particular case. I think it is to get the stakeholders to the table early in the advance of coming up with a solution. Have them committed to doing it. I love our system and I love the rights I have as a citizen. I love the constitutional protections. I respect everybody and every profession. I have nothing against law firms whatsoever. But I have seen in action the damage that can be done by out-of-control tort liability cases by out of control lawyers using that case to accomplish ends which aren't always good for the society no matter what happens.

I think if we have a situation where they are blocking the expediting or even the tackling of trying to find a solution for a problem, that we ought to try everything we can to level the playing field, whether it is a waiver of liability because the manufacture agrees to do something or whatever might be. I think we need to be proactive on that end rather than operating in fear. It is my personal opinion.

Dr. HAHN. Senator, I think being proactive in a lot of these fears makes sense. I look forward to working with you on it, sir.

Senator ISAKSON. Thank you very much.

Dr. HAHN. Thank you.

Senator MURRAY. Thank you, Senator Isakson.

Senator Casey.

Senator CASEY. Thank you, Ranking Member Murray, and doctor, welcome. Sorry I wasn't here earlier for your testimony. It is one of those days we are pulled in a couple different directions, but grateful that a native Philadelphian is here and someone who spent so much time at the University of Pennsylvania Medical School, School of Medicine I should say. And we are grateful you are willing to put yourself forward for public service. And I know your family is with you and they are part of that service were you to be confirmed. So thank you for that. I wanted to move and I know a vote is just starting so I will try to be as brief as I can.

I wanted to move to a question about legislation that Senator Isakson and I have worked on for many years and I am grateful for his continuing help on this issue. And that is the over the counter monograph issue. We talked about that when you and I met. Senator Isakson, Chairman Alexander, Ranking Member Murray have worked closely with us for years on this legislation. We got it through this Committee recently. We had to work with several of your predecessors. We are trying to obviously protect public health and promote innovation in the OTC, the drug marketplace. And we believe that we are going to get this done and get it passed. It will be up to the FDA to swiftly implement the legislation. So first question is, if you are confirmed, will the OTC monograph reform still be a priority for the FDA and will you make it a priority as Commissioner?

Dr. HAHN. Senator, thank you for that question. I am aware that it has been many years since there has been an update in the OTC monograph system and it, I believe it is in need. I believe the agency feels the same way of modernization and I commit to working with you. I will faithfully execute the laws passed by Congress.

Senator CASEY. I look forward to that and I look forward to having more discussions with you about it. Here is another version of that question regarding a plan because it is possible that if a bill were signed into law but language authorizing the collection of user fees is not included in this year's Appropriations legislation, basic question I have is would you have a plan to deal with that?

Dr. HAHN. Senator, I think this is a resource issue and I would have to dig into the details. My personal belief is that the user fee program has been a success with respect to expediting products on the market. I have to understand more about the finances of the institution and how that would be affected by the legislation that you described with the lack of inclusion, but I would very much want to work with Congress on that.

Senator CASEY. The next and last question I have is on challenges facing the FDA. You have got a lot of them obviously as any agency does when you are coming in the door, drug shortages, lack of new antimicrobial drug development to combat growing resistance is the second, a third would be of course the ongoing opioid epidemic. How would you, if confirmed, use both FDA's capabilities and its regulatory authority to address these pressing issues?

Dr. HAHN. Senator, I feel very strongly that FDA's role in protecting the public health on all of these issues is critically important to Americans. My general approach is to be guided by the principles of integrity and transparency and putting the interests of patients first. And if I am fortunate enough to be confirmed as Commissioner of Food and Drugs, I promise that we will use science data in the law in our decision making and that I will faithfully represent that.

Senator CASEY. Doctor, thanks. I am going to be cutting my time short so we can move forward but thank you very much.

Dr. HAHN. Thank you, Senator.

Senator MURRAY. Thank you, Senator Casey.

Senator Roberts.

Senator ROBERTS. Thank you, Ranking Member. Doctor, when you came to my office it was obvious to me that he was certainly

qualified. I know here you are supported by the American Society for Radiation Oncology, American Association for Cancer Research, American Cancer Society Action Network, American College of Radiation Oncology, American Hospital Association National Organization for Rare Disorders, and the American Feed Industry Association. As chairman of the Ag Committee, I appreciate that very much. Just say to my distinguished friend that we ought to move his confirmation as fast as possible if we can talk to leadership to get that done. Thank you, sir, for your service.

Dr. HAHN. Thank you, Senator.

Senator ROBERTS. The United States quietly insists on the adherence to a risk-based science-based principles when evaluating standards for animal health, food, safety, and international trade. Last year the FDA received a five-year AMR strategic plan, a collection of activities for the stated purpose of addressing the potential risk for antimicrobial resistance, AMR, from agriculture production. However, her concern is that some parts of the FDA's plan take more of a hazard based approach where a risk-based approach would be better to achieve the best outcomes for animal health and human beings. How will you ensure the FDA will follow a risk-based approach when implementing all of the five-year AMR strategic plan in working, of course, with the animal health industry?

Dr. HAHN. Yes, sir. Thank you for the question. I am a huge fan both in my previous career at Penn and now as a medical executive of using a risk-based approach to looking at problems and enforcement. I think there has been a long history at FDA and that I look very much forward to getting more information about the issues that you described and working with you on that to assess the role of a risk based versus a hazard based approach.

Senator ROBERTS. I might add that Senator Baldwin brought up on the question on the efficacy of milk. If you just put a parenthesis after that in your memory and put meat in there too. And you might put impossible in front of it.

[Laughter.]

Dr. HAHN. Yes, sir.

Senator ROBERTS. Thank you. Animal biotech. I understand the FDA is looking at revising its guidance under the 1992 update to the coordinated framework for the regulation of biotech. I understand the need to update and examine the framework. Will the revised guidance be consistent with a 1992 update and is it considering emerging technology such as animal gene editing? Do you commit to giving timely and meaningful information regarding upcoming update to the industry stakeholders?

Dr. HAHN. I commit to giving timely and accurate information. Yes, sir.

Senator ROBERTS. My last question is about hemp. Hemp is the latest thing with regards to farmers, ranchers, and growers, about the only thing we can get above the cost of production in a recession. And it has already been asked by Senator Rosen with regards to CPD. There are many questions about the safety of using these products including interactions with other drugs, dosing, even manufacturing standards to conform that what is in the bottle is the same as what it says and not contaminated with other substances.

I have a personal interest in this and that I have—I don't know why I am bringing this up but I have football knees.

My wife insists that this little bottle of CBD stuff, that if you can put that on your knees, it is going to work. It doesn't. Well at least for me it doesn't. But this is being used for everything. I am not unaware—or I was going to mention Bob Casey, myself, and then you sir, with the possibility of growth of hair.

[Laughter.]

Senator ROBERTS. I mean, this is ridiculous. This is the last thing since had a call and that really dates me way back in the day when that was being a product going across state lines. So I know you have started a process to develop a framework for how these products might continue to be marketed but understand that farmers really want to get into this crop because it is a positive thing in terms of price recovery.

Dr. HAHN. Senator, I think you have described very well the balance that is needed here. As you know from a manufacturer survey, a significant proportion of Americans are using these products and a significant proportion of Americans that are using the products think that they are already judged to be safe and effective by FDA when they are not. So I think there are unanswered questions that need to be filled in my data and science and research. I also know that there are signals that CBD, for example, can be an effective medical product. And I think we have to have a clear and transparent framework for assessing them certainly on the medical products.

Senator ROBERTS. Let me know.

Dr. HAHN. Thank you.

Senator MURRAY. Senator Smith.

Senator SMITH. Thank you. Thank you, Dr. Hahn, and thank you very much for coming in and speaking with me the other day, and thanks also to your family for being here. You know, you said a couple of times, if I were fortunate enough to be confirmed, and I have to say thinking about this job in the world we live in right now, I don't know if I would go right to fortunate.

[Laughter.]

Senator SMITH. I think this looks like a really hard job to me. I also think that in this job you really are going to be between a rock and a hard place. You have said quite a few times and I believe you that you are a physician and a scientist ruled by science and data and the law, and yet colleagues on both sides of the aisle have acknowledged that in many circumstances that there are pressures, political pressures, political influence I would say, that is going to be brought to bear on you. And so I have to ask you, there is an open question here. I want to just go back to something that Senator Murray was asking you about earlier and ask you whether you can say yes or no, whether you would commit to finalizing the administration's proposal to clear the market of unauthorized flavored e-cigarettes?

Dr. HAHN. Senator, as I mentioned before, I am aware that the final compliance policy is being considered and I just can't prejudge that decision at this point. I am not involved in that. I don't have the data. Senator, I want to stress to you how important I think this issue is and again say to you that throughout my career, as

you probably know from my record, I have been put in situations where I found myself in positions of leadership where making tough calls needs to be done that aren't popular, that aren't being made in the best interest of Stephen Hahn, but in the best interest of the people that I am helping, the patients. And I can promise you that I will follow that.

Senator SMITH. Would you agree that as head of the FDA, that you would have the authority to advance that rule, to finalize that rule?

Dr. HAHN. Senator, I am always hesitant to opine on the law, on regulation without having all the facts.

Senator SMITH. I am pretty sure you would have the authority. We could all check that but I am pretty sure you would. Let me just ask you, are you aware or can you imagine evidence on the other side that these candy flavored e-cigarettes don't contribute to youth addiction to nicotine and if that is actually there? Are you aware of any evidence on the other side?

Dr. HAHN. I am not aware of any evidence on the other side, Senator.

Senator SMITH. Nor am I. Dr. Hahn let me ask you something else. When we met earlier, also, as we were talking about the importance of following the science and the data and the evidence. We have this issue with the rising price of prescription drugs and the FDA has been under pressure to expedite the review and approval of generic drugs. And as the FDA has approved more generic drugs and more generic drugs have come to market, there has been some consequences to this.

One is these drugs that are manufactured overseas and companies are reportedly falsifying data and failing to comply with good manufacturing practices. And all of this can lead to very adverse outcomes for patients. So let me ask you, how would you see following the science and the data to make sure that these record approvals don't place the public health at risk?

Dr. HAHN. Senator. This is of critical importance to the American people as you have outlined. We must ensure that the products that are approved by FDA are safe and efficacious, and we must ensure the good manufacturing procedures are followed by industry. As part of this is enforcement, I am very interested also in looking at what technical assistance FDA can provide to manufacturers. I am very interested in advanced manufacturing techniques and the processes that are used in other Industries and actually how some of that can occur here in the United States.

Senator SMITH. Thank you. Well, I think I agree. I think this is a very important problem. Another issue I would like to quickly raise with you. In March 2020, the FDA will begin regulating insulin products as biologics rather than drugs. Many of my colleagues have talked about the importance of—great concern about the price of insulin and this should help bring lower-cost insulin products to the market.

But there is this issue which is that pending insulin applications that might not be approved by this deadline in 2020 and if nothing is done to address this cliff, then these pending insulin applications would have to be withdrawn as the transition is made to regulating insulin as biologics. And Americans could easily be required to wait

even longer for these medicines to come to the market. So Senators Durbin and Kramer and I have a bill that would address this insulin cliff and I would just like to ask if you should be so fortunate to be confirmed, whether you would be willing to work with us on this, what could be a big problem?

Dr. HAHN. Absolutely, Senator Smith. This could be a big problem. Diabetic patients need this life-saving therapy. So I do commit to work with you.

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

The CHAIRMAN. [presiding] Thank you, Senator Smith.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And Dr. Hahn, thank you for the opportunity to visit with you on so many of these issues. Thank you for the very clear and open answers you have shared with the Committee Members today on a whole range of issues. I want to add my voice to that of so many on the Committee that have expressed the concern of what we are seeing with rising levels of nicotine addiction through e-cigs, through the vaping products. Just the dangers that we know with kids and nicotine. The fact that we are absolutely going the wrong way when it comes to nicotine addiction after making the turn if you will on that trend and now to see where we are is not only alarming, it is frightening.

Knowing that you will do everything within your authorities should you be confirmed, which I certainly assume you will, you will have my support, but to make sure that we are taking off the table these products that are designed to entice young people. And as they do so, they are addicting our young people. So every effort that you make on that, I so appreciate. I also want to thank you for some of the comments that you provided to Senator Braun as he was asking about how we deal with those who are facing these terminal diseases like ALS and a pathway to maintain the integrity of the FDA process while also allowing our terminal patients access to drugs that help.

You have given him a commitment on doing all that you can to work on these barriers that I think really do deprive so many that are terminally ill with the opportunity to try something that just might be promising and give them that little increment of hope that today might be the day. That with this we are going to find a cure. In that vein, one of the things that I have learned from all of my interactions with the ALS advocates is that patient partnership is really essential to move forward in the research and your predecessor had committed to the ALS community in meetings with patients that he would have patients in every investigational new drug meeting.

I think that making that kind of commitment is important. I think that it is important that at these meetings the question be asked, who here is the patient at the table to ensure that those patient voices are heard throughout the trial process. So I would ask that you would make that same commitment with that focus toward the patients.

Dr. HAHN. Senator, I commit with you very much to including the patients' voice in the decisions that FDA makes. As a cancer

provider, we make so much better decisions when the patient's perspective is included in those decisions.

Senator MURKOWSKI. They know more than anyone. They and their families. I appreciate that. When we visited, I shared with you that most of my colleagues would talk about drug pricing and much of this but I want to talk about the food side that Senator Baldwin said. The food side for her included the dairy food side. For me it is seafood. And we talked about the seafood guidance. Back in 2014, FDA published this study on the net effects of seafood consumption for pregnant and for nursing women, but yet the FDA seafood consumption advice doesn't reflect this. Contrary to the Government's own finding, effectively FDA relied not on their own research, but on EPA's Mercury reference dose, which is a toxicology standard that ignores the benefits of seafood in my view and measures risks in isolation.

I have been pushing on this to get the FDA to correct this, to reflect the FDA's own science instead of the EPA Mercury data. So I would like to know from you whether you are willing to put some focus and energy into ensuring that effectively the FDA follows its own guidance here, its own science and in making sure that we do not send conflicting or confusing messages or signals to those pregnant women and to children when it comes to proper seafood advice and guidance.

Dr. HAHN. Senator, I promise to focus energy on it and also want to thank you. I enjoyed that discussion very much and had a very great discussion with my pregnant daughter about the brain food associated with seafoods. And thank you.

Senator MURKOWSKI. Well, I don't want to throw out statistics out here but an average 7.7 percent point increase in IQ for babies whose moms ate seafood during pregnancy. You want a smart baby, eat that seafood now and in good quantities there. And then finally I wanted to raise also with you the issue that we face with genetically engineered salmon FDA approved for human consumption back in 2015 through the new animal drug process, a process that is intended to regulate things like veterinary medicine and livestock animals. This is the first genetically engineered animal approved by the FDA for human consumption. We are in completely new territory.

A couple of million Americans who have submitted comments to the FDA have opposed the approval of the GE salmon. We are kind of lost on that. But what we have argued for is that there be strong and consistent and clear labeling requirements. So I am asking whether you will agree to work toward establishing a regulatory system outside of the new animal drug approval process that is appropriate for approving genetically engineered animals for human consumption?

Dr. HAHN. Senator, one of the most important things that the FDA can do is to ensure the safety of food products for Americans and I commit to working with you on this subject.

Senator MURKOWSKI. I appreciate that commitment to work with us on the regulatory system as well as on the transparency so that people know what it is that they are actually purchasing. With that, I thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murkowski. I think that boils down to pregnant women should eat seafood but not genetically modified seafood.

[Laughter.]

The CHAIRMAN. Thank you, Senator Murkowski.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman. Dr. Hahn, great visiting with you the other day. You have big shoes to fill. I was a big fan of your predecessor Scott Gottlieb who I voted for and I was really impressed with the work he was doing. And one of the things that impressed me and it has been raised in the hearing so we don't need to go into it, but he was very proactive in looking at non-opioid based strategies for dealing with pain management. My concern about the FDA is that FDA is in sort of a receive mode. When an application comes in then we will consider whether to approve a drug or a technique or medical device, but I was worried that the FDA was not being proactive to look at what had been approved and whether there was a real spectrum of pain management strategies available. And Scott Gottlieb got right on that in a good way and we talked about it. I don't need to ask you about it here because others have but I was encouraged by your comments in that way.

I do want to say an additional word about the e-cigarette issue and look you are a dad and you are a lung doctor and you have seen this and how debilitating lung disease, lung cancers, addictions are to the health, especially health of kids. And I am troubled by what my young people tell me about trying to do their own research online about the health effects of e-cigarettes and then finding that the research they have done triggers algorithms and social media companies and then they get flooded with ads to buy e-cigarettes or talking to school administrators who kind of throw up their hands and say, gosh, we don't have the experience in dealing with how to help a 14 year old break an addiction.

We just have been dealing with that and now they are having to deal with it. So this is dire and the hearing last week made me deeply concerned that the Trump administration was going to do a 180 on the proudly announced policy from September that we were going to clear unauthorized flavors from market until there was a process by which they could be authorized if they were safe. You have been asked about that but here is what I do want to go into a little bit more, nicotine levels. Nicotine levels because we can learn from not only research that is taking that other place around the world but even the experience of other public policy positions.

In 2016, the UK implemented an EU directive restricting the capacity of e-cigarette tanks, or the maximum volume of nicotine containing e-liquid for sale on a refill container and e-liquid nicotine strength to no more than 20 milligrams per milliliter. So that is an EU policy that the UK has embraced. And there is other labeling and packaging requirements as well. But just to compare that 20 milligram per milliliter limit, a 5 percent nicotine Juul pod sold in the United States contains 59 milligrams per milliliter and that is not because of some limit, it can contain 75, it can contain 150. There isn't a limit.

The UK and EU have not seen the youth epidemic and they have not seen the vaping linked to illnesses to the extent that we have. I think I couldn't say that they have not seen any challenges but they have not seen them to the extent that we have and since nicotine is one of the most addictive substances there is, I think there is strong suggestion that the nicotine limitation that they put in place as one of the reasons that they may not have seen some of the problems that we are seeing. As Senator Alexander mentioned in response to testimony or his questions last week, the head of the program at the FDA indicates the FDA currently does have the authority to promulgate regulations setting standards for nicotine yields and other characteristics of the e-cigarette devices.

You pledged here to focus on the science and go where the science goes. I would like your commitment to look at the science around nicotine levels and to consider whether limitations on nicotine to protect the public health are part of a comprehensive strategy that we should be embracing as we deal with this epidemic.

Dr. HAHN. Senator, you have my 100 percent commitment to the science and data on the subject of nicotine levels. As we discussed, there is a lot of great research going on in this area and I think where the data and science take us, we should go.

Senator KAINE. Thank you so much for that commitment. I have one more topic. We have a very unusual, to my way of thinking, a very unusual problem in this country that is getting more and more attention and it deals with maternal health. Our maternal mortality statistics, death of moms while they are pregnant or during the first year of a child's life are bizarre when compared with other nations. Given that we have wealth and we have some of the best medical institutions and some of the best medical professionals, we shouldn't be where we are in maternal mortality.

Moreover, the gaps in those mortality statistics between Caucasian and minority populations are really, really frightening. Even if you control for income, you find that high income Latina and African-American moms are experiencing more maternal mortality at a just shocking rate. There is an organization, intergovernmental panel called the Task Force Specific to Research and Pregnant Women and Lactating Women, and the FDA is already a partner in this effort. Will you commit to continuing the FDA playing the role that it can in helping us solve this problem?

Dr. HAHN. I commit. This is a terrible, and I agree, heartbreaking problem, and I commit to that.

Senator KAINE. Thank you very much. Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. Thank you for allowing a second round of questions. Dr. Hahn you were asked by both Democrats and Republicans this morning about your ability to stand up to potentially the President in view of his reversal on policy related to flavored vaping products, your ability to stand up to powerful corporate interests who are going to be lobbying and cajoling around their bottom line and hope for profits. I know it is hard to answer a hypothetical about how you would pursue and advocate for children's health over these other interests. Can you describe an instance in your past management experience where you have had

to stand up to a directive that you think is wrong and push for a data and science-based approach?

Dr. HAHN. Senator, in my career as a physician and in my career as a researcher and then as a medical executive there have certainly been situations where recommendations have been made that in my opinion weren't always in the best interests of patients, for whatever the reason and the motivation. I am going to say this again, Senator, and I so appreciate your bringing this up. I am deeply, and I mean deeply committed to my patients and the public health of the American people. That is the most important and awesome responsibility of FDA and I commit to you that I will stand up for that.

Senator BALDWIN. Thank you. You have had some questions already about drug shortages. We had the opportunity to discuss a shortage of a different type of in this case a radioisotope that is used in imaging and diagnostics. I wonder if you can talk about what the impact would be if there were increased shortages in the supply of the medical isotope known as Molly 99, molybdenum is I think how you accurately pronounce the longer title but Molly 99 is what it is referred to.

It is used in 40,000 medical scans each day in the United States to diagnose urgent heart conditions and provide early detection and enable treatment of cancer. We have a very fragile supply chain for this critical medical isotope. As a radiation oncologist, can you describe how you have used Molly 99 in your work and how a shortage could harm patient access to crucial diagnostic imaging and treatment?

Dr. HAHN. Senator, thank you for that question. You are right. As a radiation oncologist and as an oncologist in general, this is an important compound, technetium. My personal practice experience has been on the imaging side of this and it is very interesting you bring that up because I have been in clinical situations where we have had to delay diagnostic tests because of a shortage of technetium. So it is critically important for decision making on the diagnostic side. I would love to have a conversation with you about maybe the pragmatic way of approaching this, the great research that was going on at the University of Wisconsin to help solve this problem, and I look forward to addressing these issues in a proactive manner.

Senator BALDWIN. Thank you. Lastly, we have had a lot of discussions about the high price of many prescription drugs that are life-saving or life-extending in nature. So, Dr. Hahn, do you believe that drug companies are setting prices too high?

Dr. HAHN. Senator, I don't spend a lot of time on the price side as an oncologist. What I can tell you is that rarely a day goes by where this isn't an issue that is addressed by patients. But also in academic institutions, the pressure on the prices of drugs is substantial. I mean, it is an urgent issue and the American people want us to act on this. So I think there are some actions that FDA can do, particularly an indirect way of stimulating innovation and competition. And I am very interested in those because I think that is important to the American people, and ultimately this gets to an access issue. And sometimes an access issue for our most underserved and we have to address that.

Senator BALDWIN. The President has signaled a degree of support for importation. Do you believe that we should move forward with a plan to allow the safe importation of prescription drugs?

Dr. HAHN. Senator, this gets back again to the issue of data and science. The FDA's role in this as, you know, Senator is to assess the safety and security of the Nation's drug supply, which is the best, safest, and most secure in the world and something we are all proud of. I look forward to looking at the data associated with that and giving that information to the Secretary who is responsible for certifying to Congress. I am open to all science and data that could potentially support that as a solution.

Senator BALDWIN. Thank you.

Dr. HAHN. Thank you.

The CHAIRMAN. Thank you, Senator Baldwin. Senator Jones is trying to come back so we are going to wait on him. In the meantime, I have got a couple of areas I would like to explore. Let me go back to the vaping issue. Assuming you are confirmed, hopefully that will happen before the end of the year, and you will be on the job, you will be in the midst of a—the FDA will be in the midst of a review with the Center for Disease Control on why these mysterious diseases have been occurring in lungs around the country as related e-cigarettes, and there is some evidence of THC, there is some evidence of vitamin E oil, but it would seem to me that is one area that there should be no hesitancy about the administration moving ahead rapidly to deal with this.

I mean nobody on this Committee, Republican or Democrat, who doesn't want to see that problem related to e-cigarettes resolved. And second, I think it has been emphasized by many of the Senators here both Republican and Democrat that the FDA already has the authority to take significant steps to more effectively combat the use of e-cigarettes by high schoolers and middle schoolers. Already this Committee by a vote of 22 to 3 has agreed to increase the tobacco buying age from 18 to 21, which should be of some help.

We are talking about teenagers all of whom shouldn't be able to buy tobacco products at all. So I would hope that there would be some sense of urgency by the FDA under your leadership to use the authority you already have to deal with the epidemic that we have seen of young people using e-cigarettes and of the lung diseases that are occurring related to e-cigarettes. Now, two other areas that—one is pain. You should be an expert in pain giving your background.

We worked through the opioids legislation here and as I mentioned earlier, we had 70 Senators with 72 proposals. That was a huge response to the epidemic. Many ideas and I did my best and Congress ended up agreeing generally with it to resist having the Federal Government establish a lot of hard and fast rules that would override what states would decide or what doctors or hospitals would decide about prescribing opioid medicine. The Centers for Disease Control came out with some guidelines that many doctors and hospitals apparently found it convenient just to automatically adopt both for acute people who had acute pain and people who had chronic pain.

That concerned me a lot because it seemed to me that in some cases, I mean I am sure some of your patients—and I guess I shouldn't put words in your mouth. Let me just ask you a question, in your practice, was it true that some of your patients were prescribed opioids as a painkiller and for more than three days or five days?

Dr. HAHN. Absolutely, Senator.

The CHAIRMAN. What was the policy that you used in your leading cancer organization to deal with these?

Dr. HAHN. To relieve human suffering, Senator.

The CHAIRMAN. What would be typical of a prescription of opioid? Can you give me an example or two of how a physician might appropriately prescribed opioids that might be inconsistent with the Center for Disease Control guidelines?

Dr. HAHN. Senator, I can't speak to practices that would be inconsistent per se with the guidelines. What I can tell you is that most of us in oncology are using an evidence-based approach which is a multidisciplinary. So behavioral approaches, opioids, non-opioids, pain medicine now is a very sophisticated practice. We had experts at MD Anderson that I refer many of my patients to and there are many different options that are available now to give——

The CHAIRMAN. Rather than your person? Having that you have a specialist who makes the decision about——

Dr. HAHN. Correct. And they are experts in this and they use opioid and non-opioid. And they are very cognizant of the addictive and the misuse and the diversion aspects to this. Every patient is an individual and these treatment decisions are individualized by our experts.

The CHAIRMAN. What would be based upon your background and experience, what is your estimate of the potential for the discovery of treatments for non-addictive pain medicine? This Committee and Congress put a lot of money and encouragement behind the research on non-addictive pain medicine. What about that? Is that practical? Is that likely to happen?

Dr. HAHN. Mr. Chairman, definitely practical and definitely I believe likely to happen. Great research is being done in pain. I think it will allow us to use the precision medicine techniques we use on other diseases for pain. So we will have targeted therapies in the future for this. I am not a pain expert by training but I have seen much of this research and I am really very optimistic about the path forward.

The CHAIRMAN. My fear was that the, in our country when we get a fever, we all go one way until we do something and that usually creates a counter action. And my fear was that the need we had to deal with opioids, fentanyl, and other medicines like that would somehow interfere with the ability of physicians to prescribe pain medicine to patients who really needed that and that we would go too far. I have one other question and then I will go to Senator Jones. Do you—often in this Committee we ask the FDA, is there any way we could use the work that is done by other countries whose processes we respect, Japan, Great Britain, Canada, others, for example, to shorten the period of time that it takes for treatments and cures to go through our FDA system and still have the gold standard? In my opinion, we talked about imported drugs

in a misleading way because we import all kind of drugs all the time.

The key is not whether medicines are made in other parts of the world, plenty of them are, but as you pointed out in your testimony, if they are manufactured anywhere, they have to have an FDA approval at the manufacturing place and the supply chain has to be approved by the FDA. So we import that—couldn't we shorten the period of time that it takes to gain approval of the life-saving treatment or cure by taking more advantage of the work done in other countries on the same subject?

Dr. HAHN. Senator, I believe it is possible. I would like to know more about this because as you point out we need to make sure that the gold standards maintained, but I am open to having conversations that science and data would provide to go in that direction.

The CHAIRMAN. Senator Jones.

Senator JONES. Thank you, Mr. Chairman, and also, I would be remiss if I didn't recognize the Chairman's very skillful use of rope-a-dope to try to get me back here to ask these questions. I very much appreciate that. Dr. Hahn, thank you. Thank you for all you have done. Thank you for your willingness to serve. I have got one question and I want to make a comment before I close.

We talked about data and you have mentioned that a whole bunch about the use of big data to help in this job should you be confirmed. We seem to be collecting more and more data in everything we do these days. I think that FDA has made great strides in that but from your perspective, how can the use of big data—where do you see that going and how can it help us and help the job of the FDA getting drugs to market quicker, getting the appropriate drugs to market? How can that help you?

Dr. HAHN. Senator, thank you for that question. I am incredibly enthusiastic about the big data efforts that are going around the country as we discussed many places, including in your home state, are looking at these approaches to actually help patients. I believe there is great value there. We need expertise at the FDA, if I am fortunate enough to be confirmed. And we need the advanced data analytics to let us do that. I think there is a balance as you describe make sure that the data are accurate, that there is a lot of fidelity around them, but let's try to use those to expedite the processes to get innovative products in the hands of Americans. I am enthusiastic about that, sir.

Senator JONES. Great. Well, thank you for that. I am going to forego some of the other questions I have got on biosimilars and others and I may submit them for the record, but I feel compelled to make a comment, Dr. Hahn, because I was very impressed with you. I told you that your enthusiasm for this job is very infectious sometimes and I appreciate that and I appreciate all you have done in your career. But I will tell you that I was less than happy with many of the answers you gave to Members of this Committee with regard to vaping and the potential ban on flavored e-cigarettes and those things. I thought that was very—I just don't think that was you. I think it was prout from handlers that kept going back to science and data.

I think you could tell from the questions of so many Senators that is one of the biggest issues that the U.S. Senate and the Congress is facing right now. It is at the top of our agenda. It is with this Committee. We want to see something happen. From where I sit the data is in, the evidence is in. It is really strong. You are a lung cancer doctor.

You have been in this position before and I am really concerned that the administration has prepped you in a way that is not you to give you an out of dodge and bob and weave a little bit and I am just being candid with you, sir. I thought the, if you are basing things on evidence and science, I think that is great. You should be doing that. But it seems pretty clear to me and I think the administration has pulled back on this right now. It is not a good thing for the health of young people and the health of Americans.

I think we have seen it before, though. I think we have seen the pullback on potential issues concerning gun violence that the administration said that they would support following mass shootings in the killing of a lot of Americans and then all of a sudden when a lobbyist and people get to them, they seem to pull back instead of finding common sense and the courage to do things, it actually goes out the window. This is going to require some courage. This is a big industry out there that has got a lot of money invested and it is going to require some courage to pull back and say you are damaging the health of so many children in this country, much less adult. You are damaging that and I think you know that. And I think the question becomes not how we go about banning these, it is just a question—the question is how we go about doing it, it is not a question of if we go about doing it.

I am going to submit another question for the record, sir, and that question is simply going to be to get you to review your answers and ask you to give a more thoughtful and opinionated—personal opinion, not about the details of a rule but about whether or not that this opinion, that what the administration has pulled back now is right or wrong and whether or not these flavors should be banned right now in order to protect the health of our children and the health of many Americans.

I am not asking for a comment or an answer now but given what I thought was a really good meeting with you and my wanting to support this, I just felt compelled to tell you how disappointed I was in the answers to at least five or six Senators, and maybe more. So with that, thank you for being here. Thank you for your willingness to serve. And Mr. Chairman, thank you very much for giving me the opportunity to scoot back from those folks.

The CHAIRMAN. Thank you, Senator Jones. Dr. Hahn, I think this will—I think we will wrap up the hearing. This has been from my point of view a very good exchange of views. You can see we have 23 Members of very different points of view here on this Committee. We don't agree on everything but we work pretty hard to find those things that we do agree on and I would encourage you, if you are confirmed which I believe you will be, to work with both the Democratic and Republican Members of the Committee to look for areas of agreement. I too am concerned about the vaping epidemic among high school students and middle school students. Just

speaking as one Senator, I don't expect you to be able to state the position of an administration of which you are not yet a part.

I mean, I don't see how you could do that. And from my point of view, I am glad to have as a candidate for the head of the Food and Drug Administration someone with as distinguished a background in clinical medicine, oncology, the science of cancer and lungs, and tobacco as a voice that would be in the highest councils of an administration on what to do about the vaping epidemic.

I am glad you are willing to be there and look forward to supporting you. If Senators wish to ask additional questions to the nominee, those questions for the record will be due by 5 p.m. on Friday, November 22d. It is my intent to schedule a markup of Dr. Hahn's nomination on December 3d, after we return from Thanksgiving.

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

[The information referred to an be found on page 42]

The CHAIRMAN. Thank you for being here. The Committee will stand adjourned.

ADDITIONAL MATERIAL

LETTERS OF SUPPORT FOR STEPHEN HAHN

THE AMERICAN SOCIETY FOR RADIATION ONCOLOGY,
251 18TH ST. SOUTH, ARLINGTON, VA,
November 6, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The American Society for Radiation Oncology (ASTRO),[1] on behalf of our 11,000 members of the radiation oncology team, strongly supports the nomination of Stephen Hahn, M.D., FASTRO, as Commissioner of the Food and Drug Administration.

Dr. Hahn is highly qualified to be the next FDA Commissioner, and he enjoys the strong support of his specialty and other stakeholders.

A culture of safety is woven into the fabric of radiation oncology, making Dr. Hahn uniquely suited to further FDA's mission of protecting the public health. At the same time, Dr. Hahn's experience using some of the most sophisticated medical devices in health care gives him insight and expertise to drive progress for the benefit of patients and consumers. He is also extremely well-versed on the drug, biologic and device development pipeline, demonstrated by his role in developing multiple medical products.

Dr. Hahn, who obtained the rank of Commander in the U.S. Public Health Service, is trained in radiation oncology, medical oncology and internal medicine, and he has broad knowledge as a clinician, researcher, educator and administrative leader. In his roles as a physician leader and executive at premier medical centers, Dr. Hahn has proven himself as a remarkably talented physician and cancer specialist. He is exceptionally versatile in his understanding of medicine and public health and would bring enormous energy and creativity to the role of FDA Commissioner.

[1] ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

Dr. Hahn previously served on the ASTRO Board of Directors, spearheading innovative educational initiatives, such as the creation of a leadership development program focused on diversity and steering the selection of top science for ASTRO's Annual Meeting, the leading meeting dedicated to radiation oncology and patient care in the world.

The public health of United States citizens faces incredible challenges, and the FDA needs a strong leader who can inspire the agency and confront difficult and controversial matters directly. Dr. Hahn has demonstrated the impressive ability to do both. He has the ability to make great institutions greater and drive measurable cultural change when it's needed most. Dr. Hahn asks the tough questions and builds consensus, bringing to bear intelligence and expertise in an engaging style.

His clinical expertise and international recognition in treating lung cancer gives him the ability to tackle some of the toughest issues faced by the FDA. His familiarity working with Federal grantmaking agencies gives him the understanding necessary to navigate the regulatory environment to advance important initiatives that balance innovation and safety.

Dr. Hahn has an extraordinary track record of patient-centered leadership and service. He is the right choice to accelerate the critical work of the FDA.

To take a major step forward in protecting the public health of Americans, we urge you to vote in favor of Dr. Hahn's nomination.

Sincerely,

LAURA I. THEVENOT,
CHIEF EXECUTIVE OFFICER,
The American Society for Radiation Oncology.

AMERICAN COLLEGE OF RADIOLOGY,
November 7, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The American College of Radiology (ACR)[1] urges the Senate to confirm the nomination of Stephen Hahn, M.D., to serve as Commissioner of the Food and Drug Administration (FDA). With his broad knowledge as a clinician, researcher, and educator, Dr. Hahn is uniquely qualified to lead the agency.

His research spans topics including lung cancer, cancer immunotherapies, and brain tumors, positioning him at the forefront of topics affecting the FDA. Dr. Hahn's experience with sophisticated medical devices in healthcare also provides an insight to its utilization and safety for patient care.

His role as Chief Medical Executive at the University of Texas MD Anderson Cancer Center and his prior service at the National Cancer Institute makes him an asset to the FDA's mission of advancing public health.

For the aforementioned reasons, Dr. Hahn would make an astounding FDA Commissioner and ACR fully supports his nomination.

Respectfully,

WILLIAM T. THORWARTH JR.
MD, FACR, CEO,
American College of Radiology.

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[1] The American College of Radiology is a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear physicians, and medical physicists.

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS,
2121 K STREET NW, WASHINGTON, DC,
November 15, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the American College of Emergency Physicians (ACEP) and our 40,000 members, I would like to express our strong support for the nomination of Stephen Hahn, M.D., FASTRO, to become the next Commissioner of the U.S. Food and Drug Administration (FDA).

Dr. Hahn's appointment comes at a time when emergency physicians, emergency departments, and emergency medical services are facing substantial challenges obtaining essential medications for our patients, which is significantly hindering our ability to deliver high-quality care. The shortage crisis in emergency medicine affects drugs across all classes of medications. As of September 2019, there were 92 preparations of 45 emergency care medications that are in shortage, including most forms of adenosine, atropine, bicarbonate, calcium, dextrose, dopamine, epinephrine, fentanyl, furosemide, labetalol, lidocaine, magnesium, lorazepam, and paralytic agents. These shortages have resulted in delayed care, higher costs, reduced time for patient care, and increased risk to patients when alternative medications and dosages must be used.

While important strides have been made since the height of the drug shortage crisis in 2012 and the subsequent enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA), physicians are still experiencing a greater intensity of current shortages. Because of our first-hand involvement with this issue, ACEP was proud to take a lead role is supporting the efforts by Senators Bill Cassidy (R-LA) and Chris Murphy (D-CT), as well as Representatives Brett Guthrie (R-KY) and Mike Doyle (D-PA), in obtaining the signatures of 31 Senators and 107 House members urging the FDA to establish a task force that would identify the root causes of drug shortages and develop subsequent recommendations to address them.

When the FDA's Drug Shortages Task Force released its report on October 29, 2019, it identified three primary causes of drug shortages and recommended specific solutions to address these underlying concerns. ACEP believes that Dr. Hahn will make a great partner in working through these issues and helping us to obtain the medications that our patients so desperately need.

ACEP appreciates Dr. Hahn's dedication to patients, his understanding of the FDA's complex regulatory issues, and his commitment to working with the relevant stakeholders to ameliorate essential medication shortages.

Sincerely,

WILLIAM P. JAQUIS,
MD, MSHQS, FACEP,
ACEP President.

THE UNIVERSITY OF TEXAS,
MD ANDERSON CANCER CENTER,
1515 HOLCOMBE BOULEVARD, HOUSTON, TX,
November 15, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the faculty and staff of The University of Texas MD Anderson Cancer Center, I am writing to express my full support of Dr. Stephen Hahn to be the Commissioner of the United States Food and Drug Administration (FDA) at the Department of Health and Human Services. I am confident in Dr. Hahn's ability to successfully lead the FDA as the U.S. Senate considers his nomination.

Throughout his career, Dr. Hahn has proven to be a trusted leader, with the highest integrity, committed to both caring for patients and advancing his field through scientific research. As a physician scientist, Dr. Hahn knows the importance of protecting public health and ensuring that new discoveries rapidly translate into safe and effective products that enhance and improve overall health, reduce health burdens and save lives.

Dr. Hahn's experience at MD Anderson includes leading more than 1,700 faculty members working in a clinical enterprise that sees over one million patients a year. Additionally, during a time of leadership transition at the institution, Dr. Hahn led the largest cancer center in the country, with 21,000 employees, 1,250 clinical trials, greater than $800 million in research expenditures and an operating budget of more than $4 billion at the time. Dr. Hahn boldly took on these challenges and demonstrated success offering our entire community the opportunity to see him as a resilient leader with the intellect, emotional intelligence and drive necessary to succeed in a dynamic, multi-dimensional organization, similar to the FDA.

I respectfully request your full consideration of Dr. Hahn, and would be happy to discuss my support at length with you and your colleagues in the U.S. Senate.

Sincerely,

PETER WT PISTERS,
President.

ALLIANCE FOR AGING RESEARCH,
1700 K STREET NW, WASHINGTON, DC,
November 18, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the Alliance for Aging Research (Alliance), I am pleased to offer our strong support to Dr. Stephen Hahn for his nomination to serve as Commissioner of the U.S. Food and Drug Administration (FDA). The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. For more than 30 years, the Alliance has guided efforts to substantially increase funding and focus on aging at the National Institutes of Health (NIH) and FDA; built influential coalitions to guide groundbreaking regulatory improvements for age-related disease clinical development and access to care; and created award-winning, high-impact educational materials to improve the health and well-being of older adults and their family caregivers.

The Alliance is confident that Dr. Hahn possesses the qualifications that make him the right person for the esteemed role of FDA Commissioner. In his leadership roles as chief medical executive at The University of Texas MD Anderson Cancer Center, chair of the Radiation Oncology at the University of Pennsylvania School of Medicine, chief of the Department of Prostate Cancer Clinic at the National Cancer Institute at the NIH, Commander in the U.S. Public Health Service, researcher—and, perhaps most importantly as a clinician—Dr. Hahn has shown outstanding dedication to improving and protecting the health of patients.

As chief medical executive at The University of Texas MD Anderson Cancer Center, the largest cancer center in the U.S., Dr. Hahn oversees hundreds of clinical trials as well as clinical care for more than 141,000 patients annually. He is well-versed in, and has published on, the importance of involving representative populations, including older adults, in research studies in order to truly understand the impact of a potential drug or medical product on the primary groups likely to use the product under study. Dr. Hahn has been a vocal advocate for comparative effectiveness research, which is a top priority for the Alliance. He recognizes the importance of identifying what treatment approach works for which patient and under what circumstances and conditions. He has additionally been outspoken with colleagues about the value of research that predicts or enhances treatment response—innovation that will significantly benefit patients and society. The Alliance is confident that given the opportunity as FDA Commissioner, Dr. Hahn will continue to advocate for and prioritize patient-centered research.

Throughout his career, Dr. Hahn has prioritized transparency in the implementation and evaluation of medical research, development, and treatment. A broad openness to transparency at the top level is critically important for the Federal agency in charge of assessing the safety and effectiveness of new medical products that may harm or heal.

The FDA Commissioner is a public servant, who must be committed to improving the health of the public. This is a role with which Dr. Hahn is very familiar. He held the rank of commander in the U.S. Public Health Service Commissioned Corps while working at the National Cancer Institute, a position dedicated to protecting and improving public health. The rapidly aging population deserve to have allies in top roles within the Federal Government who will advocate for their health and well-being and inclusion in the process. The Alliance is confident that Dr. Hahn is this ally.

If you have any questions about our support for Dr. Hahn, please do not hesitate to contact me. We thank the Committee for your consideration of his nomination.

Sincerely,

SUSAN PESCHIN,
MHS,
President and CEO.

FORMER FDA COMMISSIONERS,
November 19, 2019.

Hon. MITCH MCCONNELL, *Majority Leader*,
U.S. Senate,
Washington, DC.

Hon. CHARLES SCHUMER, *Democratic Leader*,
U.S. Senate,
Washington, DC.

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

DEAR LEADER MCCONNELL, LEADER SCHUMER, CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

As former Commissioners of the Food and Drug Administration, we are writing to provide our perspectives on the Committee's consideration of the nomination of Dr. Stephen Hahn as Commissioner of Food and Drugs.

We appreciate the Committee's prompt consideration of Dr. Hahn's nomination. As four of us previously wrote to the President and Secretary Azar in urging a timely nomination, the FDA urgently needs a well-qualified permanent Commissioner. The FDA regulates up to one-quarter of the US consumer economy, including potentially life-saving therapies and most of the Nation's food supply, and is constantly under pressure to adapt to changes in science and public health threats. The agency has a dedicated and talented professional staff to carry out its mission, but a permanent Commissioner provides the support needed to enable that work. The absence of a confirmed Commissioner complicates their ability to undertake and sustain the FDA's continuously evolving role in protecting and promoting the health of Americans.

We believe Dr. Hahn has the experience and commitment to public health and public service needed to provide this leadership. He has extensive public-sector experience in clinical research, serving at the National Cancer Institute for seven years, including as an officer in the US Public Health Service. He also has significant expertise in the conduct of the biomedical research that FDA regulates, with more than 200 peer-reviewed publications and multiple patents from his career in academic medicine. Finally, he has extensive executive leadership experience at both the University of Pennsylvania School of Medicine and at the M.D. Anderson Cancer Center.

This is a critical time for public health and for leadership on the many challenging issues and opportunities facing the FDA and the Nation. We hope that Dr.

Hahn will be able to bring his clinical expertise, leadership experience, and commitment to public service and science to the FDA as soon as possible.

Sincerely,

ROBERT M. CALIFF,
M.D., MACC,
FDA Commissioner 2016–2017.
SCOTT GOTTLIEB,
M.D.,
FDA Commissioner 2017–2019.
MARGARET HAMBURG,
M.D.,
FDA Commissioner 2009–2015.
MARK MCCLELLAN,
M.D.,
FDA Commissioner, 2002–2004.
ANDREW C. VON ESCHENBACH,
M.D.,
FDA Commissioner 2006–2009.

AMERICAN MEDICAL ASSOCIATION,
AMA PLAZA, 330 N. WABASH AVE., CHICAGO, IL,
November 20, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The American Medical Association (AMA) is very pleased to offer our strong support for the nomination of Dr. Stephen Hahn, M.D., FASTRO, to serve as the Commissioner of the Food and Drug Administration (FDA).

As you know, Dr. Hahn's impressive resume shows significant leadership experience in academic medical settings. Dr. Hahn has been widely praised for his work at MD Anderson Cancer Center, one of the Nation's premier oncology providers, where he assumed the role of Chief Medical Executive after several years leading MD Anderson's radiation oncology unit. Throughout his career, Dr. Hahn has held numerous management positions and has positively navigated a number of challenges. Dr. Hahn is credited with "righting the ship" at MD Anderson during a time of financial strain. Furthermore, while at MD Anderson, Dr. Hahn has been well regarded for his handling of several high-profile controversies. Such leadership and management experience at such a renowned institution as MD Anderson is excellent training for leading the FDA.

Dr. Hahn specializes in radiation oncology, receiving his medical degree from Temple University, with residency training at the University of California San Francisco and the National Cancer Institute in Bethesda, Maryland. He is board certified in both radiation oncology and medical oncology. Dr. Hahn spent a significant portion of his career at the University of Pennsylvania, serving as division head and ultimately department chair of the university's radiation oncology unit. He has played an active role in organized medicine; he is an AMA member, and is affiliated with the American Society of Radiation Oncology and the American Society of Clinical Oncology.

The AMA believes Dr. Hahn's expertise makes him well suited to be a successful Commissioner of the FDA. We look forward to his prompt consideration and confirmation in the Senate.

Sincerely,

JAMES L. MADARA, MD,
Executive Vice President, CEO.

SEATTLE CANCER CARE ALLIANCE,
825 EASTLAKE AVE., E. SEATTLE, WA,
November 19, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the Seattle Cancer Care Alliance, I am writing to express support for the nomination of Dr. Stephen Hahn to serve as the commissioner of the United States Food and Drug Administration. If confirmed, we believe Dr. Hahn will be a thoughtful advocate for cancer patients.

Dr. Hahn has devoted his career to caring for cancer patients, discovering breakthrough radiation oncology treatments, and teaching the next generation of physicians and caregivers. As a clinician and teacher, he has demonstrated an understanding of the value of advanced cancer therapies, the promise of breakthrough anti-cancer drugs, and the impacts they can have on cancer patients. As an administrator, Dr. Hahn is equally mindful of balancing the value proposition of innovative treatments with appropriate cost-containment policies.

Dr. Hahn's clinical and research expertise, administrative experience, and commitment to patient care make him an excellent choice to lead the FDA. For these reasons, we respectfully urge the Committee to confirm his nomination.

Sincerely,

NANCY DAVIDSON,
MD, EXECUTIVE DIRECTOR AND PRESIDENT,
Seattle Cancer Care Alliance.

CANCER SUPPORT COMMUNITY,
734 15TH STREET NW, WASHINGTON, DC,
November 21, 2019.

Hon. MITCH MCCONNELL, *Majority Leader*,
U.S. Senate,
Washington, DC.

Hon. CHARLES SCHUMER, *Democratic Leader*,
U.S. Senate,
Washington, DC.

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

DEAR LEADER MCCONNELL, LEADER SCHUMER, CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to people impacted by cancer, supports the nomination of Dr. Stephen M. Hahn as the next Commissioner of the Food and Drug Administration (FDA) and urges the Senate to vote in favor of his confirmation.

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. CSC's Research and Training Institute (RTI) has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, the psychosocial impact of cancer, and cancer survivorship. We look forward to sharing our knowledge and working with Dr. Hahn to ensure that clinical trials measure not just a patient's *physical* experience in a clinical trial but also the psycho-social experience. We applaud Dr. Hahn's pledge to make science based, patient-centered decisions if confirmed and support his commitment to put patients first.

The Cancer Support Community believes that Dr. Hahn, a radiation oncologist who specializes in the treatment of lung cancer and sarcoma, has both the professional background and clinical experience to succeed as FDA Commissioner. We

trust that Dr. Hahn will successfully lead the FDA at a time when it is critical to find the balance between medical innovation, stakeholder responsiveness, and patient safety.

Sincerely,

ELIZABETH F. FRANKLIN,
MSW, EXECUTIVE DIRECTOR,
Cancer Policy Institute,
Cancer Support Community Headquarters.

HEMATOLOGY/ONCOLOGY PHARMACY ASSOCIATION,
8735 W. HIGGINS ROAD, CHICAGO, IL,
November 22, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the Hematology/Oncology Pharmacy Association (HOPA), I am writing to writing to express HOPA's support for the nomination of Dr. Stephen Hahn to be the Commissioner of the Food and Drug Administration (FDA).

HOPA is a nonprofit professional organization launched in 2004 to help hematology and oncology pharmacy practitioners and their associates provide quality cancer care. HOPA's membership is predominantly oncology pharmacists, but also includes pharmacy interns, residents, nurses, technicians, researchers, and administrators specializing in hematology/oncology practice. The roles of our membership span from direct patient care, to education, to research. HOPA represents approximately 3,400 members working in hundreds of hospitals, clinics, outpatient oncology practices, home health practices, community pharmacies, and other healthcare settings.

Some of us have worked with Dr. Hahn for years as a result of his leadership at MD Anderson, his volunteer leadership of cancer organizations, and others of us have more recently become acquainted with him. We support him because of his focus on patients, commitment to public health, and pledge to honor science-based decision making. His record in cancer clinical care, clinical research, and institutional leadership prepares him well to lead FDA. We are concerned about attracting and retaining a stellar FDA staff, and we believe that Dr. Hahn can provide leadership on FDA staffing matters.

Because of the significant responsibilities of FDA, there is never a time that the agency does not face challenges. However, the agency confronts especially daunting trials now, including regulation of increasingly complex therapies, addressing the critical issue of drug shortages, contributing to efforts to address the opioid epidemic, and maintaining an outstanding staff to manage all of these issues. We trust Dr. Hahn to lead the agency through these challenges.

Please know HOPA stands ready to work with Dr. Hahn should the Senate confirm him at the new FDA Commissioner. If you have any questions about our letter, please feel free to contact me or HOPA's Health Policy Associate, Jeremy Scott.

Sincerely,

SUSANNE LIEWER,
PHARMD, BCOP, FHOPA, PRESIDENT,
Hematology/Oncology Pharmacy Association.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K STREET NW, WASHINGTON, DC,
November 27, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The Association of American Medical Colleges (AAMC) urges the Committee on Health, Education, Labor and Pensions, to favorably report out the nomination of Stephen M. Hahn, MD, to serve as Commissioner of the US Food and Drug Administration (FDA). The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers, and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The FDA plays a pivotal role in the public health continuum by regulating products consumed by all Americans including drugs, biologics, and the Nation's food supply. A permanent and skilled Commissioner is key to FDA's ability to keep up with the rapid pace of scientific progress and public health threats. The AAMC believes that Dr. Hahn's experience in research, patient care, and administration at institutions that are among the Nation's foremost venues for cancer treatment and research, as well as his public service as an officer in the US Public Health Service and at the National Cancer Institute, provide invaluable qualifications to lead the FDA. He is intimately experienced with and understands the processes for discovery and refinement of new therapies, the complex environment in which medical innovation takes place, and the centrality of patients' and families' needs. As a physician scientist, Dr. Hahn is also committed to data and evidence-based analysis at all levels of medical decision making, and he has stated that he is committed to advancing evidence-based policymaking at the helm of the FDA.

The FDA has a profound influence, both immediate and lasting, in shaping the environment for public health, safety, and medical innovation. The AAMC therefore strongly believes that Dr. Hahn's experience, leadership, public service and dedication are ideal qualifications for the role of FDA Commissioner, and we hope that the Senate will move expeditiously to his confirmation. The AAMC is grateful for your attention and the opportunity to provide these comments in support of Dr. Hahn's nomination. We are also deeply grateful to Ned Sharpless, MD, and Adm. Brett Giroir, MD, for their leadership of the FDA during this process of identifying a permanent Commissioner.

Please contact me if you believe the AAMC can be of assistance or provide further information in the confirmation process.

Sincerely,

DAVID J. SKORTON, MD.

AMERICAN ASSOCIATION FOR CANCER RESEARCH,
1401 K STREET NW, WASHINGTON, DC,
December 2, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the Board of Directors of the American Association for Cancer Research (AACR), and the 44,000 laboratory researchers, physician-scientists, other health care professionals, and patient advocates who constitute our national and international membership, I urge you and your colleagues on the Senate HELP Committee to approve the nomination of Stephen M. Hahn, MD, to lead the Food and Drug Administration (FDA).

Dr. Hahn possesses an extraordinary dedication and commitment to cancer patients, and the AACR is extremely confident that he will be an outstanding leader for the FDA. Dr. Hahn is board certified in both radiation and medical oncology, and he has consistently advocated for a drug review process at the FDA that is both science-directed and patient-focused.

Dr. Hahn has been a member of the AACR since 1999. He served as an inaugural member of the AACR Radiation Science and Medicine Working Group Steering Committee and the AACR Radiation Oncology Task Force. Dr. Hahn has also served

as a member of other AACR committees. He also served with distinction in 2018 as co-chair of the Workshop on Clinical Development of Drug-Radiotherapy Combinations held in partnership with the FDA, the AACR, and the American Society for Radiation Oncology (ASTRO).

The unprecedented research opportunities that exist today, coupled with our rapidly improving ability to translate these scientific advances into improved treatments for patients, require an experienced and highly effective scientific administrator, as well as a visionary and innovative leader. Dr. Hahn's impressive qualifications make him ideally poised to succeed at the FDA.

I urge you to vote in favor of Dr. Hahn's nomination so that the full Senate can vote to confirm him before the end of the year.

Respectfully,

MARGARET FOTI,
PHD, MD (HC),
Chief Executive Officer.

CANCER LEADERSHIP COUNCIL,
2446 39TH STREET NW, WASHINGTON, DC,
December 2, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The undersigned cancer organizations, including patient organizations, professional societies, and research foundations, are writing to express support for the nomination of Dr. Stephen Hahn to be the Commissioner of the Food and Drug Administration (FDA).

Some of us have worked with Dr. Hahn for years as a result of his volunteer leadership of cancer organizations, and others have more recently become acquainted with him. We all support him because of his focus on patients, commitment to public health, and pledge to honor science-based decision-making. His record in cancer clinical care, clinical research, and institutional leadership prepares him well to lead FDA. We are especially concerned about attracting and retaining a stellar FDA staff, and we believe that Dr. Hahn can provide leadership on FDA staffing matters.

Because of the significant responsibilities of FDA, there is never a time that the agency does not face challenges. However, the agency currently confronts an especially daunting agenda, including regulation of increasingly complex therapies, addressing the teen vaping epidemic, contributing to efforts to address the opioid epidemic, and maintaining an outstanding staff to manage these issues. We trust Dr. Hahn to lead the agency through these challenges.

Sincerely,

CANCER LEADERSHIP COUNCIL,
AMERICAN SOCIETY FOR RADIATION ONCOLOGY,
AMERICAN SOCIETY OF CLINICAL ONCOLOGY,
CANCER*Care*,
CHILDREN'S CANCER CAUSE,
FIGHT COLORECTAL CANCER,
INTERNATIONAL MYELOMA FOUNDATION,
LUNGEVITY FOUNDATION,
LYMPHOMA RESEARCH FOUNDATION,
NATIONAL COALITION FOR CANCER SURVIVORSHIP,
NATIONAL COMPREHENSIVE CANCER NETWORK,
OVARIAN CANCER RESEARCH ALLIANCE,
PREVENT CANCER FOUNDATION,
SARCOMA FOUNDATION OF AMERICA,
SUSAN G. KOMEN.

December 2, 2019.

Hon. MITCH MCCONNELL, *Majority Leader*,
U.S. Senate,
Washington, DC.

Hon. CHARLES SCHUMER, *Democratic Leader*,
U.S. Senate,
Washington, DC.

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

DEAR LEADER MCCONNELL, LEADER SCHUMER, CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

The undersigned organizations, representing millions of patients, advocates, caregivers, and health care providers, would like to affirm our support for President Trump's nomination of Dr. Stephen Hahn as Commissioner of the Food and Drug Administration (FDA). We urge the Senate HELP Committee to swiftly advance his nomination and the full Senate to vote to confirm Dr. Hahn.

The United States is at a pivotal moment in terms of public health. A confirmed commissioner is critical to ensure FDA is best positioned to continue to carry out the agency's important mission for millions of Americans.

Dr. Stephen Hahn is well qualified and has received broad-based support. As Chief Medical Executive at The University of Texas MD Anderson Cancer Center, he not only has the knowledge and experience gained by managing the cutting-edge research and medical practices of one of the world's most innovative teaching hospitals, but also firsthand expertise of patient needs and a deep understanding of the breadth of work that needs to be achieved on their behalf.

Due to his knowledge and experience, Dr. Hahn 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. Hahn can maximize value for patients through the FDA. Congress must ensure that FDA continues its important mission to provide

patients with safe and effective treatments. We ask the Senate to do what is right for patients and swiftly confirm Dr. Stephen Hahn as FDA Commissioner.

Sincerely,

ACROMEGALY COMMUNITY INC.,
ADENOID CYSTIC CARCINOMA RESEARCH FOUNDATION (ACCRF),
ALLIANCE FOR AGING RESEARCH,
AMERICAN ASSOCIATION FOR CANCER RESEARCH (AACR),
AMERICAN CANCER SOCIETY CANCER ACTION NETWORK (ACS CAN),
AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO),
ASSOCIATION OF AMERICAN CANCER INSTITUTES,
BRIDGE THE GAP—SYNGAP EDUCATION AND RESEARCH FOUNDATION,
CANCER SUPPORT COMMUNITY,
CANCER*Care*,
CARES FOUNDATION INC.,
CHILDREN'S CANCER CAUSE,
EVERYLIFE FOUNDATION FOR RARE DISEASES,
FASTERCURES,
FIGHT COLORECTAL CANCER,
FRIENDS OF CANCER RESEARCH,
GENETIC ALLIANCE,
GO2 FOUNDATION FOR LUNG CANCER,
GRANDPARENTS IN ACTION,
KIDNEYCAN,
LUNGEVITY FOUNDATION,
LUPUS AND ALLIED DISEASES ASSOCIATION, INC.,
LYMPHOMA RESEARCH FOUNDATION,
MELANOMA RESEARCH ALLIANCE (MRA),
MELANOMA RESEARCH FOUNDATION,
MEN'S HEALTH NETWORK,
MLD FOUNDATION,
MRSA SURVIVORS NETWORK,
NATIONAL ALLIANCE ON MENTAL ILLNESS,
NATIONAL ORGANIZATION FOR RARE DISORDERS (NORD),
NATIONAL OSTEOPOROSIS FOUNDATION,
NBIA DISORDERS ASSOCIATION,
NTM INFO & RESEARCH,
PANCREATIC CANCER ACTION NETWORK,
PERSONALIZED MEDICINE COALITION,
PREVENT CANCER FOUNDATION,
PROSTATE CANCER FOUNDATION,
PXE INTERNATIONAL,
RESEARCH! AMERICA,
SOLVING KIDS' CANCER,
THE NICHOLAS CONOR INSTITUTE,
UNITED LEUKODYSTROPHY FOUNDATION.

NATIONAL ORGANIZATION OF RARE DISORDERS,
1779 MASSACHUSETTS AVENUE NW, WASHINGTON, DC,
December 2, 2019.

Hon. MITCH MCCONNELL, *Majority Leader*,
U.S. Senate,
Washington, DC.

Hon. CHARLES SCHUMER, *Democratic Leader*,
U.S. Senate,
Washington, DC.

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

DEAR LEADER MCCONNELL, LEADER SCHUMER, CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the 25 to 30 million Americans with one of the over 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) and the undersigned NORD member organizations write to support the nomination of Dr. Stephen

Hahn as Commissioner of the Food and Drug Administration (FDA). We urge the Senate Health, Education, Labor, and Pensions, (HELP) Committee to swiftly advance his nomination and the full Senate to vote to confirm Dr. Hahn.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

Ensuring the continuation of FDA's work in support of the rare disease community is more important now than ever. There are over 7,000 rare diseases that afflict almost 30 million people in the United States alone. More than 90 percent of these diseases still have no FDA-approved therapy. Dr. Hahn has demonstrated, in both his own experience and in the recent HELP Committee hearing, that he understands and has the tools to support the critical public health mission of the agency, including helping deliver innovative, safe, and effective therapies to rare disease patients.

As a practicing oncologist most recently at the University of Texas MD Anderson Cancer Center, Dr. Hahn has first-hand knowledge of patients' experiences and has demonstrated his understanding of the importance of keeping these needs front and center in his work. At MD Anderson, Dr. Hahn also served as the Chief Medical Executive, which allowed him to acquire the requisite skills to lead a large organization like FDA. Further, Dr. Hahn has overseen many clinical trials, providing him with valuable experience and insight into FDA's regulatory science pertaining to innovative clinical trial designs.

During the HELP Committee hearing, Dr. Hahn repeatedly affirmed his commitment to identifying and employing best practices within the agency to facilitate medical product development for diseases with unmet needs, including rare diseases. He emphasized the need to accelerate innovation and get treatments to patients. Finally, Dr. Hahn demonstrated during the hearing that he appreciates the critical role FDA plays in the stimulation of robust generics and biosimilars pathways, which promote accessibility and affordability of drugs for many rare disease patients.

For these reasons, NORD and its undersigned member organizations support the swift confirmation of Dr. Hahn as FDA Commissioner. Dr. Hahn has shown that he is committed to ensuring that FDA's appropriately high safety and efficacy standards for medical products are both upheld and balanced with the critical need for innovation, particularly in the rare disease space. Dr. Hahn will keep the patient at the center of this work.

FDA needs strong leadership, and we believe Dr. Hahn will provide it. We urge the Senate to swiftly confirm Dr. Stephen Hahn as FDA Commissioner.

Sincerely,

ALL THINGS KABUKI,
AMERICAN BEHCET'S DISEASE ASSOCIATION,
AMERICAN MULTIPLE ENDOCRINE NEOPLASIA SUPPORT,
APBD RESEARCH FOUNDATION,
ASSOCIATION FOR CREATINE DEFICIENCIES,
AVALON FOUNDATION,
CHILDREN'S PKU NETWORK,
CONGENITAL HYPERINSULINISM INTERNATIONAL,
CURE CMD,
CURE VCP DISEASE,
DREAMSICKLE KIDS FOUNDATION,
FAMILIESCN2A FOUNDATION,
FIBROMUSCULAR DYSPLASIA SOCIETY OF AMERICA,
FOUNDATION FOR PRADER-WILLI RESEARCH,
FRIEDREICH'S ATAXIA RESEARCH ALLIANCE (FARA),
GLUT1 DEFICIENCY FOUNDATION,
INTERNATIONAL FIBRODYSPLASIA OSSIFICANS PROGRESSIVA (FOP) ASSOCIATION,
INTERNATIONAL PEMPHIGUS PEMPHIGOID FOUNDATION,
LI-FRAUMENI SYNDROME ASSOCIATION (LFS ASSOCIATION/LFSA),
LUNG TRANSPLANT FOUNDATION,
MARFAN FOUNDATION,
MILA'S MIRACLE FOUNDATION,
MLD FOUNDATION,
MOEBIUS SYNDROME FOUNDATION,
NATIONAL EOSINOPHILIA MYALGIA SYNDROME NETWORK,
NATIONAL ORGANIZATION FOR RARE DISORDERS (NORD),
NATIONAL PKU NEWS,
NBIA DISORDERS ASSOCIATION,
PTEN HAMARTOMA TUMOR SYNDROME FOUNDATION,
SSADH ASSOCIATION,
TURNER SYNDROME SOCIETY OF THE UNITED STATES,
UNITED LEUKODYSTROPHY FOUNDATION.

NATURAL PRODUCTS ASSOCIATION,
440 1ST STREET NW, WASHINGTON, DC,
December 2, 2019.

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

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY:

On behalf of the Natural Products Association (NPA) we ask for your vote of approval in President Donald Trump's nomination of Dr. Stephen Hahn to lead the Food and Drug Administration (FDA). Dr. Hahn's medical and science background and expertise make him the ideal candidate to use current statutory authority in the Dietary Supplement Act of 1994 (DSHEA) and other amendments in the Federal Food, Drug, and Cosmetic Act to regulate dietary supplements. NPA asks for the speedy approval of his appointment so that we can begin working with his staff under his oversight to address much-needed regulation for cannabidiol (CBD) products and enforcement for adulterated dietary supplements.

Inaction to date in the CBD marketplace has created a scenario that may lead to the next vaping-like health crisis. With more than 1,500 CBD products on store shelves across the country and 1 in 7 Americans using CBD, it is past time for consumers to have accurate information on CBD and time for producers to be properly regulated.

Dr. Hahn recently told the Senate Health, Education, Labor and Pensions, Committee that "a significant proportion of Americans are using [CBD] products, and a significant proportion of Americans who are using the products think that they're already judged to be safe and effective by FDA when they're not." We share Dr. Hahn's concerns and that is why NPA supports legislation that would require the

FDA to set a safe level for CBD consumption and create an urgently needed legal pathway for regulation of CBD products.

In addition to regulating CBD, action is needed in FDA's new dietary ingredient (NDI) notification process. Adulterated ingredients that have not completed the NDI notification process are entering our country at an alarming rate and it's been roughly 6 years since the FDA provided dietary supplement import alerts to prevent this. This puts American consumers at risk and compliant U.S. supplement-makers at a terrible disadvantage. It is our hope that with Dr. Hahn as its next Commissioner, the FDA will take on these much-needed actions to protect American consumers.

NPA is the largest trade association for the natural products industry, representing since 1936 the interests of manufacturers, distributors and retailers of foods and dietary supplements as well as health and beauty products. NPA represents more than 650 member companies including more than 10,000 retail storefronts as well as suppliers, manufacturers and related natural products industry leaders.

As a leader in both the natural products and dietary supplement industries, NPA has witnessed firsthand the nationwide economic growth in creating good-paying industry jobs for over 80 years. According to an independent analysis, the dietary supplement industry alone serves as both a barometer of economic health in the country and an engine to drive jobs as this $43.4 billion industry presently employs more than 750,000 Americans nationwide.

Over 200 million Americans consume a dietary supplement daily and we look forward to discussing the positive role supplements can play in public health for all Americans. NPA supports Dr. Hahn and regulatory agencies to enforce laws already on the books, to ensure a comprehensive and fair enforcement strategy, and to implement all tools at their disposal, including but not limited to misdemeanors in order to keep this marketplace the safest in the world.

Natural products, including foods, beverages, dietary supplements and cosmetics, are manufactured and sold in every state as well as the District of Columbia and Puerto Rico. NPA asks you to please consider your constituents who are employed in the natural products and dietary supplement industries when voting on the FDA nomination of Dr. Hahn. We look forward to the opportunity to meet with yourself and members of your staff to speak about this and other important issues effecting both industries in greater detail.

Thank you for your time and consideration,

DANIEL FABRICANT,
PH.D., CEO & PRESIDENT,
Natural Products Association.

QUESTIONS AND ANSWERS

RESPONSES BY STEPHEN M. HAHN, TO QUESTIONS OF SENATOR SANDERS, SENATOR CASEY, SENATOR BALDWIN, SENATOR MURPHY, SENATOR WARREN, SENATOR KAINE, SENATOR HASSAN, SENATOR SMITH, SENATOR JONES, SENATOR ROSEN, SENATOR MURRAY, SENATOR COLLINS, SENATOR SCOTT, SENATOR ISAKSON, AND SENATOR BRAUN.

SENATOR SANDERS

Question 1.

President Trump has directed FDA, on behalf of states like Florida and Vermont, to implement a prescription drug importation plan. If confirmed, how will you, as the head of FDA, collaborate with HHS to implement drug importation from foreign markets? What specific policies and regulations will you pursue? Additionally, how will you ensure that safe personal importation continues?

Answer 1. High prescription drug prices and affordability are a significant problem and addressing this issue through a variety of means has been a priority of Congress, the administration and the Department. The American people have made it clear that this is an urgent issue for them and I intend for this to continue to be a top priority of the Agency if fortunate enough to be confirmed. I have seen firsthand at MDACC the impact of this financial toxicity on patients and the institution. Although pricing of prescription drugs is not a direct FDA responsibility, I agree that strong action is needed and appreciate their consideration of all options to address the problem including drug importation. I understand that the central issue

is how to establish a program of drug importation to relieve high drug prices without risking patient safety and health or eroding the US pharmaceutical drug supply chain. As you know, FDA is responsible for determining whether any product offered for importation is in compliance with or in violation of a law enforced by FDA. Section 804 of the FDCA allows for the Secretary of HHS to certify to Congress that a drug importation program from Canada poses no additional health and safety risk and would substantially reduce the cost of drugs in the US. FDA has a critical role to play in assessing drug importation programs including issuing regulations permitting wholesalers and pharmacists to import drugs from Canada. I look forward to working with career staff, Congress and the department and pledge that science, data, and the law will guide all decision making.

Question 2.

As you may know, multiple studies, including one in the New England Journal of Medicine from March 2017, have found that an overwhelming number of patient advocacy organizations have received financial support from the pharmaceutical industry. In 2015 alone, pharmaceutical companies gave $116 million to patient advocacy groups. As you know, patient advocacy groups play an important role in FDA Advisory Committee meetings and the product approval process. During the hearing on your confirmation, you committed to including the patient voice in the decisions that FDA makes and to having science and data guide your actions. If you are confirmed, will you commit to requiring patient advocacy groups to disclose their industry donors and donation amounts prior to participating in Advisory Committee meetings? Further, if you are confirmed, will you make it a priority to seek out patient advocacy groups, when they exist, that do not receive funding from industry?

Answer 2. I commit to continue the very important practice of including the patient voice in the decisions that FDA makes. As a cancer provider, I have seen firsthand that better decisions are made when the patient's perspective is included.

Nothing is more important for a patient to trust that you are making a decision that's in their best interest and no one else's interest. I also believe strongly that transparency is a critical factor to maintain the public trust. I commit to you that science, data and the law will guide decisions that I would make if I'm fortunate enough to be confirmed by the Senate as Commissioner of Food in Drugs. I promise to be guided by the core values of integrity and transparency, and I promise to put the interest of the American people first.

Question 3.

On September 5 of this year, FDA issued a recall for the drug Natpara due to a potential issue with rubber particulates from the injector pen contaminating the medicine. More than 2,000 patients in the U.S. rely on Natpara to manage hypoparathyroidism, a rare disease affecting blood calcium levels—for most of these patients, there is no alternative treatment. FDA has not shared any substantive information with patients regarding how long the recall may last or if other treatment options were available. The Vermont congressional delegation wrote to FDA on October 18, 2019, expressing deep concern for patients with hypoparathyroidism in Vermont and around the country impacted by the recall. Without this medicine, patients can get very sick, and patient advocates have informed me that more than 170 patients have visited emergency rooms around the country due to not having Natpara. Some of these patients have been hospitalized and admitted to intensive care units. If confirmed, will you provide patients with an immediate update about the status of the Natpara recall and a projected timeline for its resolution?

Additionally, it is my understanding that FDA does not currently track adverse events following a drug recall caused by a lack of the drug itself. If hundreds of people got sick because a medicine was contaminated, that would be big news. But when hundreds of people get sick because the medicine they need was taken off the market, FDA keeps no such records. If you are confirmed, will you commit to reviewing FDA's internal process for making recall determinations and evaluating adverse events caused by the recall itself, particularly in cases where the recalled product is a sole source product?

Answer 3. As a physician, I understand how important timely and consistent access to medication is, and all Americans should be able to count on FDA to ensure the drug supply is safe. If confirmed I will act promptly to ensure the American people have the most current information available pertaining to the recall of Natpara. I will also undertake a full review of the agency's processes related to recalls as well as adverse event tracking because I agree this is an important public health issue.

Question 4.

Should you be confirmed, and upon concluding your tenure at the agency, do you commit to not taking a position within or on behalf of the pharmaceutical or medical device industries?

Answer 4. 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).

I am a scientist and a medical doctor. Science and fighting for the best interest of my patients has guided my entire professional career, and will continue to do so in any role I undertake in my career.

Question 5.

In August 2019, FDA's Center for Devices and Radiological Health (CDRH) finalized guidance on when the agency may accept inconclusive data that result in uncertainty of a device's benefit-risk determination.

- Do you commit to upholding CDRH's mission "to protect and promote the public health" and ensure that patients have access to safe and effective medical devices?

Answer. Yes, if confirmed I commit to upholding the mission of FDA and the mission of CDRH.

- How will you ensure that this guidance allowing incomplete clinical evidence to inform device approvals does not result in unsafe devices reaching the market?

Answer. FDA guidance documents do not establish legally enforceable requirements or change the standard for approval in any way. I think it is important that FDA regularly examines its thinking to ensure its approval pathways keep pace with innovation in science and technology so that patients have timely access to high-quality, safe, and effective medical devices. While this guidance provides insight to the agency's current thinking on the risk-based framework for FDA approval of medical devices, patient safety must remain a top priority and will if I am confirmed.

- How will you ensure that the medical device industry does not take advantage of the ability to submit inconclusive clinical evidence and force new devices onto the market without doing complete research?

Answer. Upholding the Gold Standard of FDA's assessment of medical products is fundamental to FDA's ability to protect and promote public health. I commit to ensuring that all medical devices approved for marketing authorization meet the applicable standards before such authorization is granted by the agency.

- How will you quell concerns that CDRH is putting too much focus on speeding device approvals and not prioritizing high quality pre-market and post-market research and surveillance?

Answer. If confirmed, it will be my top priority to ensure that FDA makes sound regulatory decisions based on science and data and that all products regulated by FDA continue to be subject to rigorous scrutiny even after marketing authorization.

- Knowing that many patient-advocacy groups receive financial support from industry, how will you ensure that patients' perspective on probable benefits and risks, as outlined in the guidance, are provided without influence from industry?

Answer 5. Nothing is more important for a patient to trust that you are making a decision that's in their best interest and no one else's interest. I also believe strongly that transparency is a critical factor to maintain the public trust. I commit to you that science, data and the law will guide decisions that I would make if I'm fortunate enough to be confirmed by the Senate as Commissioner of Food and Drugs. I promise to be guided by the core values of integrity and transparency, and I promise to put the interest of the American people first.

Question 6.

The FDA recently issued Nutrition Facts Label guidance for "added sugars" which will require a "percent Daily Value" to be placed without explanation on a blank line below the quantity of total sugar in the Nutrition Facts Label. The FDA then suggested that producers can voluntarily explain this confusing orphaned percent Daily Value as the quantity of "Added Sugars" in the otherwise pure product. Vermont producers work hard to guarantee the integrity of 100 percent pure maple and honey products. This suggestion by FDA that producers of pure maple syrup and honey incorporate the ill-conceived reference to "Added Sugars" on a footnote

of the Nutrition Facts Label is not only confusing for consumers, it likewise calls into question the quality of these excellent products. Our producers compete for shelf space with cheap imitation products that do, in fact, rely on added sugars. The Nutrition Facts Label for pure maple syrup and honey should clearly reflect that no sugars are "added," in the conventional meaning of the term, but that these products do contain sugar.

- Did FDA complete any market research on this topic to quantify consumer understanding and perception of labeling terminology?
- If not, do you commit to ensuring that the agency performs this research prior to mandating, or even suggesting in guidance specific terminology on product labels?
- If the agency finds that the phrase "added sugars" on single-ingredient sugars is misleading for consumers, do you commit to reopening the rulemaking process for added sugars to identify alternative terminology that is truthful and not misleading for consumers of single-ingredient sugars?

Answer 6. Although I am not currently a part of the administration and cannot speak to the specifics of what FDA considered in designating the requirements for the updated Nutrition Facts Label, I agree that consumers should be provided with accurate information about the food they buy and eat; and industry should compete on a level playing field. This is true for pure maple and honey products just as it is true for other foods. I personally make decisions on the food I buy based on the Nutrition Facts Label and rely on FDA to ensure that information is accurate and meaningful. I will commit that, if confirmed, I will support the Agency in updating the Nutrition Facts Label requirements and ensuring that the rules make sense for pure maple and honey products.

Question 7.

FDA met with the International Maple Syrup Institute on October 10, 2019. The Institute is still waiting for a response from the agency on whether their proposed additions to the footnote are sufficient to meet FDA's standards. If confirmed, will you respond to the Institute's inquiry and verify that their proposed changes to the footnote are acceptable to FDA?

Answer 7. I commit that I will look into this issue if I am confirmed.

Question 8.

As you know, the most recent farm bill legalized hemp cultivation and products. The new law also classifies hemp as a crop, moving jurisdiction of its production to the Department of Agriculture, including production of hemp derivatives like cannabidiol (CBD). The same month the farm bill became law, then-FDA Commissioner Gottlieb announced CBD and other hemp derivatives are drug ingredients. That means that while production of CBD is governed by USDA, companies that create products containing CBD must seek approval from the FDA before selling their products. While I understand the need to ensure product safety, this process can be an insurmountable hurdle for small businesses, to the benefit of the pharmaceutical industry. FDA's position is concerning to many who believe it will make CBD unattainable for consumers, restrict its use for therapeutic purposes, and limit the economic benefit of hemp production for struggling farmers and small businesses. If confirmed, will you commit to working with USDA on regulations related to CBD that prioritize the needs of farmers, small business owners, and consumers?

Answer 8. Thank you for your question. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate Federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements) that can be used by manufacturers, including small businesses.

SENATOR CASEY

Rare Diseases

Question 1.

According to the National Organization for Rare Disorders, about 25–30 million Americans are living with a rare disease. I frequently hear from constituents who suffer from rare diseases, such as amyotrophic lateral sclerosis (ALS), regarding the lack of FDA-approved treatments for their conditions. Many of these constituents are extremely ill, and are concerned that they may not live long enough to see final FDA approval of a new drug to treat their condition. I applaud the FDA for the work it has done to speed approval of new drugs for rare diseases, but I also believe that this is an issue that deserves continued attention. If confirmed as FDA Commissioner, will you:

a. Commit to ensuring that the agency remains engaged with these patients during the drug development and approval process? Please provide details on how you would strengthen the FDA's engagement with patients;

b. Commit to ensuring close coordination within the agency, particularly within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, to develop policies informed by rare disease regulatory experts, such as those who work in the Office of Orphan Products Development?

and

c. Commit to working with Congress in continuing to implement and improve the Rare Pediatric Disease Priority Review Voucher Program?

Answer 1a. I am and will be deeply committed to engaging patients in the drug and device approval process. This has been a priority for FDA and I look forward to continuing their work. I look forward to working with your office and other stakeholders on the details of how we can expand this work. As Secretary Azar, Commissioner Gottlieb, and Acting Commissioner Sharpless have all emphasized in speaking to rare disease groups, this is a key commitment for FDA and all of HHS.

Answer 1b. I will be strongly committed to having CDER and CBER develop policies that are focused on and informed by advancements in how we can research rare diseases, including ways we can bring more patients into clinical trials.

Answer 1c. I am committed to working with Congress on the Rare Pediatric Disease Priority Review Voucher Program, which helps to accelerate development of therapies, bringing patients hope. I am committed to ensuring that this and other Priority Review Voucher Programs are effectively implemented.

Vaccines

Question 2.

The overwhelming scientific consensus is that FDA approved vaccines are safe for the vast majority of the public, and that they save lives. However, the public is routinely exposed to a great deal of misleading information on the safety of vaccines, much of it from online sources.

a. What role do you feel the FDA should play in pushing back against this misinformation?

b. What additional efforts do you feel the agency should undertake to push back against vaccine hesitancy and anti-vaccine sentiment?

Answer 2. As a public health agency that always strives to use the best available scientific evidence to promote and protect the well-being of individuals, FDA has a critical role to play, with its many key partners and stakeholders, in building and maintaining the trust and confidence of parents and healthcare providers in the safety and effectiveness of vaccines. It is an institution that does not and should not take lightly its responsibility to ensure the safety and effectiveness of vaccines, and must work diligently with its many partners to:

- Provide timely, understandable, accurate, relevant, and actionable information to the public, partners, and health professionals about the importance of staying up to date on vaccinations across the lifespan.
- Emphasize vaccines are the best and safest ways parents can protect infants, children, and teens from 16 potentially harmful diseases, including measles.

- Support healthcare professionals with the tools and resources needed to talk to parents about vaccines and answer questions.
- Recognize that parents are working to make the best health decisions for their children, and increase their awareness that vaccine-preventable diseases can be very serious, may require hospitalization, or even be deadly—especially in infants and young children.

But simply providing the facts is not enough.

Trust is one of the most important factors associated with vaccine confidence. Trust is the willingness to rely on someone else's expertise and advice (e.g., their vaccine recommendation). For vaccinations, trust comes into play in a number of ways and with respect to a number of stakeholders. For example, parents need to have trust in the pharmaceutical companies that produce vaccines, trust in the healthcare system that delivers them, trust in the healthcare providers that recommend and administer vaccines, and trust in the organizations and policymakers that decide which vaccines are needed and when. Trust also extends to the safety and effectiveness of vaccines, including a belief that the system has adequately evaluated the safety and effectiveness of recommended vaccines. The level of trust parents have in government, the healthcare system and their healthcare providers are often associated with their ultimate decision to accept or refuse vaccinations for their children.

The public has long looked to and trusted the FDA to ensure the drugs, devices and other medical products it regulates are safe and effective. FDA should leverage that trust by working with its partner agencies and stakeholders, the health care community, and, most importantly, parents, to rebuild the Nation's confidence in one of the greatest public health achievements of all time

Drug Shortages

Question 3.

The number of drug shortages has increased over the past two years. Last year, there were 54 drug shortages, which affects patients' ability to get the care they need and even could cause them to lose their lives. These shortages appear to be linked, in part, to complexities in the manufacturing supply chain, particularly with respect to the safety and quality of products being imported from overseas. While we should be doing everything we can to keep drug prices from skyrocketing, we also need to ensure that drugs, their ingredients, and all products related to their delivery are safe and effective. If confirmed;

> 3a. What specific steps will you take to ensure that quality manufacturing practices are enforced, both in the United States and abroad?

Answer 3a. FDA plays an important role in promoting manufacturing processes that result in quality medical products. As a physician, I relay on FDA to ensure that the products I prescribe to patients are not contaminated and contain the amount of active ingredient specified. One important aspect is recruiting and retaining the appropriate workforce with the necessary knowledge and experience and I commit to supporting the Agency in these efforts if confirmed.

> 3b. In addition, please describe how you will work with the Department of Defense (DOD) and the Assistant Secretary for Preparedness and Response (ASPR) on drug quality management and the medical supply chain to ensure our national security with respect to public health emergency response medical countermeasures.

Answer 3b. Medical countermeasures are essential to protect our citizens, including our military personnel from a range of threats, including chemical and biological hazards. I am committed to collaborating with ASPR and with DOD as part of the critical medical and public health preparedness and response efforts to protect our Nation.

Question 4.

The recent report by the FDA on drug shortages suggests implementing financial incentives for manufacturers who continue to produce those lower-profit drugs to ensure they experience lowered risk on their continued investment, thereby assuring continuity of important older and less profitable drugs. In addition to the above responses, please describe other ways in which FDA can, if you are confirmed, provide incentives to companies to ensure that manufacturers continue to produce lower-profit drugs.

Answer 4. I applaud FDA's efforts to involve a range of stakeholders to investigate and report on the root causes of drug shortages. But the Agency must continue its work to reduce the instances of drug shortages, especially those that are critical to the treatment of patients. I understand that although some of these root causes, such as financial incentives, are not directly under FDA control that we must be creative in our approaches.

Antibiotic Resistance

Question 5.

According to the Centers for Disease Control and Prevention, more than 35,000 Americans die from infections caused by antibiotic-resistant bacteria each year. However, there are few new antibiotics on the market, and manufacturers are hesitant to invest in the development of antibiotics. Public health experts are warning of a potential future without antibiotics, when currently treatable infections could become deadly. Under the Generating Antibiotic Incentives Now (GAIN) Act, FDA has the authority to review and approve certain antimicrobial drugs that are designated as a qualified infectious disease product under a fast track or priority review designation, and certain products could also receive extended exclusivity. As of 2018, the agency had approved 12 such qualified products. Further, the 21st Century Cures Act authorized the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD); to date, two drugs have been approved through LPAD pathway. In addition to the GAIN Act and the LPAD pathway, what other actions can the agency take immediately to combat antimicrobial resistance?

Answer 5. This is a top public health priority and I believe the Agency is a global leader in combating antimicrobial resistance (AMR). The Agency is working strategically across all medical centers and with key offices, including the Office of the Chief Scientist to implement the 2019 Strategic Approach for Combatting AMR.[1] This comprehensive approach addresses the many critical components of AMR, including use of antibiotics in food producing animals, innovative diagnostics for identifying infections and appropriate treatment, innovative antibiotics for both animals and humans, innovative clinical trials that include appropriate breakpoints and post market studies, and finally stewardship.

One immediate step the agency could take is leverage this cross agency working group to partner with physicians to revise utilization and reporting of antibiotics. The Agency could potentially use a similar approach that was used for addressing prescribing patterns with opioids and apply it to antibiotics.

I also understand this is a high priority for this Committee and many Members of Congress and the public health community and I would welcome the opportunity to partner on potential actions and solutions to AMR.

Opioids

Question 6.

Several concerted efforts to combat the ongoing epidemic have helped lead to a decline in opioid over-prescribing. However, despite a recent decline in opioid prescribing, Americans continue to die due to opioid overdoses, and people continue to become addicted. In June 2019, the agency released a draft guidance for assessing the risks and benefits of opioid analgesic drugs. The guidance states: "FDA also considers the broader public health effect of opioid analgesic drugs; this involves consideration of the risks related to misuse, abuse, opioid use disorder, accidental exposure, and overdose, for both patients and others. Likewise, FDA considers any properties of a drug expected to mitigate these risks."

a. If confirmed as FDA Commissioner, will you ensure that the broader public health and safety is taken into account when approving new opioid products?

b. If you are confirmed, when will FDA finalize its guidance on opioid analgesics under your leadership?

c. As FDA Commissioner, how would you prevent future abuse/misuse of opioids prescribed for long-term use?

d. A recent set of guidelines from the Veterans Administration and the Department of Defense warns against the use of opioids for treating mild, chronic pain. If confirmed, what additional steps will you take to reduce

[1] *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance-information-fda.*

over-prescribing of opioids, particularly regarding the approval of alternative pain medications and treatments, especially for chronic pain?

i. In your confirmation hearing, you mentioned we need to take action on packaging, increased approval of non-opioid products, and take a holistic approach to pain medication. Please provide specific examples of how FDA will address each of these approaches in its response to the opioid epidemic.

e. Will you commit to promote the use of medication-assisted treatment in the treatment of substance use disorder, particularly opioid use disorder?

f. What steps will you take to increase the availability of naloxone, such as extending the shelf-life of naloxone products and promoting co-prescribing practices?

Answer 6a–f. Thank you for your question. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. An evidence-based holistic approach to treating pain with non-opioid medications, behavioral therapies, and when appropriate, opioids is now being used effectively in many medical settings to effectively treat pain. We have new ways of prescribing pain medications that create a balance between relief of suffering and preventing addiction. There is outstanding research being performed on addiction and the causes of pain. I am optimistic that even better approaches will be developed in the future. That being said, we are still dealing with a devastating and urgent crisis with opioids. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I understand that FDA is also evaluating other activities that could be helpful including setting standards for new opioid approvals, additional doctor education, and revising regulatory procedures for mandatory recall authority of opioids that have a substantial risk for adverse health consequences or death. I am supportive of efforts by the agency to help innovators of non-opioid alternatives for pain control and abuse-deterrent formulations because we cannot forget the importance of safely helping Americans with pain syndromes. I am also supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT in a holistic therapy setting. I have cared for numerous patients with serious and debilitating pain, and understand that we must strike a balance between maintaining patients' access to effective opioid drugs and non-opioid alternatives, while reducing misuse and abuse of opioid drugs.

Question 7.

Standards of identify (SOI) for food products are important because they ensure consumers are assured a minimum level of quality. They also establish required and/or prohibited ingredients and ensure that packages contain the correct amount of food. The United States is the only country that still uses a "pressed weight" SOI for tuna, while all other countries use a "drained weight" SOI for canned tuna. I urge FDA to retire the outdated standard of "pressed weight" and harmonize with the rest of international community's SOI of drained weight for canned tuna. This reform would ensure that all U.S. canned tuna companies and importers use a consistent and quality tuna, thus benefiting consumers and regulators. It would also help to achieve FDA's goal of modernizing its own SOI portfolio.

a. What are FDA plans to move toward adopting the drained weight SOI for canned tuna fill of container?

b. When do you expect this reform to be completed?

Answer 7a–b. Although I cannot speak to the specifics of FDA's work in this area as I am not currently a part of the administration, I recognize the importance of ensuring consumers have access to accurate and useful information about the food they buy, including canned tuna. I think FDA should also strive to harmonize rules with foreign requirements to the fullest extent possible.

Food Safety

Question 8.

How will you ensure the Agricultural Water Requirements of the Produce Safety Rule (from the Food Safety Modernization Act) are rewritten in a manner that ensures both realistic options for farmers who rely on a variety of water sources and accurate results that will identify the pathogens that are most likely to cause foodborne illnesses? How will you ensure actual progress is being made to rewrite the agricultural water requirements before the 2022 compliance date for the recently delayed agricultural water requirements?

Answer 8. It is critical that FDA find the appropriate balance in issuing rules to ensure the safety of the food supply in the United States while not unnecessarily burdening American farmers. I am also a proponent of regulating based on a risk-based approach focusing on the most likely sources of contamination and those that pose the biggest risk to the public health. Farmers should be provided the appropriate amount of time to comply with any new rules and also be supported with sufficient learning opportunities to assist their ability to comply. I commit that, as Commissioner, I will review FDA's efforts around food safety and the implementation of the Food Safety Modernization Act.

Question 9.

The FDA was recently required by court order to write a proposed rule for the Food Safety Modernization Act Section 204 by September 2020. FSMA Section 204 requires recordkeeping for any product FDA deems to be "high risk." Within this section of FSMA, there is an exemption within FSMA for farms that have labels that preserve the identity of the farm through the supply chain to the consumer (farm identity preserved marketing). Farms are also exempt from keeping records of food that are direct marketed (to stores or individual consumers) by the farmer. How will you ensure the proposed rule includes these exemptions, which are required by FSMA?

Answer 9. As mentioned above, I commit that if fortunate enough to be confirmed, as Commissioner, I will review FDA's implementation of the Food Safety Modernization Act to ensure a balanced approach and FDA's adherence to the law.

Question 10.

How will you encourage FDA officials to evaluate the first few years of Produce Safety Rule inspections on farms to ensure inspections are not decreasing conservation and biodiversity? The Produce Safety Rule requires monitoring and addressing any potential contamination from wildlife and domestic animals, which has led some farmers to destroy wildlife habitats, remove domestic animals from their diversified operations, among other actions. However, the Food Safety Modernization Act requires that the new regulations, including the Produce Safety Rule, do not undermine beneficial on-farm conservation and wildlife practices.

Answer 10. I agree that it is important to ensure that FDA's rules around produce safety do not have unintended consequences on the environment. If confirmed, I will support the Agency as it solicits a range of stakeholder feedback on the Produce Safety Rule and all rules implementing the Food Safety Modernization Act.

Nutrition Innovation Strategy

Question 11.

FDA's Nutrition Innovation Strategy, unveiled in 2018, can play a critical role in reducing preventable deaths and diseases related to poor nutrition. This is an extremely important process looking at a wide array of issues, and while there is certainly a lot of good work that is already underway, I believe that there also a lot still to be done. As the incoming Commissioner, how do you plan to move forward FDA's food and nutrition work, and what are your priorities in terms of what issues the agency will move forward on next?

Answer 11. I support FDA's efforts to promote food safety and sound nutrition for the country. In all the decisions we make, we must follow the best and most current science and engage in stakeholders who can provide the necessary information to inform the best course of action.

SENATOR BALDWIN

Question 1.

Wisconsin has long been a leader in advancing new technologies to better diagnose and screen for disease, including tests used to promote earlier detection of can-

cer. As a practicing oncologist, you are no doubt familiar with the array of clinical diagnostic tests, which are becoming more and more complex. However, the regulatory system for these tests have not kept up.

Both the FDA and Congress are devoting efforts to modernize the regulation of all diagnostic tests. How should FDA balance the desire for lab developed test reform with preventing barriers to the development of and patient access to life saving diagnostic tests? As FDA Commissioner, will you work to ensure continued progress is made on updating the regulatory system for clinical diagnostics?

Answer 1. As an oncologist, I am very aware of the need to ensure that in-vitro clinical diagnostics provide patients and physicians with accurate diagnostic information to guide treatment decisions, particularly some of the newer more complicated testing procedures. I also recognize that any approach needs to promote innovation and not put unnecessarily burdens on developers. If confirmed as Commissioner, I will bring this perspective to the discussion and work closely with Congress and other stakeholders to modernize FDA's regulatory approach.

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. FDA has now held a comment period for farmers, consumers, and food companies to provide input on the mislabeling in the marketplace, but action is needed.

Do you agree that it is unfair that dairy alternatives have been allowed to proliferate in the marketplace without proper labeling enforcement, while dairy products have been abiding by numerous FDA regulations to ensure consumers have accurate information? Do you believe that standards of identity play a role in promoting health and consumer confidence?

If confirmed, how will you enforce FDA regulations against all plant-based imitation products that use dairy terms? What is the status of the review of comments and stakeholder feedback at FDA and will you commit to beginning enforcement within 60 days of your confirmation?

Answer 2. As I said during my confirmation hearing, I am in favor of clear, transparent and understandable food labeling for the American people. The American people need this so that they can make the appropriate decisions for their health and their nutrition. I understand that FDA has already collected stakeholder comment on this issue and I commit that, if confirmed, I will ensure that FDA follows the scientific evidence to guide actions in this area.

Question 3.

The Institute of Medicine, the Patient-Center Outcomes Research Institute, the American College of Surgeons Commission on Cancer, the American Society of Clinical Oncology, and the Community Oncology Alliance all recognize psychosocial care as the standard of care in oncology. Currently, there is no such standard at the FDA, despite the fact that between one-third and one-half of cancer patients report distress is a "significant" problem. In the 21st Century Cures Act and FDARA, Congress made clear to the FDA the importance of incorporating insights from the patient experience in its decisions on new drug approvals and post marketing surveillance. And, the FDA now recognizes that patient-focused drug development is applicable throughout the drug development process, and acknowledges that trials should measure more than just patient-reported symptoms and physical function.

As an oncologist, do you believe including the assessment of a patient's psychosocial status in clinical trials would help to achieve a better understanding of the patient experience with the investigational agent? How would you work to ensure that FDA works with manufacturers to include comprehensive and reliable measures on patient experiences that capture physical and psychosocial symptoms in clinical trials?

Answer 3. Thank you for your question. I am aware that the 21st Century Cures Act and FDARA required the FDA to advance patient-focused drug development. The FDA announced it is developing a series of four methodological patient-focused drug development guidances to implement these provisions. As an oncologist, I recognize the importance of patient psychosocial status assessment in clinical care and research. I am committed to continuing to implement the requirements of 21st Century Cures and FDARA as well as work with FDA staff to determine additional steps that can be taken to advance patient-focused drug development.

Question 4.

During the 2004 and 2009 flu seasons, including the H1N1 pandemic, the Nation experienced a dangerous shortage of influenza vaccines due in part to insufficient domestic production capabilities. Although domestic production and infrastructure of flu vaccine and other drugs and vaccines has partially improved since then, supply chain vulnerabilities and a lack of domestic production of various drug components may continue to place the Nation at risk.

How can we continue to improve domestic manufacturing and reduce the future likelihood of drug shortages? What do you believe is the role of the FDA in mitigating drug and vaccine shortages that result from supply chain and production issues, and how can the FDA work to expedite the development and approval of novel vaccines? How will you work to incorporate advanced techniques and technologies such as cell-based manufacturing processes in the development of new vaccines?

Answer 4. I agree that advanced manufacturing will play a key role in preventing and mitigating drug and vaccine shortages in the future. I also believe that we may see an increasing role of domestic manufacturing if we move toward broader adoption of these technologies. Influenza vaccines could particularly benefit from advancement since reducing the required time needed can result in more accurately predicting the strains prevalent in a given flu season.

Question 5.

In August, public reports emerged that AveXis, a subdivision of Novartis, had knowingly submitted falsified data to the FDA to obtain approval of Zolgensma, the most expensive medication in history. AveXis also benefited from a number of Federal taxpayer-funded benefits and incentives for Zolgensma, including Fast Track, Breakthrough Therapy, and Priority Review designations, and had benefited from taxpayer-funded NIH research before setting its staggering $2.1 million price.

How will you ensure drug data accuracy and hold pharmaceutical companies accountable if confirmed as Commissioner? Will you commit to using the FDA's full regulatory, civil, and criminal authorities to hold pharmaceutical companies accountable when they mislead the FDA and the public?

Answer 5. Throughout my career I have relied on the trust and peace of mind the gold standard the Food and Drug Administration provides. The gold standard requires accuracy of data. Because of FDA, I had confidence for my patients in the treatments that I prescribed for them. As I reflect on the trust I placed in FDA, I'm now humbled that with your consent, I may be in the position to lead that very agency I relied on and trusted for my entire career. If confirmed, I promise to be guided by the core values of integrity and transparency and I promise to put the interest of the American people first, and hold accountable to the fullest extent made possible by the law, those who violate that standard.

Question 6.

Even in the midst of the opioid crisis, the FDA has continued to approve new and stronger opioid drugs. Raeford Brown, MD, the Chair of the FDA's Anesthetic and Analgesic Drug Products Committee, called one of these recently approved medications, Dsuvia, "an extremely divertible drug," with significant potential for abuse and overdose. In a statement, former Commissioner Gottlieb described a need to examine the agency's broader risk-benefit framework for approval of new opioid analgesics, and the agency put out draft guidance in June.

What is the FDA's role in examining the larger context of the opioid crisis and mitigating potential harms in approving new drugs? What additional steps to address the opioid crisis, beyond what the FDA is currently taking, will you pursue if confirmed as Commissioner?

Answer 6. Thank you for your question. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. An evidence-based holistic approach to treating pain with non-opioid medications, behavioral therapies, and when appropriate, opioids is now being used effectively in many medical settings to effectively treat pain. We have new ways of prescribing pain medications that create a balance

between relief of suffering and preventing addiction. There is outstanding research being performed on addiction and the causes of pain. I am optimistic that even better approaches will be developed in the future. That being said, we are still dealing with a devastating and urgent crisis with opioids. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I understand that FDA is also evaluating other activities that could be helpful including setting standards for new opioid approvals, additional doctor education, and revising regulatory procedures for mandatory recall authority of opioids that have a substantial risk for adverse health consequences or death. I am supportive of efforts by the agency to help innovators of non-opioid alternatives for pain control and abuse-deterrent formulations because we cannot forget the importance of safely helping Americans with pain syndromes. I am also supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT in a holistic therapy setting. I have cared for numerous patients with serious and debilitating pain, and understand that we must strike a balance between maintaining patients' access to effective opioid drugs and non-opioid alternatives, while reducing misuse and abuse of opioid drugs.

Question 7.

Personal care products and cosmetics are among the least regulated consumer products on the market. Currently, the Food and Drug Administration (FDA) oversees the marketing and labeling of cosmetics, but does not have the authority to approve the safety of cosmetics before they go on the market. Yet, research suggests that chemicals contained in many of the personal care products we use every day are linked to serious health problems, and FDA recently issued a number of alerts advising consumers not to use certain cosmetic products because of concerns related to asbestos exposure.

If confirmed, what additional steps will you take to monitor and enforce the safety of cosmetic products? What specific authorities do you believe the FDA needs to enforce a high safety standard for cosmetics, and will you work with Congress to modernize and expand oversight of personal care products?

Answer 7. Thank you for your interest in this issue. I commit that, if confirmed, I will work with staff at FDA, industry, consumers, and members of the scientific community to understand what needs to be done to take a proactive stance to monitoring the safety of the cosmetics market for consumers. I will also work to better understand the risks to public health presented by cosmetics products. It is important that consumers be able to trust that the cosmetics they buy are not contaminated by harmful substances or manufactured under substandard conditions.

Question 8.

There is a persistent shortage of donated blood products in the United States, and blood donation policies that encourage as much healthy donation as possible are critical to secure our Nation's blood supply. It is important for donor deferral policies to be based on an individual's risk of transmitting infection, rather than blanket, non-risk-based criteria that discourage healthy donation. In 2015, the FDA finalized guidance to update the deferral criteria for men who have sex with men (MSM) from a lifetime ban to a one-year deferral. While this was a step in the right direction, this policy is not based on individualized risk, and is not driven by science and continues to be discriminatory.

If confirmed, will you commit to reviewing FDA's donor deferral policies to ensure that they are based on the most up-to-date scientific knowledge, and working toward criteria based on individual risk of infection transmission?

Answer 8. I know how important it is to make sure there is a safe and ample donated blood supply. It is absolutely critical and life-saving to the American people. If confirmed, I will continue the work of the FDA to implement policies that ensure that we have access to a safe and adequate blood supply. I will also commit to continuing to work with FDA staff to review the donor policies to ensure they are up to date, and reflect current science and data.

Question 9.

On November 19, 2019, the Center for Veterinary Medicine at FDA issued draft guidance for industry #256, "Compounding Animal Drugs from Bulk Substances." In May 2015, FDA published draft guidance on this issue, which was later withdrawn based on feedback from the veterinary community and compounding industry, as

well as other stakeholders. The new draft GFI #256, like the withdrawn GFI #230, contains a clinical need standard and a bulk ingredient positive list for certain animal drug compounding, similar to provisions that apply to section 503B outsourcing facilities for human compounding.

If confirmed, will you commit to actively engaging with stakeholders to gather feedback on this guidance, and can you provide more information on the statutory provisions that allow the agency to expand these provisions to animal drug compounding?

Answer 9. I recognize the importance of gathering stakeholder input on all issues, including in the area of animal drug compounding. Compounded drugs play a critical role in providing patients, human or animal, with the appropriate therapy when filling a medical need. I commit that, if confirmed as Commissioner, I will work to ensure FDA makes progress in implementing the authorities over compounded products taking into account the range of stakeholder needs.

SENATOR MURPHY

Sesame Allergen Labeling

In late 2018, the FDA solicited comments to inform agency action to require food manufacturers to label for sesame as a priority allergen and received more than 4,800 comments in response. I previously wrote to the FDA on this topic and am pleased they took action in this year. This year, I secured language in the Fiscal Year 2020 Senate-passed Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act encourages the FDA to continue action in this area and require sesame allergen labeling.

Question 1.

Do you agree that sesame should be labeled as a major allergen? What is your timeline to review the comments and data sets submitted to the docket and take action on sesame allergen labeling?

Answer 1. American consumers should be alerted to potential allergens in their food to the extent practicable. I am glad to hear that Congress and FDA have already begun looking at whether it would benefit the public health to include sesame as a major allergen. I cannot give a timeline as I am not currently at the Agency but I commit that I will support the Agency in moving this work forward as expeditiously as possible.

Drug Shortages

In June 2018, Senator Cassidy and I led a letter with 29 other Senators to ask the FDA to convene the Drug Shortage Task Force to develop a report and recommendations regarding the root causes of drug shortages. In response, last month the FDA released the report *Drug Shortages: Root Causes and Potential Solutions* that outlined some prominent obstacles and recommendations to address the drug shortage issues affecting patient care nationwide.

Question 2.

Would you outline the steps you would take to implement the recommendations, as well as a timeline? Also, would you commit to keeping HELP Committee Members abreast of any major steps that your agency undertakes on this issue?

Answer 2. I applaud your leadership on this issue and believe FDA's recent report on drug shortages is a significant step forward in addressing this problem. I will make preventing and alleviating drug shortages one of the highest priorities of the Agency should I be confirmed as Commissioner. I have seen first-hand how shortages affect patient care. I also commit to be proactive in my communications with you and other Members of the HELP Committee.

Opioids

As you know, opioid prescribing in the U.S. has declined in recent years. However, Americans continue to consume far more opioids per capita than any other country, which may lead to more people becoming newly addicted.

Question 3.

What would you do as Commissioner to reduce the overprescribing of opioids, while maintaining access for those who have a genuine need?

Answer 3. Thank you for your question. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top pri-

ority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. An evidence-based holistic approach to treating pain with non-opioid medications, behavioral therapies, and when appropriate, opioids is now being used effectively in many medical settings to effectively treat pain. We have new ways of prescribing pain medications that create a balance between relief of suffering and preventing addiction. There is outstanding research being performed on addiction and the causes of pain. I am optimistic that even better approaches will be developed in the future. That being said, we are still dealing with a devastating and urgent crisis with opioids. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I understand that FDA is also evaluating other activities that could be helpful including setting standards for new opioid approvals, additional doctor education, and revising regulatory procedures for mandatory recall authority of opioids that have a substantial risk for adverse health consequences or death. I am supportive of efforts by the agency to help innovators of non-opioid alternatives for pain control and abuse-deterrent formulations because we cannot forget the importance of safely helping Americans with pain syndromes. I am also supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT in a holistic therapy setting. I have cared for numerous patients with serious and debilitating pain, and understand that we must strike a balance between maintaining patients' access to effective opioid drugs and non-opioid alternatives, while reducing misuse and abuse of opioid drugs.

Question 4.

Currently, there is a citizen petition from public health officials and doctors that is pending before the FDA asking for the removal of ultra-high dosage opioids—opioids that come in doses so strong a single pill can cause an overdose in someone without a tolerance to opioids. One example is the 80mg OxyContin tablet that is the equivalent of 24 Vicodin tablets in a single pill.

Answer 4. Thank you for your question. While I do not have access to non-public information from the FDA, if I am confirmed, I will work with agency staff to determine the status of the citizen's petition. Addressing the opioid crisis is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed.

Has the agency reviewed this petition to remove ultra-high dosage opioids?

Medical Gas

The FDA has yet to formally begin the rulemaking process for medical gas, despite having the authority to do so since 1978 and being given a statutory deadline in the fiscal year 2017 Consolidated Appropriations Act to do so by July 2017. In 2018, the FDA convened three public meetings with stakeholders and announced in the fall 2018 Unified Agenda that it intended to issue a proposed rule on medical gases by April 2019. That date was pushed back in the Fall 2019 Unified Agenda that now projects a September 2020 publication date for a proposed rule on medical gases.

Question 5.

What is causing the delay in rulemaking on medical gases that already is 41 years overdue? When will the FDA issue the NPRM on medical gas?

Answer 5. If confirmed, I am committed to implementing all laws passed by Congress, including Section 1112 of FDASIA. I look forward to working with you on this issue.

As you know, in 2017, FDA circulated a draft guidance on this matter that is intended to provide more clarity around good manufacturing processes for medical gases, and I look forward to continuing work on this issue.

Electrical Stimulation Devices

The FDA released a proposed rule to ban electrical stimulation devices (ESDs) in April 2016 but has not yet finalized the rule. Evidence indicates that the use of ESDs in individuals with intellectual or development disabilities are associated with a number of physical and emotional risks including depression, posttraumatic stress disorder, burns and tissue damage. In 2016, I wrote a letter with five other Senators in support of agency action to ban ESDs. Meanwhile, ESDs continue to be used on children and young adults with developmental disabilities. Last year former FDA Commissioner Dr. Scott Gottlieb expressed support for a ban saying, ESDs "present an unreasonable and substantial risk to public health that cannot be corrected or eliminated through changes to the labeling."

The Fall 2018, Spring 2019, and recently released Fall 2019 Unified Agenda include finalizing a ban on electrical stimulation devices that are used on individuals with intellectual or developmental disabilities but so far this hasn't moved from FDA to OMB.

Question 6.

When does the agency plan to complete its work to issue a final rule to ban electrical stimulation devices?

Answer 6. I am committed to working with your office on this issue and working to protect American patients. I cannot speak to a proposed timeline, as I am not part of the administration yet. I look forward to working with FDA's professional staff to study this issue and understand the most efficient path forward that protects patients.

Maple Syrup

The FDA is currently debating changes to nutrition panel labeling, one of which is more prominently listing added sugars. While the FDA defines this term as the sugars that are added to someone's diet, consumers often interpret it as sugars added to the product. Producers of pure maple syrup are concerned about how their products will be viewed under this label because consumers will think that if a bottle of maple syrup lists "added sugars" it means there are other processed sugars added to the product—even when it's pure maple syrup.

While the FDA has attempted to address these concerns by publishing non-binding guidance, producers must now publish an unidentified percent daily value on a blank line below the amount of total sugar on the nutrition facts panel. Producers remain concerned that the orphaned, floating percent daily value would suggest to consumers that pure maple syrup producers, and other single ingredient sugar producers included a typographical error on their labels, thus exposing producers to consumer complaints. To address this concern the FDA offered in guidance that producers could voluntarily use an obelisk by the orphan percent daily value and include an explanatory footnote explaining that this refers to a percent daily value of "added sugar". Producers are now requesting an answer from FDA on whether the following phrase would suffice as that footnote, "One serving adds 24g of sugar to your diet and represents 48 percent of the Daily Value for sugars added to your diet."

Question 7.

Can you work with producers to confirm that this explanatory footnote will be recognized by the FDA as truthful and not misleading?

Answer 7. Yes, I commit that if confirmed, I will prioritize FDA's interactions with stakeholders including on the issue of Nutrition Facts Label requirements. I believe that FDA is most effective when stakeholder input is fully considered in developing regulatory requirements.

Finished Drug Product Testing

It is vital that consumers feel confident in the products that bear the FDA seal of approval. Earlier this year there was a recall across the U.S., Canada, Taiwan, Pakistan, and several European countries of the heartburn drug Zantac and its generic due to concerns that it contained a probable carcinogen and posed a potential health risk for patients. The problem was identified by a pharmacy in Connecticut—Valisure—because they conduct chemical testing of every batch of drugs before they dispense them to patients. To my knowledge, this is not commonly done in the U.S., either by the FDA or by other pharmacies.

Question 8.

What can the FDA do to reassure the public about the safety and integrity of the U.S. drug supply chain? While the agency has a limited ability to inspect all of these facilities, do you think the FDA should consider conducting more widespread chemical testing of finished products? Has the FDA considered opportunities to partner with private industry to help conduct this type of testing to ensure the safety of our Nation's supply chain?

Answer 8. I am not currently a part of the administration and cannot speak to the specifics of the agency's capacity or actions that have come under consideration to address any shortcoming. If I am confirmed, I commit to working closely with FDA staff to understand this issue and will carefully consider any proposals that will protect the Nation's drug supply. I am committed to FDA remaining the gold standard for ensuring the safety.

SENATOR WARREN

I. Antibiotic Resistance

Antibiotic drugs are critical tools for treating serious bacterial infections, but they are becoming less and less effective as bacteria develop a resistance to the antibiotics that are currently available. Today, resistance has been seen in almost all antibiotics ever developed. The World Health Organization (WHO) has described antimicrobial resistance (AMR) as "one of the biggest threats to global health, food security, and development today," and the threat is no less significant right here in the U.S. According to the Centers for Disease Control and Prevention (CDC), nearly 3 million people in the U.S. develop antibiotic-resistant infections every year, resulting in over 35,000 deaths.

Unfortunately, discovery of new antibiotics is failing to keep pace with the emergence of new "superbugs." Almost every antibiotic in use today is based on a scientific discovery made more than 30 years ago. Currently, there are only 42 antibiotics in clinical development worldwide. While that number may seem sufficient, only 11 of those have the potential to address the most dangerous superbugs as identified by the WHO, and historical data indicates that only 1 in 5 infectious disease drugs entering phase 1 trials typically receive FDA approval. Developing new antibiotics is essential in the effort to combat AMR, yet a number of unique scientific and economic challenges hamper drug development efforts. Furthermore, there is strong and growing evidence that antibiotic overuse in food animals can lead to antibiotic resistance in humans. The 2014 *National Strategy for Combatting Antibiotic-Resistant Bacteria* brought together the Secretaries of Health and Human Services, Agriculture, and Defense to declare that, "the misuse and over-use of antibiotics in health care and food production continue to hasten the development of bacterial drug resistance, leading to the loss of efficacy of existing antibiotics."

Question 1.

Do you agree that supporting the development of new antibiotics is an important part of FDA efforts to combat antimicrobial resistance? If confirmed, what steps would you take to encourage the development of new antibiotics?

Answer 1. Yes, supporting the development of new antibiotics is a critical part of combating antimicrobial resistance. If confirmed, I would rely on FDA career experts to support the LPAD pathway and examine whether the program requires anything additional to stimulate the innovation of new antibiotics.

Question 2.

If confirmed, will you commit to continue the implementation of the priorities and goals outlined in the FDA's 2019 Strategic Approach for Combatting AMR?

Answer 2. Yes, if confirmed, I would commit to implementing the 2019 Strategic Approach for Combatting AMR.

Question 3.

If confirmed, what will you do to improve physician education on the safe prescribing of antibiotics?

Answer 3. My first step, if confirmed, would be to engage with the career staff in both Center for Drug Evaluation and Review (CDER) and Center for Veterinary Medicine (CVM) to learn about their ongoing work. I believe the work the Agency has done on prescribing guidelines to help combat the opioid crisis is a model we could use to engage physicians and create a strategy for improving physician education. I personally commit to being a forceful educator and advocate for safe prescribing of antibiotics by physicians.

Question 4.

As part of the FDA's Strategic Approach for Combatting AMR, the FDA released a five-year plan to support antimicrobial stewardship in veterinary settings. A key component of the five-year plan is the establishment of defined durations of use for animal drugs. Currently, roughly 1 in 3 medically-important antibiotics can be provided to animals for "very long or undefined durations of use"—increasing the likelihood of AMR. In June 2018, I introduced the Strengthening Antibiotic Oversight Act, a bill that would require the FDA to review the durations of use of medically-important antibiotics labeled for use in animals and withdraw approvals for antibiotics with unjustified duration limits. In April 2019, the FDA released a funding opportunity to help jumpstart the process of defining duration limits.

4a. If confirmed, will you commit to continue the implementation of the FDA's five-year plan to support antimicrobial stewardship in veterinary settings?

Answer 4a. Yes, I look forward to supporting the implementation of the FDA's five-year plan to support antimicrobial stewardship in veterinary settings.

4b. If confirmed, will you commit to finalizing defined durations of use for medically-important antibiotics in a timely manner?

Answer 4b. Yes, if confirmed, I will work to finalizing defined durations for use for medically-important antibiotics in a timely manner.

Question 5.

If confirmed, how will you evaluate the effectiveness of guidance designed to limit animal antibiotic overuse, including Guidance for Industry #209 and #213, and the Veterinary Feed Directive?

Answer 5. I will partner with the experts at CVM to establish meaningful metrics on the effectiveness of the guidance. One helpful metric the Agency currently collects to examine antibiotic utilization is the volume of sales data for antibiotics, but I would look forward to learning about other tools the agency could use to establish metrics and tools for measurement.

Question 6.

If confirmed, how will you direct the FDA to work with the Departments of Agriculture and Defense, among other executive agencies, to combat AMR?

Answer 6. No one country, organization, or company will be able to address AMR and I would rely on strong domestic partnerships with USDA and the Department of Defense, in addition to other executive agencies to combat AMR. If confirmed, I would first learn more about the Agency existing partnerships and discuss how we can build off of them.

II. Blood Donation Policy

Ensuring a safe and adequate blood supply is a critical aspect of our public health system. The FDA develops blood donation policy for the Nation's blood banks—a task that is even more important as we respond to emerging diseases 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. In June 2016, the FDA started collecting public input on scientifically sound solutions to risk-based screening, and the information collection period closed in November 2016. In 2019, the FDA solicited contractors to conduct an "HIV Risk Questionnaire (HRQ) Study" to assess the "predictive value of a panel of questions for recent infection with" HIV. Building on these steps will require leadership from the next FDA Commissioner.

Question 1.

As FDA Commissioner, how would you support the FDA's efforts to move to a risk-based referral policy for all blood donors?

Question 2.

Do you commit to respect the advice of the FDA's Blood Products Advisory Committee Meeting in their scientific findings and recommendations with regard to the safety and public health risks of blood donation?

Question 3.

Will you commit to developing a risk-based, on-site questionnaire to be used at blood donation clinics? What is the current status of the FDA's HRQ Study?

Question 4.

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?

Answers 1–4. I know how important it is to make sure there is a safe and ample donated blood supply. It is absolutely critical and life-saving to the American people. If confirmed, I will continue the work of the FDA to implement policies that ensure that we have access to a safe and adequate blood supply. I will also commit to continuing to work with FDA staff to review the donor policies to ensure they are up to date, and reflect current science and data.

The work of the Blood Products Advisory Committee (BPAC) is so critical, as it reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings. I commit to using the data provided by this Committee to driving the decision making surrounding blood product polices.

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.

III. Clinical Trial Data Transparency

Increased sharing of clinical trial data could strengthen academic research, improve the practice of medicine, and protect the integrity of the clinical trials system. Noting the potential benefits of increased transparency, leading medical journals have begun to require authors to disclose their plans to share de-identified data from their studies as a condition for publication. Furthermore, a new scorecard tool that rates companies on their ethics and transparency practices has spurred some pharmaceutical companies to improve their reporting practices. Unfortunately, some efforts to improve data sharing have been hampered by incomplete compliance with Federal requirements. The Food and Drug Administration Amendments Act (FDAAA) of 2007 required trial results to be registered and reported on ClinicalTrials.gov, with penalties up to $10,000 per day for non-compliance, but despite uneven compliance, the FDA has never levied a monetary penalty or withheld research funding for researchers who failed to meet the registration requirements. 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, and in September 2018, it published draft guidance on the circumstances and process by which the agency would seek civil money penalties against researchers who fail to submit results or submit false or misleading information.

Question 1.

What do you believe the impact of greater transparency of clinical trial data and results would be on clinical trial efficiency, the cost of drug development, drug safety, and biomedical innovation?

Question 2.

If confirmed, what specific steps will you take to increase sharing of clinical trial data?

Question 3.

Currently, the FDA allows applicants to release the complete response letters they receive in response to their applications, but does not require the letters to be made public.

a. What would be the impact of making complete response letters publicly available on clinical trial efficiency, the cost of drug development, drug safety, and biomedical innovation?

b. If confirmed as Commissioner, will you commit to making complete response letters publicly available?

c. If confirmed, what specific steps will you take to make complete response letters publicly available?

Question 4.

If confirmed, how will you ensure compliance with the disclosure policy implemented by FDAAA and the September 2018 guidance? Will you enforce the law using civil monetary penalties or by other means?

Answer 1–4. Thank you for your questions regarding transparency of clinical trial data. As a clinical trialist, I understand the importance of transparency and the sharing of information to spur new research. Transparency is critical to advancement of science and medicine. FDA has announced a pilot program to evaluate whether disclosing certain information included within a clinical study report improves public access to drug approval information. The FDA also announced it will add the ClinicalTrials.gov identifier numbers to FDA materials for future FDA drug approvals so that members of the patient, academic, and scientific communities can learn more about the drug's development. If confirmed, I will work with Agency staff to determine what can be done to build upon the recent progress by the agency to enhance transparency of clinical trial information. If fortunate to be confirmed as Commissioner, my decision-making will be guided by science, data and the law.

IV. Drugs

Drug Pricing

Millions of Americans are struggling with the high cost of prescription drugs. Nearly one in four Americans taking prescription drugs "report difficulties affording their medications," and according to a recent poll conducted by the Kaiser Family Foundation, at least three in ten adults reported skipping drug doses, delaying filling prescriptions, or taking less of a drug than prescribed to save money. As the agency responsible for evaluating the safety and efficacy of brand-name, generic, and biosimilar drugs, the FDA has a role to play in government-wide efforts to lower the costs of drugs for American families.

Question 1.

In your view, what role should the FDA play in efforts to lower prescription drug prices?

Question 2.

If confirmed, what steps will you take to help lower the cost of drugs for American consumers?

Question 3.

If confirmed, how will you work with other agencies within HHS and the executive branch as a whole to coordinate and develop policies designed to reduce prescription drug costs?

Response to 1–3. Thank you for these questions. High prescription drug prices and affordability are a significant problem and addressing this issue through a variety of means has been a priority of Congress, the administration and the Department. I agree that strong action is needed to address this issue. It's also important to ensure that whatever solutions we consider, do not have the unintended consequences of stifling innovation and the development of new medical products for the American people. There are indirect ways that FDA can assist in lowering prescription drug prices such as facilitating innovation and competition. As you know, FDA has a Drug Competition Action Plan and I look forward to working with Congress and career staff on this plan. I am particularly supportive of introducing more competition to help reduce drug prices including generic approvals, working to improve the biosimilar pathway, and ensuring that there is transparency and a clear regulatory pathway, not game-playing in the generic and biosimilar spaces. I look forward to working with you on measures to reduce high prescription drug prices. I will make this a priority and do all that I can as FDA commissioner to ensure access of medical products for all Americans.

Drug Shortages

In recent months, a number of high-profile drug shortages have dominated the news, including shortages of immune globulin and vincristine. According to the American Society of Health-System Pharmacists, there have been more than 100 drug shortages per year since 2007. In 2018, the number of drug shortages reached 186, the second highest since the peak of 267 drug shortages in 2011. In addition to harming patients, shortages cause severe financial burdens for hospitals. A recent survey of 700 hospital pharmacy managers found that all of them experienced a drug shortage in the previous year—forcing 81 percent of the pharmacy managers to hoard medications and 66 percent to ration medication. Every year, drug shortages cost hospitals $216 million in labor costs and an additional $200 million to substitute drugs in shortages. In October 2019, the FDA released a report, "Drug Shortages: Root Causes and Potential Solutions." The report identified three "root causes" of drug shortages, including (1) a "lack of incentives to produce less profitable

drugs" (a problem that is particularly acute in the antibiotics market); (2) the market's failure to adequately "reward manufacturers for mature quality management systems"; and (3) "logistical and regulatory challenges" that "make it difficult for the market to recover after a disruption." The report identified three potential solutions to prevent drug shortages and highlighted existing FDA efforts to combat shortages.

Question 1.

If confirmed, will you commit to making the prevention of drug shortages a top priority at the FDA?

Answer 1. I commit that, if confirmed, I will prioritize the prevention and alleviation of drug shortages. I will bring the perspective of a physician who has had to make changes to my patients' treatments because of drug shortages.

Question 2.

If confirmed, what specific steps will you take to combat drug shortages in the brand-name and generic drug marketplaces, respectively? What additional steps will you take to address the unique challenges facing manufacturers of antibiotics?

Answer 2. I found FDA's recent report on the root cause of drug shortages to be very informative. This is not a new issue nor is it one that will be solved with a single action. But I am optimistic that with the commitment I have seen from Congress, we can make progress.

Question 3.

If confirmed, how will you direct the FDA to work with Federal agencies, Congress, manufacturers, and other stakeholders to implement the recommendations included within the 2019 report?

Answer 3. If confirmed, I will work to take the next steps recognizing that the solutions may require FDA to work with a number of stakeholders including Congress. I commit to prioritizing this work. The first action I would take is it to consult with the staff at FDA, and I believe I will bring a new perspective.

Question 4.

In July 2018, then-Commissioner Gottlieb stated that the FDA would "be looking at whether it makes sense to develop a critical drugs list, or a list of essential drugs where it would be especially important, from a clinical perspective, to ensure an uninterrupted drug supply."

4a. What is the current status of this "critical drugs list"?

Answer 4a. Although I cannot speak to the status of FDA's critical drug list, I see real promise in this initiative. I will bring an important perspective as an oncologist who has seen the real-life effects of drug shortages.

4b. If confirmed, will you commit to finalizing this "critical drugs list" to help combat drug shortages?

Answer 4b. If confirmed, I will commit to looking into the status of critical drugs to promote the public health.

Drug Supply Chain and National Security

Last week, the U.S. China Economic and Security Review Commission released a report highlighting "China's dominance as a global [active pharmaceutical ingredient] producer and the United States' growing reliance on Chinese pharmaceutical products." Active pharmaceutical ingredients (APIs) are the raw chemical components of drugs that "furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease." APIs are necessary to manufacture pharmaceutical products such as generic drugs and vaccinations. Despite the critical role of APIs in drug production, the U.S. "only makes about 20 percent of the APIs used in domestic pharmaceutical production." Instead, the U.S. relies heavily on China for the import of these materials.

Experts warn that the Nation's "growing reliance on Chinese pharmaceutical products puts U.S. consumers—including active service members and veterans—at risk." However, the FDA reportedly has little formal means for quality surveillance or oversight of Chinese manufacturers and drug plants.

Question 1.

Do you agree that the United States' reliance on Chinese pharmaceutical products places American consumers at risk? If so, what role do you believe the FDA should play in mitigating this risk?

Question 2.

If confirmed, what steps will you take to improve the FDA's ability to monitor the quality of imported pharmaceutical products, particularly those products produced in China? What steps will you take to ensure that the United States' supply line of these pharmaceutical products is secure and safe from disruption?

Question 3.

If confirmed, how will you direct the FDA to work with the Department of Defense and other executive agencies to address national security and public health risks posed by the Nation's reliance on Chinese pharmaceutical products?

Question 4.

In July 2018, then-Commissioner Gottlieb stated that the FDA would "be looking at whether it makes sense to develop a critical drugs list, or a list of essential drugs where it would be especially important, from a clinical perspective, to ensure an uninterrupted drug supply." Though this statement was made in the context of reducing drug shortages, a "critical drugs list" could also be helpful as the Federal Government analyzes the Nation's reliance on Chinese pharmaceutical products. If confirmed, what steps would you take to ensure that this list can be used to both prevent drug shortages and address national security and public health risks posed by the Nation's reliance on Chinese pharmaceutical products?

Answer 1–4. Thank you for your question. FDA's role is to ensure the safety of the drug supply. The U.S. has the safest drug supply in the world and if confirmed, I am committed to maintaining the safety of drugs and biologics used by the American people. According to recent testimony from FDA, as of August 2019, only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were in our country. By contrast, the remaining 72 percent of the API manufacturers supplying the U.S. market were overseas, and 13 percent are in China. I believe advanced manufacturing could help to bring this manufacturing back to the U.S. If confirmed, I look forward to working with the staff at the FDA, along with partnering with Congress, ASPR, BARDA, the Department of Defense and others to address this issue and ensure that the U.S. drug supply remains safe.

V. Ethics

With public trust in government at an all-time low, it is essential for public officials to hold themselves to the highest ethical standards. This is especially true for the FDA, given that the pharmaceutical industry spent record amounts on lobbying last year: the Pharmaceutical Research & Manufacturers of America spent $27.5 million, and the industry as a whole spent more than $194 million as of October 2018.

My Anti-Corruption and Public Integrity Act would require common-sense measures to avoid conflicts of interest for officials in positions of public trust to assure Americans that their government is working for them, and not for deep-pocketed lobbyists. I ask that if you are confirmed, you voluntarily comply with the conflict of interest and revolving door provisions of the Act to give the public confidence that your decisions at the FDA are in the best interest of patients and consumers, rather than lobbyists and corporations.

Question 1.

If confirmed, from what issues, if any, do you plan to recuse yourself due to your own or your family members' financial conflicts of interest?

Question 2.

If confirmed, will you commit to recusing yourself from all issues that could provide a financial benefit to your previous employer, M.D. Anderson Cancer Center?

Question 3.

If confirmed, will you commit to divesting from all individual stocks outside of widely held investment vehicles (such as mutual or index funds)?

Question 4.

If confirmed, will you commit to refraining from lobbying activities after your tenure ends?

Question 5.

If confirmed, will you commit to refraining from employment with any company that lobbied the FDA for at least one year?

Answer 1–5. 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 will also follow the Office of Government Ethics recommendations regarding my personal financial portfolio. I am committed to leading the FDA driven by science, data and the law, and will uphold the gold standard of the FDA that provides Americans peace of mind in the reliability of the FDA.

VI. FDA Workforce

FDA's work is supported by highly skilled, professional employees who uphold the agency's mission and protect public health in the United States.

Question 1.

If confirmed, will you work cooperatively with employees and employees' representatives, including unions?

Question 2.

If confirmed, will you meet with national leadership of employees' union representatives soon after you begin your duties?

Answers 1–2. The FDA's gold standard comes directly from the great men and women who make up the dedicated outstanding career workforce. If confirmed, I plan to make workforce issues a top focus and will immediately get to know the wonderful staff, and their representatives, to better understand the opportunities, challenges and needs that affect their work and mission. I will work with all appropriate stakeholders to ensure that FDA has the best and brightest to accomplish its mission.

VII. Over-the-Counter Hearing Aids

Approximately 48 million Americans experience age-related hearing loss, including over half of adults in their seventies. However, only an estimated 14 percent of Americans with hearing loss use hearings aids, primarily because they cannot afford to buy them. Medicare and most private insurance plans do not cover hearing aids, and out-of-pocket costs for a single hearing aid averaged $2,400 in 2015—far out of reach for many Americans. Furthermore, in 1977, the FDA issued regulations preventing individuals from purchasing hearing aids unless they had obtained a medical evaluation (or signed a waiver of that evaluation). These regulations meant that Americans could not purchase hearing aids over-the-counter.

To expand Americans' access to hearing aid technology, I introduced the Over-the-Counter (OTC) Hearing Aid Act with Senators Grassley, Hassan, and Isakson in March 2017. In August 2017, the bill was signed into law. The OTC Hearing Aid Act makes certain types of hearing aids available over-the-counter. It requires the FDA to issue regulations establishing safety and efficacy requirements for OTC hearing aids and to update and finalize its draft guidance, "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." The FDA must issue proposed regulations no later than August 2020 and must finalize its guidance when final regulations are issued.

Question 1.

If confirmed, will you commit to issuing the proposed regulations required under the OTC Hearing Aid Act in a timely manner and in compliance with statutory deadlines?

Answer 1. I commit to following the laws of Congress.

Question 2.

If confirmed, will you commit to finalizing the draft guidance on personal sound amplification products in a timely manner and in compliance with statutory deadlines?

Answer 2. I am not privy to current decision making of the FDA. If confirmed, I look forward to looking into this matter and reporting back to you.

Question 3.

If confirmed, what additional actions will you take to expand access to affordable hearing aid technologies?

Answer 3. I'd like to know more about this and am open to having conversations that science and data would provide to provide Americans with the safest and most effective medical products.

VIII. Medical Devices

Pre-Cert for Software Pilot Program

The FDA has established a "Software Pre-Cert Pilot Program" to test the feasibility of altering the traditional device approval pathway for certain software as medical devices (SaMD). Senator Murray, Senator Smith, and I have repeatedly communicated with the FDA about the Pre-Cert Pilot, and we continue to have concerns about the program's impact on public safety and its compliance with existing statute. Specifically, these concerns relate to: (1) the agency's ability to ensure public safety under a "precertification" regime, particularly through its proposed "Excellence Appraisals"; (2) the appropriateness of the De Novo pathway as a statutory basis for the pilot; and (3) the agency's use of real world performance to assess the safety and efficacy of SaMD devices approved through the pilot. Most recently, in October 2019, we sent a letter to the FDA requesting information about the program.

Question 1.

If confirmed, will you commit to re-examining the Software Pre-Cert Pilot Program to assess its compliance with existing statutory authorities?

Answer 1. If confirmed, I commit to working closely with staff at the FDA, and the Department of Health and Human Services, and all other appropriate parties to ensure that all programs at FDA are in compliance with existing law. I strongly believe in FDA's ability to advance tools that give patients more information about their own health, and I will support FDA's efforts to do so within its existing statutory authority.

Question 2.

Please provide detailed answers to the questions included in the October 2019 letter referenced above, which include:

a. Since responding to us in June 2019, has the FDA gained additional clarity on the type of data or evidence that would be appropriate—and inappropriate—to demonstrate excellence during an Excellence Appraisal? If so, please describe the type of data or evidence that the agency is considering. If not, please provide a description of the steps the agency will take to identify this type of data or evidence.

b. Since responding to us in June 2019, has the FDA gained additional clarity on how it will "appropriately limit" the flexibility granted to entities seeking to demonstrate excellence via an Excellence Appraisal?

c. As part of its retrospective testing, the "Pre-Cert team developed a mock Excellence Appraisal summary" for pilot participants that had previously received FDA approval for a SaMD regulatory submission. The team developed these summaries "based on the pilot participant site visits and public comments."

i. Please provide a copy of each "mock Excellence Appraisal summary" developed as part of this retrospective testing, including a copy of all "public comments" used to develop these summaries.

ii. What data or evidence did the Pre-Cert team review during pilot participant site visits, and how did this data or evidence contribute to the reviewers' ability to determine whether the pilot participant complied with the Excellence Principles? Does the agency believe it has the authority to collect and review all of the data and evidence it examined during the site visits and anticipates examining in future site visits?

iii. In developing these summaries, how much flexibility—if any—did the agency grant pilot participants in demonstrating compliance with the Excellence Principles? How did granting this flexibility to participants impact the data or evidence examined during the Pre-Cert team's site visits? Was the data or evidence standardized across all sites, or did it vary from site to site?

iv. The FDA concluded that its retrospective tests demonstrated the "feasibility" of the Excellence Appraisal (along with the Streamlined Review) "to be sufficient to conduct a premarket review of SaMD."

v. How did the FDA determine that the Excellence Appraisal was "sufficient"?

vi. What would "failure" of the Excellence Appraisal have looked like during this retrospective testing?

d. The FDA is currently engaged in "prospective testing" of the precertification model. This testing involves simultaneously reviewing SaMD submissions using both the traditional and Pre-Cert approval pathways. In July 2019, the FDA announced that, based on its tests, "the elements identified in the [Working] model can be demonstrated and provide a comprehensive view of an organization's capabilities."

i. Please provide a summary of all Excellence Appraisals performed under the FDA's prospective testing to date. For each Excellence Appraisal, please provide a list of the data and evidence used—including KPIs—to demonstrate adherence to each element and principle listed in the Working Model.

ii. In the Excellence Appraisals it has performed so far, what type of data or evidence has the FDA relied on to "demonstrate" the elements identified in the Working Model?

iii. Has this type of data or evidence been consistent across all of the Excellence Appraisals? If not, what flexibility has the FDA allowed in the type of data or evidence used to demonstrate the elements?

e. In July 2019, the FDA announced that it "has learned" based on testing "that some of the elements [of the Excellence Appraisal] may need to be separated or removed."

i. Which elements of the Excellence Appraisal is the FDA considering "separating" from the appraisal? Why? How will the FDA separately assess companies' compliance with those elements?

ii. Which elements of the Excellence Appraisal is the FDA considering "removing" from the appraisal? Why?

f. In its Working Model, the FDA states that it "does not intend to make individual organizations' KPI reports or results available publicly, to the extent consistent with the Freedom of Information Act." In its July 2019 update, it also described Excellence Appraisals as "confidential."

i. On what basis would the FDA withhold Excellence Appraisals—and the KPIs used to develop them—in whole or in part from public disclosure under the Freedom of Information Act?

ii. What information, if any, does the FDA anticipate providing the public about Excellence Appraisals should the Pre-Cert Pilot Program extend beyond the pilot stage?

g. The FDA has proposed utilizing third parties to conduct precertification assessments in cases where it "can identify existing entities with the capacity and expertise to conduct a Pre-Cert appraisal"—though it will not be doing so "in the first phase of implementing the Software Pre-Cert Program." In its June 2019 response, the FDA notes that the "FD&C Act currently authorizes a third-party review program for 510(k) submissions and for accrediting third part[ies] to perform inspections of eligible device manufacturers so the concept is not entirely new." It also states that the agency "will consider whether the future use of third parties would be consistent with our existing statutory authorities." Has the FDA determined whether allowing third-party entities to conduct precertification assessments during the Pre-Cert Pilot Program would "be consistent with existing statutory authorities"?

h. Given the FDA's assertion that the De Novo pathway was established "to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation," does the agency believe that Congress intended for the pathway to be used to establish pilot programs that fundamentally alter the FDA's existing method of device review and approval? If so, please explain why.

i. Since the De Novo pathway was established in 1997, how many times has the FDA used it as the statutory basis to establish a pilot program? Please provide a summary and the outcomes of all pilot programs identified.

j. The December 2018 proposed rule lists a series of content requirements for a De Novo request (proposed 21 CFR 860.234). For each requirement listed in the proposed rule, please indicate whether a manufacturer participating in the Pre-Cert Pilot Program would be required to provide information fulfilling the requirement during an Excellence Appraisal or during a subsequent De Novo submission. Please also indicate whether a manufacturer participating in the Pre-Cert Pilot Program would be required to pro-

vide information not included in the content requirements for a De Novo request as outlined in the December 2018 proposed rule.

k. In its Working Model, the FDA has proposed two levels of precertification "based on an organization's excellence": "Level 1 Pre-Cert" would "allow organizations to develop and market certain lower risk software without review while requiring a streamlined review for other types of software," and "Level 2 Pre-Cert" would "allow organizations to develop and market certain lower and moderate risk software without review while requiring a streamlined review for other types of software." Please indicate how the content requirements for De Novo requests outlined in section 513(f) of the FD&C Act and the December 2018 proposed rule would be met by Level 1 Pre-Cert and Level 2 Pre-Cert organizations that develop and market software without review.

l. The Pre-Cert Pilot Program proposes utilizing the De Novo pathway in ways that are not identified in the December 2018 proposed rule—most notably, through the receipt of required information periodically rather than all at once. How would the standards and processes described in the proposed rule, if implemented as written, affect the agency's ability to utilize the De Novo pathway for the Pre-Cert Pilot Program, given that they do not mimic the Excellence Appraisal and Streamlined Review used in the pilot?

m. The FDA proposed its De Novo Classification rule in December 2018—over one year after the agency first proposed the Pre-Cert Pilot Program in August 2017. However, the proposed rule does not mention the Pre-Cert Pilot Program, which proposes to utilize the De Novo pathway in novel ways. Why did the FDA not mention the Pre-Cert Pilot Program, and its novel use of the pathway, in its December 2018 proposed rule?

n. During the pilot, and if the Pre-Cert Program extends beyond a pilot, how does the FDA plan to ensure that the RWPA it receives from organizations are accurate, timely, and based on all available information?

o. In its 2019 response, the FDA stated that it was "still working to identify all the right information and data elements to be shared before" it addressed the "mechanisms" by which the FDA and companies would exchange data. Since June 2019, has the FDA identified the right information and data elements?

p. In its Working Model, the FDA states that post-market RWPA may form the basis of a change in claims and labeling. Please provide greater detail on the evidence that would be required to support such changes.

q. Why is the FDA not requiring Pre-Cert pilot participants to share data with the National Evaluation System for health Technology (NEST)?

r. Will the FDA retain the right to request and obtain all raw data collected by participants as part of the Pre-Cert Pilot Program?

Answer 2. Although I am not currently a part of the administration and cannot speak to the specifics of the agency's current thinking, what FDA considered in establishing the program, or what FDA has learned since establishing this program, I can commit to working closely with Congress in a transparent and accountable manner on this program. I agree that patient safety and sound science must be a top priority as FDA considers medical software products.

Progressive Approval Pathway

Following the enactment of the Minor Use and Minor Species Animal Health Act in 2004, the FDA established a "conditional approval" pathway to accelerate the development of animal drugs in commercially limited markets. Under the conditional approval pathway, manufacturers developing drugs for certain animal species have been able to bypass traditional FDA approval processes and market qualifying drugs without fully demonstrating their effectiveness. To receive conditional approval, manufacturers must only demonstrate that a drug has "a 'reasonable expectation of effectiveness'"—a lesser standard than the "substantial evidence of effectiveness"; upon receiving conditional approval, manufacturers have been able to market their drugs for up to five one-year terms as they continue to gather the data necessary to meet the "substantial evidence" standard.

In August 2018, the Animal Drug User Fee Act further expanded the conditional approval pathway by creating a 10-year pilot expansion program that allows certain other animal drugs to qualify. At the time, I joined Senator Murray in strongly ob-

jecting to any expansion of the conditional approval pathway to human medical products—and the HELP Committee received assurances from then-Commissioner Scott Gottlieb that the FDA would not extend the pathway to human drugs or devices. In a July 2018 letter, Commissioner Gottlieb wrote that the "FDA does not believe this pathway would be suitable for human medical products."

Despite Commissioner Gottlieb's assurances, however, the FDA's Fiscal Year 2020 budget justification referenced an FDA proposal called "progressive approval for devices" which, as written, seemed hardly distinguishable from the "conditional approval" pathway. In June 2019, Senator Murray and I sent a letter to the FDA requesting information about the program. After receiving a response in August 2019, we sent a follow-up letter requesting additional information in November 2019.

Question 1.

Do you agree that assuring patient safety and device effectiveness must be the primary goal of any device approval system managed by the FDA?

Answer 1. FDA must continue to operate under its mission to protect and promote patient health, and I believe that it can only do so by making safety and efficacy the top priority in product review and approval programs.

Question 2.

Do you believe that developing a "progressive approval" pathway for medical devices contributes to or detracts from the FDA's goal of assuring patient safety and device effectiveness?

Answer 2. I look forward to learning more about this policy and the FDA's current thinking on this issue. If confirmed I will work with FDA staff to assess the progressive approval pathway in order to conclude how it will impact the FDA's mission.

Question 3.

If confirmed, will you commit to re-examining the "progressive approval" proposal included within the FDA's fiscal year 2020 budget justification to determine whether it adequately safeguards patients?

Answer 3. If confirmed, I commit to examining all policies that come before me with a focus on patient safety and public health protection.

Question 4.

Please provide detailed answers to the questions included in the November 2019 letter referenced above, which include:

a. The FDA envisions progressive approval as a pathway that would "expedite[] access to devices intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition and address an unmet medical need."

i. For the purposes of the progressive approval pathway, how would the FDA define "unmet medical need"?

ii. In its August 21st response, the FDA repeatedly uses the example of children as an example of a population underserved by existing medical device pathways. Does the FDA envision limiting the progressive approval pathway to certain populations, such as children? If so, please provide an overview of the populations the FDA is considering.

iii. Does the FDA envision limiting the progressive approval pathway to disease populations with a certain number of patients, similar to the Humanitarian Device Exemption pathway? If so, please provide an overview of the numbers the agency is considering.

iv. What additional limits, if any, is the FDA considering on the populations and devices eligible for the progressive approval pathway?

b. In its August 21st response, the FDA pointed to the limited success of the Humanitarian Device Exemption (HDE) pathway in spurring device innovation to justify the need for a progressive approval pathway. The agency notes that the HDE pathway, as "the only existing regulatory marketing pathway intended to support medical device innovation for small populations like pediatric patients," does "not adequately meet the needs of children." It continues to state that, "despite multiple actions by Congress . . .[to] optimize the potential of the HDE program to help small patient populations . . . there has been no significant change in the number of Humanitarian Use Device (HUD) or HDE applications submitted or approved." In contrast, the agency states, "progressive approval would foster safe innovation in medical devices to meet many unmet needs."

i. What are the primary economic challenges facing device makers interested in producing devices for small, underserved populations, such as pediatric patients? For each economic challenge identified, please describe which aspects of the progressive approval pathway (as envisioned by the FDA) would mitigate the challenge and increase the number of devices available to these populations.

ii. What specific aspects of the HDE pathway have made it unsuccessful at increasing the number of devices available to these populations? Could modifications to the HDE pathway address the problems in product development that the FDA has identified as necessitating the conditional approval pathway? If so, what are these modifications? If not, why not?

iii. What additional policies, if any, should Congress consider in an effort to expand the types of devices available to these populations?

c. In its initial description of the progressive approval pathway, the FDA stated that devices approved via the pathway would "be eligible for provisional approval . . . and could remain on the market after an established time period only after a demonstration of reasonable assurance of safety and effectiveness." In its August 21st response, the agency narrowed down the established time period to "up to three years." How did the FDA decide upon the three-year provisional approval period?

d. According to the FDA's initial description of the progressive approval pathway, in cases where a device sponsor could *not* "demonstrate reasonable assurance of safety and effectiveness," the device's "initial approval would automatically sunset and the device could no longer be legally marketed."

i. What challenges, including those presented by patients, physicians, sponsors, investors, and other device industry stakeholders, does the agency anticipate could arise in cases where the agency seeks to remove provisionally approved devices from the market?

ii. How could uncertainty concerning the possible removal from the market of a device that has received provisional approval under the progressive approval pathway limit the pathway's ability to mitigate the economic forces inhibiting device development described in Question 2?

e. In its August 21st response, the FDA states that the progressive approval "proposal would provide accountability to ensure that devices demonstrate a reasonable assurance of safety and effectiveness to remain on the market." The FDA also indicated that a device sponsor using the progressive approval pathway "would be required to collect additional information through a registry, electronic health records (EHRs), or another source of real-world data on more patients and for a longer duration than the time period for obtaining the initial, provisional approval, and then demonstrate a reasonable assurance of safety and effectiveness."

i. Please provide a complete summary of the oversight that the FDA envisions conducting on progressive approval pathway participants to ensure that safety and effectiveness standards are met. What resources would be necessary to make this post-market surveillance effective?

ii. Independent audits of the FDA's expedited approval pathways by the HHS Office of Inspector General and the U.S. Government Accountability Office have revealed challenges associated with implementing post-marketing requirements and indicate the need for better oversight measures. How would the FDA ensure that post-market studies of provisionally approved devices are completed in a timely manner?

iii. A recently published analysis of the Manufacturer and User Facility Device Experience (MAUDE) database has underscored the challenges of post-market data collection, including the underreporting of adverse events. The analysis also found a significant degree of miscategorization of deaths as reports of injury and malfunction. If safety determinations will be made at least in part through post-market data collection and analysis, what will the FDA do to ensure that the information provided by sponsors is accurate—especially when there is a significant incentive for them to underreport and misclassify adverse events?

iv. Is it the agency's view that real-world evidence would be sufficient to demonstrate "a reasonable assurance of safety and effectiveness"? If so, what precedent, if any, is there for relying exclusively, or almost exclu-

sively, on real-world evidence to support the initial approval or clearance of a device?

v. The FDA notes in its response that the labeling for a provisionally approved device "would have to make clear that the medical device [meets] only the safety and performance standard, rather than the reasonable assurance of safety and effectiveness standard, to allow patients and health care professionals to make informed decisions." What, if any, additional patient protections does the FDA envision being necessary for devices possessing only provisional approval?

vi. In the agency's view, are EHRs sufficiently widespread (and interoperable) that the FDA can rely on them for data collection for the purposes of the progressive approval pathway? If not, what could Congress and HHS do to increase the reliability of EHRs as a data collection tool?

vii. In the agency's view, are device registries sufficiently widespread and well-developed such that the agency can rely on them for data collection for the purposes of the progressive approval pathway? If not, what could Congress and HHS do to increase the reliability of registries as a data collection tool?

f. What additional data sources are the FDA considering using to collect data for the progressive approval pathway?

g. In its August 21st response, the FDA notes that the agency "is in an ideal position to continue leveraging [real-world evidence], in part, due to its work to develop the National Evaluation System for health Technology (NEST)."

i. Does the FDA plan to require sponsors seeking progressive approval to share data with NEST? If not, why not?

ii. In the agency's view, is NEST sufficiently well-developed such that the agency could rely on it for data collection for the purposes of the progressive approval pathway? If not, what could Congress and HHS do to increase the reliability of NEST as a data collection tool?

Answer 4. Although I am not currently a part of the administration and cannot speak to the specifics of the agency's thinking or views, if I am confirmed, I commit to working closely with FDA staff to understand this issue and to ensure that any actions taken by the agency are grounded in sound science and the best available data. It will be my top priority to uphold the FDA's mission and adhere to its gold standard for safety and efficacy. I will also commit to getting you detailed answers to these questions promptly.

Third-Party Servicing of Medical Devices

Some medical devices, such as patient examination gloves, are disposable or designed to be used only once. Other devices, however, are used repeatedly and on multiple patients. Original equipment manufacturers (OEMS) and third party entities often refurbish, repair, recondition, rebuild, remarket, or remanufacture these devices to ensure that they continue to operate safely and effectively after entering the market.

Entities that perform maintenance activities face different regulatory requirements depending on the type of maintenance being performed. Activities that "significantly change" the performance, safety specifications, or intended use of a finished device are considered "remanufacturing." Remanufacturers, which can include OEMs and third party entities, must comply with numerous FDA requirements to ensure the safety of remanufactured devices. Activities that do *not* "significantly change" the performance, safety specifications, or intended use of a device—but instead provide "preventive or routine maintenance . . . for the purpose of returning [a finished device] to the safety and performance specifications established by the OEM and to meet its original intended use"—are considered "servicing." Third-party servicers are not subject to the same safety and reporting requirements as remanufacturers. In May 2018, in response to Section 710 of the FDA Reauthorization Act of 2017 (Public Law No. 115–42), the FDA issued a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing. The report noted significant stakeholder confusion over the difference between "servicing" and "remanufacturing." In response, the FDA announced that it would publish guidance clarifying the difference between "servicing" and remanufacturing" to "allow more consistent interpretation and clarification."

The FDA original announced that it would issue draft guidance by the end of Fiscal Year 2019; however, draft guidance is now on the agency's list to release in Fiscal Year 2020. In October 2019, Senator Cassidy and I sent a letter to the agency requesting information about the guidance.

Question 1.

If confirmed, will you commit to publishing draft guidance on distinguishing between medical device servicing and remanufacturing in a timely manner and no later than the end of Fiscal Year 2020?

Answer 1. If confirmed, I will commit to engaging with FDA's professional staff the information available that is related to this issue. I will prioritize taking steps to provide clarity to the public on the difference between servicing and remanufacturing in a timely manner. 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 effectiveness of medical devices.

Question 2.

Please provide detailed answers to the questions included in the October 2019 letter referenced above, which are:

a. In its May 2018 report, the FDA stated that "[a] majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing."

i. If so many entities believed to be involved in "servicing" are actually "remanufacturing" devices, and FDA has said "the precise number of entities that perform servicing of medical devices in the U.S. is not known," how does FDA intend to identify the universe of actors to whom its upcoming guidance will apply?

ii. How does the FDA intend to educate those entities who are unknowingly involved in remanufacturing activities about their obligations when the upcoming guidance is released?

b. The FDA has estimated approximately 16,000 to 20,000 entities are engaged in servicing activities. How will the FDA promote compliance with the guidance by those entities who consider themselves as only servicers but who may in fact also be involved in remanufacturing?

c. What surveillance mechanisms are available to the FDA to detect servicers who are also performing remanufacturing?

d. What actions does the FDA currently take if it identifies unregistered entities engaged in remanufacturing? What, if any, new options for action are under consideration?

Answer 2. Although I am not currently a part of the administration and cannot speak to the specifics of the agency's intentions, current thinking, or activities, I can commit to working closely with Congress in a transparent and accountable manner on this program.

Unique Device Identification System

In 2007, Congress instructed the FDA to establish a "unique device identification system for medical devices" to better track medical device outcomes and adverse events. In response, the agency developed a system requiring device labels and packages to include Unique Device Identifiers (UDIs). UDIs include both a device identifier (DI), a "fixed portion of a UDI" that identifies the "specific version or model of a device," and a production identifier (PI), a "variable portion of a UDI" that identifies information about a device's expiration date, serial number, and lot or batch number.

For years, Members of Congress have advocated for the inclusion of UDI information in electronic health records and insurance claims forms. Insurance claims forms capture longitudinal data on patient outcomes across healthcare providers and are a critical component of the FDA's efforts to establish the National Evaluation System for health Technology (NEST). However, claims forms—including the Medicare claim form—do not currently have a field to record UDIs. This lack of ability to track device outcomes is costly for taxpayers. A 2017 investigation by the Office of the Inspector General at the Department of Health and Human Services found that recalls or premature failures of just seven faulty cardiac devices resulted in $1.5 billion in Medicare payments to providers and $140 million in out-of-pocket costs to beneficiaries. Moreover, the report was not able to examine the total cost of all de-

vice failures because of the lack of information about specific devices in claims data. The examiners were able to assess the impact of the seven devices included in the report only through a "complex and labor-intensive" audit. Ultimately, The OIG recommended that the Center for Medicare and Medicaid Services (CMS) collaborate with the Accredited Standards Committee X12 (X12), which sets standards for electronic claims, to include medical devices' unique device identifier (UDI) on health insurance claim forms. Last month, X12 released draft recommendations to incorporate the device identifier portion of the UDI of high-risk implantable medical devices in claims forms.

The FDA has historically supported the inclusion of UDI information on claims forms. In a July 2016 joint letter to X12, the FDA and CMS identified several benefits to collecting device identifiers on medical claims forms. The agency agreed to develop a list of specific, high-risk implantable devices for which reporting on claims will be recommended and in 2018 released a Medical Device Safety Action Plan highlighting the benefits of UDI information to post-market surveillance. Furthermore, in a November 2018 letter, then-Commissioner Gottlieb stated that the FDA "supports the incorporation of the full Unique Device Identifier (UDI) into claims forms and believes, at a minimum, the DI portion of the UDI should be included."

Question 1.

Do you agree that including device identifier information in medical claims could support the evaluation of medical devices after approval?

Question 2.

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?

Question 3.

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 and patient health?

Answers to 1–3. I believe FDA should take every step possible to enhance the agency's ability to capture comprehensive and accurate post-market data on all medical products, including devices. If confirmed I will work with FDA staff as well as CMS to understand their work to date on the incorporation of full unique device identifiers into claims forms, and I will make it a priority to ensure there is a process in place to achieve the best outcome for patients.

IX. Opioids

Opioid Epidemic

For decades, the United States has found itself in the midst of the opioid epidemic—a public health crisis that takes dozens of lives and impacts countless families each day. Massachusetts has been greatly impacted by this epidemic, leading local and state officials to work closely with first responders, health care providers, and community advocates to develop a comprehensive approach to help those suffering from substance use disorder access treatment and recovery services. The Massachusetts Department of Public Health (DPH) estimates that there were 1,974 opioid overdose deaths in Massachusetts in 2019—a 4 percent reduction from 2018. Despite this decrease, it is critical that we continue to provide support to states like Massachusetts through the work of relevant Federal agencies, and with congressional action to provide adequate resources to tackle this crisis.

Question 1.

If confirmed, what FDA authorities will you use to help address the opioid crisis?

Answer 1. Thank you for your question. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. An evidence-based holistic approach to treating pain with non-opioid medications, behavioral therapies, and when appropriate, opioids is now being used effectively in many medical settings to effectively

treat pain. We have new ways of prescribing pain medications that create a balance between relief of suffering and preventing addiction. There is outstanding research being performed on addiction and the causes of pain. I am optimistic that even better approaches will be developed in the future. That being said, we are still dealing with a devastating and urgent crisis with opioids. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I understand that FDA is also evaluating other activities that could be helpful including setting standards for new opioid approvals, additional doctor education, and revising regulatory procedures for mandatory recall authority of opioids that have a substantial risk for adverse health consequences or death. I am supportive of efforts by the agency to help innovators of non-opioid alternatives for pain control and abuse-deterrent formulations because we cannot forget the importance of safely helping Americans with pain syndromes. I am also supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT in a holistic therapy setting. I have cared for numerous patients with serious and debilitating pain, and understand that we must strike a balance between maintaining patients' access to effective opioid drugs and non-opioid alternatives, while reducing misuse and abuse of opioid drugs.

Question 2.

If confirmed, how will you work with other Federal agencies, such as the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA), to develop an administration-wide approach to the opioid crisis that is evidence-based?

Answer 2. If confirmed, I look forward to working across the Department and the administration to address the opioid crisis. The Department of Health and Human Services currently has a five point strategy for addressing the opioid crisis. HHS' five point strategy aims to: (1) Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to help individuals to achieve long-term recovery; (2) Target the availability and distribution of overdose-reversing medications (3) Strengthen public health data collection and reporting (4) Support cutting-edge research that advances our understanding of pain and addiction, and (5) Advance the practice of pain management. I believe the FDA should contribute to this overarching strategy by utilizing the authorities provided by Congress, including through the SUPPORT Act. Additionally, the FDA and DEA should continue to work together to combat the sale of illicit opioids online.

Question 3.

If confirmed, what will you do to accelerate FDA review of alternative therapies to chronic pain, while still ensuring that those who require such medications receive it?

Answer 3. Thank you for your question. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. An evidence-based holistic approach to treating pain with non-opioid medications, behavioral therapies, and when appropriate, opioids is now being used effectively in many medical settings to effectively treat pain. We have new ways of prescribing pain medications that create a balance between relief of suffering and preventing addiction. There is outstanding research being performed on addiction and the causes of pain. I am optimistic that even better approaches will be developed in the future.

Question 4.

Earlier this year, the FDA announced a public education campaign, "Remove the Risk," aimed at encouraging individuals to safely dispose of unused prescription medications in their home. This announcement noted that "in 2017, retail pharmacies dispensed more than 191 million opioid prescriptions to almost 60 million patients as many as 90 percent of these patients reported not finishing what was

prescribed to them." If confirmed, what will you do to enhance these ongoing FDA efforts to encourage Americans to safely dispose of unused medications?

Answer 4. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. I have seen the significant benefits of physician education on the topic of opioid prescribing. If confirmed, I am committed to continuing FDA's successful efforts, including educational efforts, to address the opioid crisis in addition to working with agency staff to determine additional opportunities for FDA to address the opioid crisis, including through encouraging the safe disposal of unused medications.

Over-the-Counter Naloxone

Over 130 Americans die each day as a result of an opioid overdose. Naloxone is an easy-to-use, life-saving drug that reverses the toxic effectives of an opioid overdose. Currently, naloxone is only available via prescription, yet doctors and public health administrators across the country have called for the provision of an over-the-counter (OTC) naloxone product to help combat the rising number of opioid-related deaths. In January 2019, the FDA issued a series of documents to "encourage drug companies to enter the OTC market," including two model "consumer-friendly" Drug Facts labels (DFLs), which are required—along with studies showing "that consumers can understand how to use the product without the supervision of a health care professional"—before a product can be marketed over the counter.

Question 1.

Do you agree that increased access to naloxone, including making it available over the counter, could meaningfully prevent and reduce deaths associated with the opioid crisis?

Question 2.

If confirmed, will you continue existing FDA efforts to expand access to OTC naloxone?

Question 3.

What additional steps could the FDA take to expand access to all types of naloxone, including OTC naloxone?

Question 4.

What efforts does the FDA have underway to encourage physicians to co-prescribe naloxone with opioid medication? What additional steps can the FDA take to safely facilitate increased rates of co-prescribing of naloxone with opioid medication?

Question 5.

How can the FDA encourage manufacturers to continue expanding access to all types of naloxone, including OTC naloxone and generic naloxone products?

Answers to 1–5. Thank you for your questions. I agree that naloxone is a critical and life-saving drug that can prevent and reduce overdose deaths. In January, in order to spur the development of OTC naloxone, FDA designed, tested and validated the key labeling requirements necessary to approve an OTC version of naloxone. I applaud the FDA's actions to make it easier for manufacturers to development an OTC naloxone amidst this urgent public health crisis, and if confirmed, I would seek actions that FDA can appropriately take to remove any additional barriers to approving an OTC naloxone. I am also supportive of HHS' recommendation in December 2018 to prescribe or co-prescribe naloxone to patients at high risk for an opioid overdose. If confirmed, I would also work with other agencies within HHS to support increase education and access for this life saving drug.

X. Reproductive Health

The United States is facing a maternal mortality and morbidity crisis. Women in the United States die as a result of pregnancy and childbirth at a higher rate than in any other developed country, and in the past twenty years, our Nation's maternal mortality rate has doubled—making it the only industrialized nation with an increasing maternal mortality rate.

Unfortunately, information about how to treat conditions in pregnancy is profoundly limited and very few drugs are approved for use during pregnancy. In large part, this is due to the fact that women, and especially pregnant and lactating individuals, have historically faced systemic barriers to participating in clinical trials.

Question 1.

What do you believe the impact of greater inclusion of pregnant and lactating women in clinical trial data and results would be on drug safety and biomedical innovation?

Question 2.

If confirmed, what efforts will you undertake to improve the inclusion of women and pregnant individuals in clinical trials?

Question 3.

What specific plans do you have to implement the goals, priorities, and recommendations of the Federal Task Force on Research Specific to Pregnant Women and Lactating Women?

Question 4.

How can FDA support the development of new therapeutic products for conditions specific to pregnant and lactating women?

Question 5.

Do you support efforts to strengthen the FDA's authority to require clinically relevant data on pregnant women and lactating women to inform drug dosing and safety decisions?

Question 6.

As FDA Commissioner, how would you strengthen the FDA's Pregnancy Exposure Registries Initiative?

Answers to 1–6 . Thank you for these questions. It is important to have more information about the safety, efficacy and dosing of drugs during pregnancy. As you know, the Federal Task Force on Research Specific to Pregnant Woman and Lactating Women issued their report to the Secretary of HHS and Congress in September 2018. I look forward to working with staff at the FDA on implementing these recommendations where appropriate.

XI. Vaping and E-Cigarettes

Rates of youth tobacco use have skyrocketed in recent years, largely due to the popularity of e-cigarettes. According to the most recent National Youth Tobacco Survey, nearly 30 percent of high school students and over 10 percent of middle school students use e-cigarettes. Of students who use e-cigarettes, seventy-two percent of high school students and 60 percent of middle school students used e-cigarettes with kid-friendly flavors like fruit and mint. It is widely known that nicotine is extremely addictive and can harm brain development.

Rising rates of e-cigarette use have also given rise to a series of vaping-related illnesses that have caused more than 2,000 people to fall ill and have led to at least 42 deaths. Experts currently believe that these illnesses are linked to the inclusion of vitamin E acetate additives in THC vape products.

Question 1.

Do you agree that rising rates of youth e-cigarette use reflect a public health emergency that the FDA should take robust steps to combat?

Answer 1. I'm a lung cancer doctor, and I have seen the ravages of tobacco-related cancers. I also know youngsters who were very close to me who use e-cigarette products. I'm aware of the National Youth Tobacco Survey data. And I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take aggressive action to stop that.

Question 2.

Do you agree that flavored e-cigarettes, such as fruit and mint, contribute to youth use of e-cigarettes?

Answer 2. I've seen the data suggesting that flavors are a significant effect for children using e-cigarettes and I am alarmed by those data. I think it's a serious issue.

Question 3.

In September 2019, the administration announced that it would "outline a plan . . . for removing flavored e-cigarettes and nicotine pods from the market," including mint and menthol. Earlier this month, however, the administration reversed course. Reportedly facing "pressure from his political advisers and lobbyists," the President "has resisted moving forward with any action on vaping." This failure to act is unacceptable. If confirmed, will you push to implement the robust ban on e-cigarette flavors announced in September?

Answer 3. I understand that the final compliance policy is under consideration by the administration. I look forward to their decision. I'm not privy to that decision making process. But I very much agree and support that aggressive action needs to be taken to protect our children.

Question 4.

If confirmed, what additional steps will you take to combat youth e-cigarette use? What steps will you take to make it more challenging for youth to access e-cigarettes?

Answer 4. I am alarmed by the situation and what we're facing right now. If confirmed, I look forward to working with partners across the academic, medical and youth outreach communities to gather ideas and deliver on results. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take aggressive action to stop that.

Question 5.

If confirmed, what steps will you take to address the targeting of youth by e-cigarette manufacturers through their products and advertising?

Answer 5. In July, the FDA announced the first targeted ad campaign to educate kids about the dangers of e-cigarette use. I was happy to see the Agency take this important step. Ad campaigns such as this were successful in combatting youth use of combustible cigarettes and I am optimistic we can deploy lessons learned from the combustible tobacco campaigns to this effort as well as look for new opportunities to reach our kids. I personally commit to being a forceful educator leading voice regarding this issue.

Question 6.

There are currently no nicotine cessation therapies approved for youth use. If confirmed, how will you direct the FDA to work with other Federal agencies and Congress to expand youth access to nicotine cessation therapies?

Answer 6. Tobacco cessation and nicotine addiction are serious problems. I see that because many of my patients want to stop. Fortunately, there is important and impactful research, much of which has been funded by Congress at NIH that's allowed us to look at this intersection between nicotine addiction, tobacco use and what we may be able to do in the future. I am very supportive of taking measures and expediting those measures to try to find out what novel products we can use to help with the tobacco cessation problem that we have. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take aggressive action to stop that.

Question 7.

If confirmed, what steps will you take to combat the outbreak of vaping-related illnesses? What is the status of current CDC and FDA investigations into the cause of the vaping-related illnesses?

Answer 7. If confirmed, I look forward to immediately getting up to speed on this issue. What I now know if from press reports—that CDC and FDA are working closely with States to investigate each reported illness and death. And that they have found some common causes, but more work remains. I will continue the good work of the Agency to work collaboratively with CDC and make the public aware of key findings and precautionary warnings as expeditiously as possible. I personally commit to being a forceful educator leading voice regarding this issue.

SENATOR KAINE

Question 1.

You spoke in my office about the importance of compliance and enforcement in addressing the youth e-cigarette epidemic. FDA has sought to curb youth access to tobacco products with warning letters, compliance checks, and no-tobacco sale orders—but the youth e-cigarette crisis continues to worsen. Enforcement and compliance can only be as effective as the laws and regulations on the books. What strategies should the FDA pursue to address the youth e-cigarette epidemic beyond standard compliance and enforcement activities?

Answer 1. If confirmed, I look forward to learning from many internal and external stakeholders about all the options and working with Congress to tackle this problem together. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Question 2.

Should Congress pass my bipartisan legislation to raise the tobacco age to 21, do you commit to updating the relevant regulations governing the minimum age of purchase of tobacco products within 180 days?

Answer 2. As part of the executive leadership at MD Anderson, I was a strong supporter of the T21 legislation that recently passed the Texas Legislature and along with strong Agency enforcement believe that these are two great starts to addressing the youth e-cigarette crisis.

Question 3.

I am concerned that we don't know much about the quality or safety of CBD-containing products, even as consumers are using them. What is the status of FDA's work to develop a regulatory approach for CBD-containing products and what is the timeline for rollout of that approach? How can we protect consumers while the regulatory framework is in development?

Answer 3. Thank you for your question. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate Federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements).

Question 4.

If confirmed, how will you direct FDA to combat drug shortages on both domestic and global supply chain levels? What steps should FDA take to reduce reliance on foreign manufacturing of important drugs?

Answer 4. Thank you for your question. FDA's role is to ensure the safety of the drug supply. The U.S. has the safest drug supply in the world and if confirmed, I am committed to maintaining the safety of drugs and biologics used by the American people. According to recent testimony from FDA, as of August 2019, only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were in our country. By contrast, the remaining 72 percent of the API manufacturers supplying the U.S. market were overseas, and 13 percent are in China. I believe advanced manufacturing could help to bring this manufacturing back to the U.S. If confirmed, I look forward to working with the staff at the FDA, along with partnering with Congress, ASPR, BARDA, the Department of Defense and others to address this issue and ensure that the U.S. drug supply remains safe.

I believe FDA's recent report on drug shortages is a significant step forward in addressing this problem. I will make preventing and alleviating drug shortages one of the highest priorities of the Agency should I be confirmed as Commissioner.

Question 5.

The Task Force Specific to Research in Pregnant Women and Lactating Women (PRGLAC) is working to learn more about women's health during pregnancy and close the knowledge gap on research in pregnant women. If confirmed, will you commit to ensuring proper implementation, including potential new guidance and inclusion of pregnant women and lactating women in clinical trials where appropriate?

Answer 5. If confirmed, I look forward to implementing these recommendations where appropriate.

SENATOR HASSAN

Question 1.

I strongly agree with your comments this morning on the importance of Americans trusting FDA as the gold standard for protecting public health.

For millions of parents with children who are nicotine dependent because of e-cigarettes, that trust took a hit this week when they watched the president cave to special interests and reverse his commitment to address the youth e-cigarette epidemic.

Whether it's Purdue Pharma influencing the approval and marketing of OxyContin, or DC lobbyists dictating FDA's response to the youth e-cigarette epidemic, the public may lose faith in FDA when they see decisions being driven by corporate special interests instead of facts and science.

How will you ensure that every decision made under your leadership is based on facts and science, and what will you do if one of your decisions is overruled by political consultants or corporate lobbyists?

Answer 1. As I stated in the hearing, throughout my career, whether it was at the patient's bedside or as a medical executive, I've made decisions based upon data and science, congruent with the law. Nothing is more important for a patient than for them to trust that you are making a decision that's in their best interest and no one else's interest. And I commit to you that science, data and the law will guide decisions that I would make if I'm fortunate enough to be confirmed by the Senate as Commissioner of Food in Drugs. I pledge to represent faithfully the decisions made by the Agency which, as stated above, will be based upon data, science and the law.

Question 2.

Reports that the administration caved to corporate special interests in reversing the e-cigarette flavor ban are incredibly disturbing.

If confirmed, you will oversee the FDA Premarket Tobacco Application process for e-cigarettes. Parents, teachers, public health advocates, and Members of this Committee will be counting on you to protect the integrity of that process.

As Commissioner, will you publicly disclose all meetings between FDA and Juul that take place before and during the Premarket Tobacco Application process, including who attended and what was discussed?

Answer 2. FDA has a very transparent process for accepting and disclosing meetings. I look forward to continuing that tradition.

Question 2b.

Will you provide this Committee with any data you receive from companies like Juul that relate to youth e-cigarette use, including data on flavors and diversion?

Answer 2b. I will disclose all data requested of the Committee, consistent with legal and ethics requirements.

Question 3.

The FDA encouraged development of 'abuse-deterrent' opioids by approving products on an accelerated approval pathway.

We know that these abuse-deterrent opioids are no less addictive than other products on the market, and can be abused.

FDA requires that drug manufacturers submit post-market data, but often fails to hold them accountable for meeting submission deadlines.

This problem is not limited to opioids. Manufacturers of high-cost drugs often fail to comply with post-market reporting requirements, and in some cases we learn years later that the drug was ineffective.

If confirmed, what actions will you take to ensure that drug manufacturers meet their post-market reporting deadlines?

How will you ensure that FDA takes swift action based on post-market data, including revoking approval of drugs where appropriate, if post-market data shows a drug is unsafe or clinically ineffective?

Answer 3. The data provided in post-market reporting is critical to ensuring the enduring safety, efficacy and overall patient benefit the gold standard of the FDA delivers. I commit to using science and data to drive decision-making, which includes leveraging these data to take swift action on products if they are no longer living up to their promise.

Question 4.

Since 2001, FDA has been asked by stakeholders to consider removing chronic pain from the label of opioid products.

What is your position on labeling opioids such as OxyContin as appropriate for patients managing chronic pain?

Question 5.

Officials from the Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs have stated that the risks of opioid therapy for chronic conditions such as headaches, fibromyalgia, and chronic back pain likely outweigh the benefits.

Do you agree? Can you explain your position on how best to move forward with labeling, marketing and prescribing guidelines for opioids to ensure patient safety?

Question 6.

The Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs have warned against prescribing opioids at doses that exceed 90mg morphine equivalents per day.

Answers 4–6. Thank you for this question. I believe science and data should inform FDA's actions. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. I refer my patients to a supportive care team that provide evidence-based pain care. If confirmed, I look forward to reviewing the science and data on opioid labeling. While patient care must be provided on an individualized basis, I agree that providers should be cautious in prescribing opioids, especially in high doses. The prescribing guidelines from the Centers for Disease Control and Prevention have transformed opioid prescribing in recent years, but much remains to be done.

SENATOR SMITH

Questions About Youth Vaping

On November 13, 2019, the Senate HELP Committee heard from the FDA about its efforts to address the issue of youth vaping. Mr. Zeller, the Director of the FDA's Center for Tobacco Products, told us that FDA is investing in a bathroom-based poster campaign to stop this epidemic.

- What are the data and evidence driving the decision to invest in posters instead of taking steps to ban kid-friendly flavors?

In July, the FDA announced the first targeted ad campaign to educate kids about the dangers of e-cigarette use. I was glad to see the agency take this important step. Ad campaigns such as this were successful in combatting youth use of combustible cigarettes and I am optimistic we can deploy lessons learned from the combustible tobacco campaigns to this effort as well as look for new opportunities to reach our kids.

- If confirmed as FDA Commissioner, will you use data and evidence to lead the FDA's efforts to stem the youth vaping epidemic?

Answer. If confirmed, I commit to using science, data and the law to guide my decisions at FDA.

- Will you invest in comprehensive youth cessation tools for kids who are already addicted to vaping?

Answer. Yes.

Questions About Drug Pricing

The first bill I introduced in the Senate is legislation to prevent the ability of generic manufacturers to park their 180-day market exclusivity and delay their entry to the market. My solution would prevent manufacturers from gaming the system, while still streamlining generic drug approvals. You heard about this issue from my colleague, Senator Scott, during your nomination hearing. There are multiple competing proposals in Congress on how to best address this issue.

- If you are confirmed as FDA Commissioner, do you commit to working with my office to listen to our concerns, listen to the concerns of stakeholders, and address this gaming issue?

Answer. Senator, I can commit to working with your office and the offices of other Senators. It is crucial that pathways for drug approval work efficiently and safely.

Questions About Drug Shortages

The FDA recently issued a report on drug shortages, its root causes, and potential solutions. My colleague, Senator Collins, and I recently introduced legislation to mitigate drug shortages.

- If confirmed as FDA Commissioner, do you commit to working with Congress on developing comprehensive solutions to address drug shortages?

One step FDA can take to prevent and alleviate drug shortages is to work with industry to promote advanced manufacturing which is more efficient and nimble in addressing drug shortages. I also believe this is an initiative which could stimulate domestic manufacturing.

The FDA recently testified at a House hearing on the drug supply chain and its contribution to drug shortages. They highlighted that there are loopholes in the current process. International manufacturers of active pharmaceutical ingredients can bypass requirements to register their products with the FDA. That brings potentially dangerous ingredients into the domestic supply chain.

- What additional authorities does FDA need to make sure the drug supply is safe and effective?
- If confirmed as FDA Commissioner, do you commit to working with Congress on these additional authorities that FDA needs?

Answer. Yes, I commit that I would prioritize initiatives for the prevention and alleviation of drug shortages if confirmed. I believe FDA's recent report on drug shortages was a very important step providing a base of information to inform the necessary next steps.

Questions About Livestock and Food Industry

Like my colleagues Senator Braun and Senator Casey on the HELP Committee, I also sit on the Senate Agriculture Committee. Minnesota is a big livestock and dairy state. We are number 8 in livestock farming, number one in turkey farming, number two in hog farming, and number four in dairy production. Minnesota also has a significant pet food industry. The FDA is vital to ensuring safe food systems in this country. Since your nomination to serve as FDA Commissioner, one thing that I have heard from the agriculture industry is that they don't know much about you. This is a fair assessment, as your career has been in cancer research.

Do you have a plan in place to learn about the food side of the FDA?

Answer. You are right that there are areas of FDA regulation in which I have had less experience. I understand that FDA regulates around 20 percent of the U.S. economy—a large number. As a physician, I am very well versed in medical products oversight but I am not as familiar with FDA's programs related to food. That does not change my commitment to these programs, particularly because the US has the safest and most secure food supply chain in the world. I commit that, if confirmed, I will engage the professional staff at FDA across the Agency.

Have you met with Secretary Perdue yet to discuss how the USDA and FDA work together?

Answer. I have not met with Secretary Perdue but commit to establishing a strong, collaborative relationship with USDA.

Will you meet with livestock and dairy farmers and tour food production facilities to prepare you for the role of FDA Commissioner?

Answer. Yes, I commit that, if confirmed I will engage with livestock and dairy farmers who play such an important role in our Nation's food supply.

Questions About CBD and HEMP

The 2018 Farm Bill legalized the farming and production of hemp. This has been a big priority for farmers across the country. However, there are still a lot of questions on how to actually legally farm hemp. The hemp provision in the Farm Bill coincides with the recent explosion of CBD products, like lotions, soaps, and supplements, in the market. Many hemp farmers are using their crops for CBD products. The USDA released their regulations on hemp in October, but we are still waiting for the FDA to issue rules and regulations on CBD products. I want you to be aware of the importance of this decision to hemp farmers across the country. There is a lot of confusion here, and FDA needs to take a leading role in addressing this uncertainty.

- If confirmed as FDA Commissioner, what will be your plan and timeline to regulate the use of CBD in foods, and how will you work with the USDA to implement this plan?
- How will you use science and data to ensure the safety of CBD consumer products?

Answer. Thank you for your question. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to prioritizing this issue and reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate Federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements). I am committed to using science, data, and the law to guide all of my decisions at the FDA and working with Congress and the administration to make the absolute best decisions for the American people.

Questions About Animal Biotech

I have heard from farmers about an ongoing outbreak of African swine fever that is disrupting livestock and feed markets. There are no treatments for African swine fever on the market. While genetic tools might address this outbreak, I have heard from stakeholders that there are regulatory roadblocks that could delay their approval.

- If confirmed as FDA Commissioner, do you commit to working with Congress and stakeholders to ensure timely approval of genetic tools involving animal DNA?

Answer. Yes, I commit that, if confirmed, as Commissioner, I will ensure FDA works with Congress and stakeholders to ensure timely approval of genetic tools involving animal DNA. We must protect our food supply from foreign pathogens both for the safety of consumers and for the benefit of American producers.

Questions About Implementation of Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act (FSMA) was enacted on a bipartisan basis in 2011, and FDA is still implementing its provisions.

- If confirmed as FDA Commissioner, what is your plan and timeline to implement FSMA?
- How would you follow data and evidence to implement FSMA and ensure we are maintaining a safe food supply?

Answer. I commit that, if confirmed, I will make the implementation of FSMA and protection of the American food supply a priority. Although I cannot speak to a specific timeline as I am not current at FDA, I share your concern that we must address foodborne outbreaks both for the sake of the public health but also to maintain confidence in food produced in the United States.

SENATOR JONES

Question 1.

Dr. Hahn, I appreciate your willingness to serve the country as the FDA commissioner. As I discussed during the hearing, I believe the youth vaping crisis and the outbreak of vaping-related lung illnesses is one of the most pressing items currently before Congress and the FDA. We have seen the media reports about the White House deciding to reverse course on a vaping flavor ban that had been announced in September. Given your history as a lung cancer physician and head of one of the Nation's preeminent cancer centers I welcome your opinion on what the FDA and Congress should do to halt the youth vaping epidemic. Do you think flavors are marketed to youth? Is a ban or pause on new flavors an appropriate way to prevent more youth from using addictive vaping products?

Answer 1. I've seen the data suggesting that flavors are a significant effect for children using e-cigarettes and I am alarmed by those data. I think it's a serious issue. Further, I understand that the final compliance policy is under consideration by the administration. I look forward to their decision. I'm not privy to that decision making process. But I very much agree and support that aggressive action needs to be taken to protect our children.

Biosimilars

Question 1.

Dr. Hahn, I know that FDA tries to educate physicians and consumers about the safety and efficacy of biosimilars. Section 206 of the Lower Health Care Costs Act that passed this Committee in June requires FDA to establish a website to provide education materials for patients and doctors about the interchangeability of biosimilar and biologic products. How can we better educate the public on biosimilars? What role should FDA play in this education process?

Answer 1. Thank you for your question. Biologics are increasingly important in American medicine to treat serious illnesses and represent about a third of the new therapies approved by FDA. I am concerned about the relatively slow pace of biosimilar use in the market and I agree that action is needed. I agree that provider education is important to increasing the uptake of biosimilars. I look forward to working with FDA staff, if confirmed, to increase education and build on current methods of outreach at FDA.

Antibiotic Resistance

Question 1.

Last week the Centers for Disease Control and Prevention found that 2.8 million people are infected and more than 35,000 people die every year from the bugs in the U.S. This CDC report placed five drug-resistant superbugs on the "urgent threat" list, meaning that our go to antibiotics may no longer work for these infections.

I know that the FDA is working to address antibiotic resistance through working groups, and antimicrobial stewardship in veterinary settings. If confirmed, what will you do to lead the FDA in combatting a growing antibiotic resistance? What more should be done?

Answer 1. If confirmed, I would support continued implementation of the 2019 Strategic Approach for Combatting AMR and learn about the progress and challenges of plan. This would be one area I could use my personal experience as a practicing physician and running a large organization to apply lessons I have learned about stewardship and the challenges of AMR in the cancer setting.

SENATOR ROSEN

Question 1.

Dr. Hahn, sexual harassment unfortunately continues to be a problem among American workplaces. I am greatly concerned by the 2018 report from the National Academies of Sciences, Engineering, and Medicine, which found that sexual harassment was even worse among STEM fields, compared to non-STEM fields. As a former computer programmer and systems analyst, I know how hard it is for women to succeed in male-dominated fields—much less adding harassment on top of that.

Dr. Hahn, what steps would you take to both prevent and address harassment within the FDA? And how would you hold recipients of FDA grants accountable with regards to those facing claims of sexual harassment? I'm very interested in what you think is currently working, and what you would change regarding policies in this area. Keeping in mind, the National Academies report stated "There is no evidence that current policies, procedures, and approaches have resulted in a significant reduction in sexual harassment."

Answer 1. Thank you for your question. I believe that sexual harassment, and sexual harassment within the workplace are unacceptable. In my time on the Executive Leadership Team at MD Anderson, we made addressing sexual harassment in the workplace a top priority. If confirmed, it would be one of my highest priorities to make sure FDA has the top talent and expertise needed in order to appropriately ensure the safety and efficacy of medical products. In order to attract and retain staff, employees must be confident that sexual harassment will not be tolerated. If confirmed, I will review the Federal Government's policies and FDA policies related to this issue to determine where they may be strengthened.

Precision Medicine

Question 1.

Dr. Hahn, as research advances to make medical treatment for patients more personalized, FDA's role in ensuring expedited review is critical—especially for patients with rare subtypes and genetic mutations, who do not respond to regular treatment

options. How would you approach how FDA evaluates investigational therapies for patients with rare mutations in relation to standards of care? How do you think the FDA could improve existing programs to help bring new targeted therapies to patients more quickly?

Answer 1. Thank you for your question. As an oncologist, I am very interested in the advancement of precision medicine. Precision medicine has transformed cancer care in recent years, and it holds the potential to help us find new treatments and cures for a variety of diseases. If confirmed, I would work with the National Institutes of Health to leverage the data collected by their precision medicine program—All of Us—to advance drug development. I pledge to work across agencies to encourage development of innovative therapies to the precision medicine and rare diseases space.

Donor Human Milk Safety

Question 1.

Dr. Hahn, it is my understanding that even as donor milk products, such as those used to prevent necrotizing enterocolitis in premature infants, are playing an important role in infant health, there is still a lack of standardized safety protocols and manufacturing requirements due to varying classifications. This creates a potential risk for contaminants, such as drugs, bacteria, or viruses, to enter the donor milk supply. What steps would you take at FDA to update and streamline donor milk screening protocols for collection and processing?

Answer 1. If confirmed, I look forward to working with the career staff at the FDA to determine how FDA can update and streamline donor milk screening protocols for collection and processing. Access to safe, effective contraception is essential to public health and women's health. Continued research is necessary to develop improved options for all people who choose to use hormonal drug products for both pregnancy prevention and non-contraceptive purposes. Clinical trials on new and emerging hormonal contraceptives should reflect the unique health needs of the wide range of individuals that use these products.

Generic Drugs/Drug Prices

Question 1.

Dr. Hahn, one of the issues I hear about most from constituents is how concerned they are about the cost of prescription drugs. This is a serious issue, to the point of patients skipping needed medication—like rationing insulin. What else could FDA do to speed the process for bringing generic drugs to market? What recommendations do you have to Congress for what other tools FDA needs to help address drug costs?

Answer 1. High prescription drug prices and affordability are a significant problem and addressing this issue through a variety of means has been a priority of Congress, the administration and the Department. I agree that strong action is needed to address this issue. It's also important to ensure that whatever solutions we consider, do not have the unintended consequences of stifling innovation and the development of new medical products for the American people. There are indirect ways that FDA can assist in lowering prescription drug prices such as facilitating innovation and competition. As you know, FDA has a Drug Competition Action Plan and I look forward to working with Congress and career staff on this plan. I am particularly supportive of introducing more competition to help reduce drug prices including generic approvals, working to improve the biosimilar pathway, and ensuring that there is transparency and a clear regulatory pathway, not game-playing in the generic and biosimilar spaces. I look forward to working with you on measures to reduce high prescription drug prices. I will make this a priority and do all that I can as FDA commissioner to ensure access of medical products for all Americans.

Marijuana Research

Question 1.

Dr. Hahn, I wanted to follow-up on one of the questions I asked during your hearing. We discussed the successful research that led to cannabidiol being used to treat seizures in children with a severe form of epilepsy. Finding new treatments that have fewer side effects, or are more effective, is so important—yet researchers, including at the University of Nevada Las Vegas, are stymied in their scientific efforts because of the challenges of gaining access to marijuana to legally study, including developing different strains. This is true even in states like Nevada where mari-

juana is legal. I've heard from UNLV that it can take 1–2 years just to get approval for the schedule 1 license required to do this research.

1a. Given the great need for alternatives to opioids for pain management, and a whole host of other conditions, why shouldn't we be making it easier for our medical community and scientific researchers to study this plant to see what positive medicinal value might be there?

1b. I understand this is also an issue involving DEA, but I'd like to know what are you specifically willing to commit to doing as FDA Commissioner to improve access for medical researchers so they can study how various compounds in marijuana plants could be used to treat a variety of illnesses and conditions? And on what timeline?

1c. Do you have specific recommendations for how DEA and FDA could work together more effectively in this area?

Answers to 1a–c. Thank you for this question. Conducting clinical research using marijuana and other controlled substances involves interactions with several Federal agencies, including obtaining the marijuana for research from the National Institute on Drug Abuse (NIDA) within the National Institutes of Health or another Drug Enforcement Administration (DEA)-registered source; review of an investigational new drug (IND) application and the research protocol by the Food and Drug Administration (FDA) and an investigator registration and site licensure by the DEA. I agree that it is important to eliminate unnecessary barriers to research that could lead to breakthroughs or new treatments for the American people. If confirmed, I look forward to working with you, Congress, the administration, and relevant Federal agencies to reduce unnecessary barriers to this research. While DEA is the Federal agency that regulates controlled substances, if confirmed, as Commissioner of Food and Drugs, I would support reducing unnecessary barriers that prevent researchers from studying compounds that could have a benefit for Americans.

CBD Regulation

Question 1.

Dr. Hahn, another area I'd like to touch on is the regulation of CBD products, which contain cannabidiol—and very low THC—so these are not what we traditionally think about as the kind of marijuana products that people use for recreational purposes. We're talking about skin creams, oils, and supplements. FDA currently has the authority to regulate these products and ensure their safety for consumers, but it has yet to establish a regulatory pathway for marketing products that contain CBD. This has caused great uncertainty among both consumers and companies making these products, including in Nevada, where both CBD and other marijuana products are legal.

1a. Dr. Hahn, what are your thoughts on FDA's responsibility to create a regulatory pathway for CBD products?

1b. What timeline will you commit to for an update to this Committee on FDA's progress, and what timeline do you expect for FDA rulemaking?

Answers to 1a–b. Thank you for your question. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate Federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements). I commit to providing timely and meaningful updates to the Committee on this issue.

Drug Development for Addiction Treatment

Question 1.

Dr. Hahn, we heard just last week in this Committee's hearing on vaping that there are no FDA-approved treatments for teenagers who are addicted to nicotine. It is my understanding that there is also a lack of options for anyone, adult or youth, addicted to psychostimulant drugs like cocaine and meth.

a. What steps would you take at FDA to proactively address this problem, beyond simply responding to approval applications that come to FDA?

Answer 1. Thank you for your question. Like you, I am concerned that there are no FDA-approved treatments for teenagers who are addicted to nicotine. We must take action to prevent youth from becoming addicted to nicotine. Unfortunately, there are already youth who are addicted and we need treatments. I believe it is critical for the FDA to provide certainty and clarity to manufacturers in order to develop applications for cessation products that can be used by youth who are addicted to nicotine. I look forward to working with the staff at FDA to determine ways that the FDA can advance the development of tobacco cessation products. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

b. Obviously, prevention is critical, but when it comes down to it, we need to do a better job of ensuring treatment options for addiction to a wide range of substances—for the specific populations that are impacted. Unfortunately, cocaine and meth are a growing problem in Nevada. Dr. Hahn, what lessons from the opioid crisis would you look to for guidance on how to address, and curb, the changing nature of the overdose crisis?

i. How does effective treatment play into that plan?

Answers to b–i. Thank you for your question. As you mention, prevention of substance use disorders is critical. For opioid use disorder, medication assisted therapy is the gold standard of treatment. However, currently, there are no FDA approved medical products for the treatment of addiction to cocaine or methamphetamines. Behavioral therapy is currently the only treatment. I understand that the National Institute of Drug Abuse is conducting significant research on addiction and treatments and I pledge to work across agencies to encourage development of innovative therapies to address all addiction illnesses.

Cosmetic Safety

Question 1.

Dr. Hahn, I'd like to ask you about the need to update FDA's oversight of cosmetic products. This includes a wide range of personal care products—shampoo, lotion, make-up, shaving cream, hair dye—products that most Americans use daily. Yet our laws have changed little with regard to FDA safety oversight of cosmetics since the Food, Drug, and Cosmetic Act was passed in 1938. A lot has changed since then, including questions about the safety of certain ingredients, and issues of contamination—like the recent cases of asbestos in make-up marketed to teens and preteens. I appreciate the work that my colleagues have done over the last several years, especially Senators Feinstein and Collins with the Personal Care Products Safety Act, which I have co-sponsored.

1a. Dr. Hahn, do you believe that FDA needs updated authority for stronger oversight and capacity to review the safety of ingredients in personal care products that Americans use on a regular basis, especially ingredients that the medical community has raised serious concerns about—like endocrine-disrupting parabens and phthalates, or chemicals like formaldehyde? How would you plan to work with this Committee to address this issue?

Answer to 1a. I commend FDA staff for their work to ensure that adulterated cosmetics products are promptly detected and removed from the market—asbestos has no place in cosmetics. If confirmed, science, data, and the law will guide every decision I make and every effort the agency undertakes. I commit to working closely with you and your colleagues as you work on legislation to modify the FDCA.

1b. Can you please speak about current limitations within FDA's capacity to screen imported cosmetic products for serious contaminants, like asbestos, lead, and mercury? What steps should FDA and Congress take to improve consumer safety for our constituents?

Answer to 1b. Although I am not currently a part of the administration and cannot speak to the specifics of the agency's capacity, if I am confirmed, I commit to working closely with FDA staff to understand and address any such limitations.

SENATOR MURRAY

Tobacco

Flavors Compliance Policy

During your confirmation hearing, I was disappointed by your answers to questions from multiple Senators on your commitment to combatting youth tobacco use. The lack of a commitment from you followed the testimony of Mitch Zeller, Director of FDA's Center for Tobacco Products, one week earlier. Mr. Zeller refused to provide the Committee, under repeated questioning, with an update on the status of the policy announced by the administration in September to remove all non-tobacco flavored e-cigarettes from the market until reviewed by the FDA. Rather than answer us, Mr. Zeller suggested that I and other Members direct our questions to the White House. At the same hearing, Dr. Anne Schuchat, principal deputy director of the CDC, told the Committee, "We know flavors are particularly attractive to youth," and said that, if a flavored e-cigarette were permitted to remain on the market, "we believe kids will likely use whatever flavor is left."

Question 1.

If confirmed, are you committed to finalizing the flavors compliance policy the administration announced on September 11?

Answer 1. I understand that the final compliance policy is under consideration by the administration. I look forward to their decision. I'm not privy to that decision making process. But I very much agree and support that aggressive action needs to be taken to protect our children. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Question 2.

If confirmed, are you committed to responding to questions about FDA matters instead of referring us to the White House?

Answer 2. I will respond to questions asked of the Committee, consistent with legal an ethics requirements.

Question 3.

Do you agree with Dr. Schuchat that flavors make e-cigarettes more attractive to youth and that, if all flavors are not removed from the market, youth will shift to the flavors that remain on the market?

Answer 3. I've seen the data suggesting that flavors are a significant effect for children using e-cigarettes and I am alarmed by those data. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Question 4.

As Commissioner, would you ensure the decisions FDA makes are based on the best available science?

Answer 4. If confirmed, I commit to using science, data and the law to guide my decisions at FDA.

Youth Tobacco Use

Question 5.

All flavored tobacco products pose a threat to children. Are you committed to clearing the market of all flavored tobacco products, including menthol cigarettes and flavored cigars?

Answer 5. I'm a lung cancer doctor, and I have seen the ravages of tobacco-related cancers. I also know youngsters who were very close to me who use e-cigarette products. I'm aware of the National Youth Tobacco Survey data. And I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take aggressive action to stop that.

Question 6.

What other steps do you intend to take to combat youth tobacco use?

Answer 6. If confirmed, I look forward to learning from many internal and external stakeholders about all the options and working with Congress to tackle this

problem together. I am open to evaluating strategies that would aggressively address this epidemic. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Question 7.

As youth tobacco use skyrockets, the need for effective youth cessation options has become especially acute. What steps would you take to improve the availability of FDA-approved youth cessation products?

Answer 7. Tobacco cessation and nicotine addiction and are serious problems. I see that because many of my patients want to stop smoking cigarettes. Fortunately, there's great research, much of which has been funded by Congress at NIH that's allowed us to look at this intersection between nicotine addiction, tobacco use and what we may be able to do in the future. I am very supportive of taking measures and expediting those measures to try to find out what novel products we can use to help with the tobacco cessation problem that we have. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Vaping-Linked Illnesses

As of November 13, more than 2,000 people have been sickened by vaping-linked lung illnesses.

Question 8.

What steps do you intend to take to combat the outbreak of vaping-linked illnesses and prevent similar outbreaks in the future?

Answer 8. If confirmed, I look forward to immediately getting up to speed on this issue. What I now know if from press reports—that CDC and FDA are working closely with States to investigate each reported illness and death. And that they have found some common causes, but more work remains. I will continue the good work of Acting FDA Commissioner Ned Sharpless to work collaboratively with CDC and make the public aware of key findings and precautionary warnings as expeditiously as possible. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Nicotine Reduction

The Trump administration now also appears to be breaking its 2017 promise to reduce the level of nicotine in cigarettes to minimally or non-addictive levels.

Question 9.

Is FDA continuing its work toward reducing nicotine levels in cigarettes?

Answer 9. I am not privy to the internal decision making of the FDA. I pledge to look into this matter should I be confirmed.

Question 10.

Are you committed to moving forward with the administration's proposal to reduce nicotine in cigarettes?

Answer 10. I commit to using science, data and the law to guide my decision-making. If evidence suggests this is a viable option to discourage the use of tobacco products, I will pursue it.

Antibiotic Resistance

The Centers for Disease Control (CDC) estimates that more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, resulting in over 35,000 deaths annually. The World Health Organization's global assessment of antibiotic resistance concluded that antibiotic resistance is a "major threat to human health." There are well-established connections between antibiotic use in food production and rising antibiotic resistance in common human pathogens. Already, the CDC estimates that antibiotic resistant foodborne pathogens cause 430,000 illnesses each year in the United States.

Question 11.

Please provide your assessment of this situation and the actions that FDA intends to take to prevent animal antibiotics from being used for unlimited or excessive durations?

Answer 11. All growth promotion indications have been removed from labeling indications, which reduced the amount of antibiotics used in animals. I would consult with careers at the Agency on additional steps FDA could take. I think this is an area that deserves attention and close monitoring of sales data and additional studies. The Agency issued grants in 2016 to study this issue and, if confirmed, I would look forward to learning about the findings from these studies and the potential recommendations. I will partner with Congress, the administration and other stakeholders moving forward on this important issue.

Question 12.

How does FDA intend to ensure that antibiotics currently available over-the-counter will not be used in excessive doses and durations that are beyond the scope of their "disease prevention" indication?

Answer 12. If confirmed, I would partner with career staff to better understand over-the-counter utilization of antibiotics and examine any data the Agency is collecting on the issue. This is a very important issue. I believe that tracking sales data of these products will be informative and could guide evidence-based actions in the future.

Question 13.

What role do you envision for veterinarians in antimicrobial stewardship in food production?

Answer 13. Veterinarians play a critical role in antimicrobial stewardship in food products. I understand that CVM has recognized the value of their role and has established an effective partnership with the veterinarian community to combat AMR. I look forward to partnering with appropriate stakeholders including the veterinarian community to address this important issue.

Question 14.

If confirmed, do you commit to requiring veterinarian involvement any time an antibiotic is used in an animal?

Answer 14. I think veterinarian involvement is critical when antibiotics are prescribed to animals.

Question 15.

What is the current status of FDA and USDA joint efforts to collect data on antibiotic use in food animal production?

Answer 15. Since I am not currently at the FDA, I do not know the current status of these efforts. However, if confirmed, I commit to looking into this issue.

Question 16.

What investments should Congress prioritize to improve data collection and antibiotic use reporting and to further improve understanding of changes in antibiotic resistance patterns?

Answer 16. If confirmed, I would consult with experts at the Agency to discuss this issue. From my own medical experience, I believe that tracking infections, prescriptions, and product sales will provide valuable tools to track utilization and potentially partner with health care systems to better understand prescribing practices. This could guide evidence-based actions in the future.

Question 17.

Please provide an assessment of FDA's progress in implementing Guidance for Industry 209 and 213 and the Veterinary Feed Directive final rule. Please preview any expected milestones for the coming year.

Answer 17. There are many well-documented challenges to conducting clinical trials for antibiotics; for example, finding and enrolling patients with rare drug resistant infections. The 21st Century Cures Act of 2016 granted FDA authority to establish a new regulatory pathway, Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), to overcome challenges specific to development of new antibiotic therapies.

Question 18.

Please give your assessment of the current state of the LPAD pathway implementation.

Answer 18. To date, two drugs have been approved in the LPAD pathway since it was authorized in 21st Century Cures in 2016. The lack of products in the antibiotic development pipeline has been a significant issue for many years and in my opinion, it is too early to assess the true impact of the LPAD pathway. My understanding is that our career staff works hard to appropriately engage with sponsors to use the appropriate regulatory tools to support development and review. Because

drug development generally takes 10 years it will take some more time to understand the full effect of the program.

Question 19.

Please describe actions FDA can take to further facilitate development of new antibiotics.

Answer 19. I believe the Agency has taken many steps to facilitate development of new antibiotics including utilizing the LPAD pathway, leveraging the flexibility of clinical trials and developing breakpoints. Diagnostics can play a critical role in stewardship and utilization so physicians could identify the appropriate drug and dosage to treat the infection. I believe that post-market surveillance and real-world evidence can play a critical role to better understanding these infections, the treatments and stewardship. If confirmed, I would be eager to engage with experts at the Agency to learn more about this critical work.

Cannabidiol (CBD)

At this time, it is unlawful to market food or dietary supplements containing cannabidiol (CBD) in interstate commerce. Under current law, for CBD to be lawfully marketed in a food or dietary supplement, FDA would have to issue a regulation allowing for the marketing of CBD in those products. FDA has said that it is exploring an approach to regulating CBD that takes into account the safety and quality of CBD-containing products. In addition, FDA has also noted the importance of preserving incentives for research and drug development. FDA has estimated that rulemaking on CBD would take three to five years.

I want to preserve FDA's role in regulating cannabis products marketed as drugs and in foods, dietary supplements, and cosmetics, as well as preserve the incentive to develop new pharmaceutical treatments. I am concerned that the FDA timeframe is too long, given the agency's concerns. It is important that FDA move as quickly as possible, without sacrificing consumer safety and the public health.

Question 20.

Will you make FDA regulation and oversight of CBD-containing products—including food, dietary supplements, drugs, and cosmetics—a top priority?

Answer 20. Yes, if confirmed, I will make this a top priority. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate Federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements). I am committed to using science, data, and the law to guide all of my decisions at the FDA and working with Congress and the administration to make the absolute best decisions for the American people.

Question 21.

Will you aggressively enforce current law against CBD products that are marketed with false or misleading claims?

Answer 21. I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data and that enforcement actions reflect this principle. I take very seriously the role of the FDA in protecting public health and ensuring consumers have accurate information to make the best decisions possible.

Question 22.

How will you preserve and enhance incentives for research and development of drugs that contain CBD and other cannabinoids?

Answer 22. I look forward to learning more about the barriers to research and development of drugs that contain CBD and other cannabinoids. I will also work with the Drug Enforcement Agency, the National Institute on Drug Abuse, the

USDA and other relevant Federal agencies to determine if there are unnecessary barriers that can be streamlined.

Compounding

In 2013, Congress enacted the Drug Quality and Security Act (DQSA), to establish a clear regulatory regime for compounded products, after a contaminated compounded injectable caused a meningitis outbreak that sickened over 800 people and killed 64 people in 2012. Since passage of the DQSA, FDA has devoted significant agency resources to implementing and enforcing its compounding-related authorities.

Question 23.

Do you commit, if confirmed, to continuing FDA's work to ensure continued access to quality compounded drugs for patients who need them and strengthen regulatory oversight to protect patients from unsafe, ineffective, and poor quality products?

Answer 23. Yes. This is an issue of importance particularly with respect in situations where there is a shortage of a prescription drug or a patient cannot use an FDA-approved product; in other words to meet a specific medical need. 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.

Cosmetics

In December 2018, a *Reuters* investigation showed a long history of asbestos contamination in talc used for baby powders. This year, FDA has released findings from testing several products, which revealed asbestos contamination in a number of cosmetic products marketed to children and teenagers. Most recently, in October, FDA alerted consumers that Johnson & Johnson had voluntarily recalled one lot of Johnson's Baby Powder after a sample tested positive for asbestos. I am alarmed by the continued reports of asbestos contamination in cosmetic products, especially those marketed to children and teenagers. FDA must do everything it can to respond to these issues and ensure our products are safe for use.

Question 24.

Do you believe FDA needs to do more to ensure cosmetic products on the market are safe?

Answer 24. I agree that FDA must do everything possible to ensure that consumer products under the agency's jurisdiction are free from adulterants like asbestos. If confirmed I will work with FDA staff to get quickly up to speed on this issue, and will work to address any shortcomings. I commend the agency on its work to detect these adulterated products and get them off the market.

Question 25.

What resources will you commit to continuing FDA's investigations of contamination in talc products—and to monitoring, testing, and enforcement of applicable laws and regulations governing cosmetic products?

Answer 25. If confirmed, I will ensure that the cosmetics program prioritizes products that have demonstrated a higher level of risk to consumers. I will also commit to working with Congress and stakeholders to better understand ways that the program can be more effective in achieving its mission.

Question 26.

What authorities and resources does FDA need to ensure the safety and quality of cosmetic products?

Answer 26. Although I am not currently a part of the administration and cannot speak to the specifics of the agency's capacity, if I am confirmed, I commit to working closely with FDA staff to understand and address any such limitations.

Question 27.

Do you believe consumers have an adequate understanding of FDA's limited legal authority over cosmetics and the extent to which FDA monitors cosmetic products on the market?

Answer 27. I look forward to learning the consumer's viewpoint of FDA's role in cosmetics. If confirmed I will prioritize transparent and effective communication with the American people.

Device Safety

In 2015, I asked my Committee staff to investigate a series of dangerous infections at Virginia Mason hospital in Seattle linked to contaminated duodenoscopes. I issued a staff report in 2016 that linked this type of medical device to at least 25 different outbreaks of antibiotic-resistant infections that sickened at least 250 patients worldwide. These devices remain difficult to clean and can contribute to the spread of infections. My staff's report recommended that FDA expand post-market surveillance of medical devices to protect patients from infection. FDA has made some progress by committing new resources to develop and implement an active surveillance system using the National Evaluation System for health Technology (NEST), but we need to do more.

Question 28.

Will you make it a top priority to enhance monitoring of marketed medical devices, including fully leveraging the functions of NEST?

Question 29.

Will you insist on greater certainty about the risks associated with the use of devices before they are marketed?

Answers to 28–29. If confirmed, I will carefully consider all tools for their ability to enhance accurate monitoring of the safety and effectiveness of marketed devices. I think it is important for FDA to take a proactive, not passive approach to upholding the gold standard for all medical products before and after they enter the market.

Dietary Supplements

The dietary supplement market has grown exponentially over the past twenty years. Today, three out of every four consumers take a dietary supplement on a regular basis. Earlier this year, former Commissioner Gottlieb highlighted the widespread use of dietary supplements and announced a new plan to modernize dietary supplement regulation and product oversight to ensure product safety and quality. As part of this plan, Gottlieb acknowledged that a "mandatory listing requirement could provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation" and "could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry." According to the Pew Charitable Trusts, a product listing requirement would "enable FDA to direct its resources and expertise toward supplements with greater potential to harm consumers" and "enhance FDA's ability to respond effectively to emerging safety concerns."

Question 30.

Do you believe FDA needs to do more to oversee marketing of dietary supplements?

Question 31.

Will you continue to advance FDA's efforts to strengthen the regulation and oversight of dietary supplements?

Question 32.

Do you support a product listing requirement for dietary supplements?

Question 33.

What other authorities and resources does FDA need to help protect consumers, without imposing unnecessary burdens on companies that market safe, high-quality products?

Answers to 30–33. So many Americans trust in the FDA to ensure the products they use are safe and effective. I have been pleased to see the new efforts surrounding the enhanced oversight of dietary supplement products, including the creation of the Office of Dietary Supplement Programs (ODSP), and the very recent announcement that the Botanical Safety Consortium (BSC) has been convened. I commit to continuing this work to modernize and enhance oversight of dietary supplements.

Drug Supply Chain

The U.S. drug supply chain is one of the safest in the world, but it has become more complex, in part because of increased globalization. Today, the majority of the active ingredients in drug products sold in the United States are manufactured in

India and China. With this shift has come troublesome news about safety. A 2016 GAO report found that FDA lacks inspectional history for one-third of the foreign drug establishments in its catalog. This year, FDA announced millions of people had been exposed to possible carcinogens found in widely used, FDA-approved blood pressure and heartburn medications, like Zantac, manufactured in part by facilities in China and India. These reports raise concerns about the FDA's foreign drug inspection program, and the agency's ability to detect contaminants before drugs reach patients, wherever they are manufactured.

Question 34.

What actions will you take to ensure the drug supply is safe for patients in the United States?

Answer 34. Thank you for your question. FDA's role is to ensure the safety of the drug supply. The U.S. has the safest drug supply in the world and if confirmed, I am committed to maintaining the safety of drugs and biologics used by the American people. According to recent testimony from FDA, as of August 2019, only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were in our country. By contrast, the remaining 72 percent of the API manufacturers supplying the U.S. market were overseas, and 13 percent are in China. I believe advanced manufacturing could help to bring this manufacturing back to the U.S. If confirmed, I look forward to working with the staff at the FDA, along with partnering with Congress, ASPR, BARDA, the Department of Defense and others to address this issue and ensure that the U.S. drug supply remains safe.

Question 35.

On October 30, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified before the House Committee on Energy and Commerce's Subcommittee on Health that data available to CDER related to the manufacture of active pharmaceutical ingredients (APIs) have several limitations, including which API supplier a finished dosage form manufacturer is using at any given time. What authorities and resources does FDA need to improve the accuracy and completeness of information about API used in drugs marketed in the United States?

Answer 35. If confirmed, I look forward to working with Dr. Woodcock and others at the FDA to determine what additional authorities FDA may need to address this issue.

FDA Hiring

FDA officials and staff have long raised concerns about barriers to hiring and retaining the staff and expertise needed to keep pace with modern science and research. In 2016, the 21st Century Cures Act included provisions intended to improve hiring of premier talent at the FDA. Soon after, MDUFA IV authorized funding for CDRH to hire several new premarket reviewers. A 2017 FDA report found that FDA's hiring process would benefit from a comprehensive redesign and modernization effort and, in 2018, FDA launched a new public campaign to recruit and retain new employees. However, FDA continues to face hiring challenges and many positions remain unfilled at the Agency.

Question 36.

What steps will you take, if confirmed, to ensure FDA is fully staffed and able to meet its performance expectations?

Question 37.

Are there additional authorities that Congress could provide to FDA to assist with hiring and retaining staff, especially in key underrepresented disciplines (for example, providing additional pay authorities or greater flexibility to directly hire staff)?

Answers to 36–37. If confirmed, one of my top priorities on day one will be to ensure that all of the new authorities that were given to FDA through the 21st Century Cures Act are in fact being fully implemented. Nothing is more important than getting the right expertise in the agency to help keep our food safe, swiftly and safely bring cures to the American people, and fulfill the mission of the agency. We must be positioned to recruit and retain the best and brightest talent at the agency, and I look forward to working with Congress to making sure the FDA is fully staffed with the right people for years to come.

Food safety

Congress passed the Food Safety and Modernization Act (FSMA) in 2011, helping to protect public health and strengthen consumer confidence in our food supply.

However, eight years later, the Agency still has not implemented parts of FSMA, and food-borne outbreaks remain a problem. For example, over the past two years, there have been four outbreaks of E. coli in romaine lettuce, resulting in 210 illnesses and 5 deaths. Just last week, FDA announced an investigation into incidents of illnesses caused by E. coli in packages of Caesar salad that contain romaine lettuce.

Question 38.

Your experience has been in the medical field, but FDA oversees the safety of 80 percent of the food supply. What actions will you take to ensure FDA fully implements FSMA and takes concrete steps to prevent food-borne outbreaks, including an effective food traceability system?

Answer 38. You are right that there are areas of FDA regulation in which I have had less experience. I understand that FDA regulates around 20 percent of the U.S. economy—a large number. As a physician, I am very well versed in medical products oversight but I am not as familiar with FDA's programs related to food. That does not change my commitment to these programs, particularly because the US has the safest and most secure food supply chain in the world. I commit that, if confirmed, I will engage the professional staff at FDA across the Agency.

Drug Pricing

As you know, patients and families around the country are concerned about the high cost of prescription drugs. FDA does not regulate drug prices, but it does have a role in increasing access to lower cost generics and biosimilars.

Question 39.

Please provide specific proposals of how you would target increased patient access to generics and biosimilars without sacrificing product safety, efficacy, or quality.

Answer 39. High prescription drug prices and affordability are a significant problem and addressing this issue through a variety of means has been a priority of Congress, the administration and the Department. I agree that strong action is needed. It's also important to ensure that whatever solutions we consider, do not have the unintended consequences of stifling innovation and the development of new medical products for the American people. There are indirect ways that FDA can assist in lowering prescription drug prices such as facilitating innovation and competition. As you know, FDA has a Drug Competition Action Plan and I look forward to working with Congress and career staff on this plan. I am particularly supportive of introducing more competition to help reduce drug prices including generic approvals, working to modernize and make more efficient the biosimilar pathway, and ensuring that there is transparency and a clear regulatory pathway, not game-playing in the generic and biosimilar spaces. I look forward to working with you on measures to reduce high prescription drug prices. I will make this a priority and do all that I can as FDA commissioner to ensure access of medical products for all Americans.

Nutrition

In March 2018, Former Commissioner Scott Gottlieb announced FDA's Nutrition Innovation Strategy. The strategy addresses a number of key agency actions to improve nutrition, including two-year short-term voluntary sodium-reduction targets for industry, and educational campaigns for menu labeling and the updated Nutrition Facts Label.

Question 40.

What are your priorities for improving nutrition?

Answer 40. FDA plays an important role in promoting the nutrition of the country. If confirmed as Commissioner, I will use the best science to guide the appropriate steps related to sodium levels.

Question 41.

What are your specific plans to continue the progress on the Nutrition Innovation Strategy?

Answer 41. I support FDA's efforts to promote the nutrition of the country, perhaps in ways that have not been considered previously. In all the decisions we make, we must follow the best and most current science and engage in stakeholders who can provide the necessary information to inform the best course of action.

Question 42.

What is your timetable for finalizing two-year sodium voluntary targets?

Answer 42. I cannot speak to a timeline as I am not currently part of FDA. But I commit that, if confirmed, I will work expeditiously on the next steps.

Question 43.

What resources and activities do you plan to commit to educating consumers about menu labeling and the updated Nutrition Facts label?

Answer 43. I cannot speak to a specific level of funding but I will commit, if confirmed, to prioritizing FDA's efforts around menu labeling and continuing to keep the Nutrition Facts Label requirements up to date.

Opioids

As an oncologist, you have mentioned the importance of holistic treatment while working on the front lines in pain management for patients who need it, while also balancing concerns of addiction. Substance use disorder (SUD) remains a deadly problem, and efforts are necessary across all areas of prevention, treatment and recovery. Research shows that medication assisted treatment (MAT) can be an effective part of treatment for opioid use disorder (OUD) and help sustain recovery. However, despite rising rates of opioid addiction in our country, millions of people still lack access to quality, evidence-based treatment for OUD, even with existing FDA-approved medications for OUD treatment, including buprenorphine, methadone, and naltrexone. Further, for people with other forms of SUD, options for MAT are even more elusive.

Question 44.

If confirmed, as Commissioner, how will you facilitate treatment options and the development of therapies to address SUD, including OUD, as a chronic disease?

Question 45.

How will you support development of options for MAT and address the challenges that remain in patient access and provider utilization of MAT as a key FDA priority in its response to the SUD epidemic?

Question 46.

This week, Public Citizen sent a letter to FDA requesting "a formal compliance investigation into an apparent clinical investigation conducted by California-based BioCorRx, Inc., and the Louisiana Department of Public Safety and Corrections that involved testing the effectiveness of sustained-release naltrexone implants—a formulation of naltrexone never approved by the FDA—for management of opioid and alcohol use disorders in prison inmates. The agency also should investigate whether BioCorRx has conducted or is currently conducting any similar clinical investigations." If confirmed, do you commit to immediately initiate an FDA investigation into this matter, including whether BioCorRx and the Louisiana Department of Public Safety and Corrections violated any applicable laws and regulations related to the protection of human subjects?

Answers to 44–46. The opioid crisis is one of the largest and most complex public health tragedies that our Nation has faced. This is a top priority for the administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I am supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT. If fortunate enough to be confirmed, I will look into the specific issue that you refer to in question 46.

Pediatric Devices

From 2008 to 2017, an average of only 24 percent of the total premarket approval (PMA) and humanitarian device exemption (HDE) application approvals in each fiscal year had an indication for a pediatric population or subpopulation, and the majority of those pediatric indications were designated for children 12 years and older. The disparity in medical device innovation for adults and for children has led to unmet needs and difficulty in finding appropriate treatments for pediatric patients. Devices for adult indications may not be suitable for pediatric use because children are, among other things, often smaller and more active than adults. To address the lack of FDA-approved pediatric devices, FDA has pursued efforts such as funding

consortia to provide seed funding and technical advice to sponsors of pediatric medical devices.

Question 47.

If confirmed, as Commissioner, how will you lead new and existing efforts to support the development and availability of safe and effective pediatric devices?

Answer 47. I agree that there is a strong need to increase access to medical devices in the pediatric population, and recognize the unique needs of this population. If confirmed I commit to working with staff at FDA, stakeholders, and Congress to understand any challenges or barriers to bringing pediatric devices to market, and to advance policies and procedures that will spur progress in this space.

Shortages

The number of new drug shortages has increased after declining from a peak of 251 in 2011. There were 39 drug shortages in 2017 and 54 drugs shortages in 2018. Recent drug shortages include critical drugs such as hydromorphone, vincristine sulfate, immune globulin, and EpiPens. I applaud last month's release of FDA's Drug Shortage Task Force report, "Drug Shortages: Root Causes and Potential Solutions," which attempts to identify many of the root cause of shortages and offer policy solutions.

Question 48.

FDA's Task Force on Drug Shortages supports the concept of a rating system to incentivize manufacturer investment in quality management maturity for their facilities. What authorities and resources does FDA need to implement this type of rating system?

Answer 48. I think the rating system you mention is an idea worthy of consideration. Before I can opine on the specific authorities and resources FDA would need, I would have to consult with the staff at FDA but I will commit to looking into this idea if confirmed.

Question 49.

On October 30, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified before the House Committee on Energy and Commerce's Subcommittee on Health that advanced manufacturing technologies can "improve drug quality, address shortages of medicines, and speed time-to-market" of medical products. If confirmed, how will you work with drug manufacturers to foster the adoption of advanced manufacturing technologies?

Answer 49. I agree with Dr. Woodcock that advanced manufacturing could go a long way toward addressing drug quality and drug shortages. FDA should work together with regulated industry to speed up the adoption of this technology and there are a few specific actions I think they can take. For example, they can work closely with industry to tailor regulatory requirements so they are not over burdensome.

FDA's Authority and Science-Based Decision-Making

FDA's gold standard and commitment to science over ideology are essential to continued public trust in FDA approved products.

Question 50.

If confirmed, do you commit to opposing efforts, legislative or otherwise, to limit FDA's authority to make decisions about the approval of safe and effective medication based on the best available evidence?

Question 51.

Do you believe FDA's ability to make scientific judgments about drug products and devices should be the same across all medical products?

Answers to 50–51. Senator, I agree wholeheartedly that FDA represents the gold standard for protecting the public health and that these decisions must be based upon the best available evidence. It is trusted by all Americans and admired around the world for its mission of ensuring the safety, security, effectiveness of medical products and ensuring the safety of our Nation's food supply. The professionals that FDA have remarkable expertise and a deep commitment to the agency's mission. I believe strongly in the importance of science, data and the law that have guided and continue to guide FDA in their decision making across all medical and food products.

New Drug Development

Access to safe, effective contraception is essential to public health and women's health. Continued research is necessary to develop improved options for all people who choose to use hormonal drug products for both pregnancy prevention and non-contraceptive purposes. Clinical trials on new and emerging hormonal contraceptives should reflect the unique health needs of the wide range of individuals that use these products.

On July 12, FDA released draft guidance for industry that included recommendations for manufacturers to expand clinical trials for hormonal drug products to include people over the age of 35 or with a Body Mass Index over 30. Inclusive research will ensure new hormonal drug products better meet the needs of all patients who can become pregnant.

Question 52.

Do you agree it is critical to continue research on hormonal contraception to develop new and improved options and ensure safe, effective methods are available to meet individual needs and preferences?

Question 53.

If confirmed, how will you ensure that clinical research during the course of developing new hormonal drug products accurately reflects the needs of the wide range of people who can become pregnant?

Answers to 52–53. Thank you for these questions. As you mention, the FDA recently issued a new draft guidance, "Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy." I believe it is important for the FDA to provide clarity to industry to advance the introduction of safe and efficacious drugs for consumers, including hormonal contraception.

Banning Electric Shock for People with Disabilities

The Judge Rotenberg Educational Center (JRC) in Massachusetts is a specialized day and residential school for people with disabilities ages five though adulthood. The JRC, despite its mission of promoting "very effective education and treatment," uses electric shock to punish students. The practice has no evidence as therapy and has been found to be inhumane and harmful. In 2016, the FDA proposed to ban the device the JRC uses to shock people with disabilities. Unfortunately, the rule has not been finalized despite widespread public support to ban the practice.

Question 54.

If confirmed, will you commit to finalizing this critical rule and banning the electric shock of people with disabilities?

Answer 54. I am committed to working with your office on this issue and working to protect American patients.

I look forward to working with FDA's professional staff to study this issue and understand the most efficient path forward that protects patients.

Question 55.

If so, please provide your proposed timeline for finalizing the rule, and if you believe the rule is on track with the FDA's fall agenda to be finalized by the end of 2019.

Answer 55. I am committed to working with your office on this issue. I cannot speak to a proposed timeline, as I am not part of the administration yet.

SENATOR COLLINS

Question 1.

An estimated 5.8 million Americans—including 29,000 Mainers—are currently living with Alzheimer's. Alzheimer's also costs the U.S. $290 billion a year, including $195 billion in costs to Medicare and Medicaid, making it our Nation's most expensive disease. If we continue along this trajectory, Alzheimer's is projected to affect nearly 14 million Americans and surpass $1 trillion in costs by 2050. Yet there is still no therapy. The FDA just announced a modernization of its Center for Drug Evaluation in order to ensure more timely access to the latest science and the most efficient review pathway for cutting edge treatments, which could provide a glimmer of hope for potential Alzheimer's therapies that are in the works. If confirmed, what ideas will you bring to advance treatments for the millions of families facing Alzheimer's disease? Do you believe it is important for the FDA to collaborate with the

NIH, the CDC or other partners in contributing to the broader research and development effort on Alzheimer's disease?

Answer 1. Alzheimer's Disease is a devastating condition with wide-ranging effects on individuals and families across the Nation. I believe FDA must continue to look for ways to support drug development and streamline the approval process for all products, and especially those with the potential to address critical unmet needs such as Alzheimer's Disease. For example, FDA should continue to work to modernize the clinical trial process to improve efficiency and reduce the costs and uncertainty present in drug development. I also think it is important that FDA work with other government agencies such as NIH and CDC to ensure that we employ a unified approach. NIH plays a critical role in funding the basic research necessary to understand the underlying mechanisms of disease and is an important partner in translating that knowledge into treatments for patients.

Question 2.

The average consumer uses 10 personal care products every day, yet the laws governing the cosmetics and personal care products industry haven't been updated since 1938. 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. I commit that, if confirmed, I will work with staff at FDA, industry, consumers, and members of the scientific community to understand what needs to be done to take a proactive stance to monitoring the safety of the cosmetics market for consumers. I will also work to better understand the risks to public health presented by cosmetics products. It is important that consumers be able to trust that the cosmetics they buy are not contaminated by harmful substances or manufactured under substandard conditions.

Question 3.

Last year, former Commissioner Gottlieb stated, "we're committed to exploring ways to help FDA scientists and product developers reduce reliance [on animal testing] and that "we have already taken significant steps to reaffirm and strengthen our commitment to replacing, reducing, and/or refining animal studies and support the development and use of alternative methods." Will the FDA commit to working with animal welfare experts and the personal care products industry to further phaseout animal testing broadly, with specific attention to animal experiments for cosmetics? What is FDA currently doing to advance recognition and acceptance of alternatives to animal test methods?

Answer 3. I agree that we should minimize the use of animals in research especially in the area of cosmetics. If confirmed, I will support efforts to develop alternative testing methods that do not require animals. I also recognize that there are a number of stakeholders, including industry, that need to work together on this issue and I will ensure that FDA works collaboratively to make progress in lessening the burden of research on animals.

Question 4.

Electronic Labeling of Prescribing Information. During the appropriations process, I often raise FDA's proposed rule on Electronic Prescribing Information and its implication for rural pharmacists. This 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. 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 4. I recognize that FDA regulation should not unnecessarily burden rural pharmacists, who play a front-line role in the health of their communities. If confirmed, I will ensure that their interests are taken into account as well as other stakeholders in deciding the path forward for rules related to electronic prescribing information.

Question 5.

Fishless Fish. I want to ask you about a truth in labeling issue that hits home for the seafood industry in my state. Recently, a variety of "fishless fish" products made from algae, plants, and legumes have appeared in the U.S. marketplace. Producers of these foods market them to consumers as salmon, lobster, shrimp, or tuna, yet none of these products contain any actual fish or seafood. These products appear to violate FDA regulations and labeling requirements. Under Sections 343(b) and (c) of the Federal Food, Drug, and Cosmetic Act, a product offered for sale under the

name of another food or as an imitation of another food is considered misbranded when the label does not expressly state that the product is "imitation". Consumers should be able to enjoy new and innovative food products, but Congress has provided FDA with the authority and responsibility to ensure those products are not mislabeled or misleading. If confirmed, will you ensure that the FDA uses its authority to remove these inaccurate labels from the marketplace and enforce its existing Seafood List with respect to these products?

Answer 5. I agree that consumers should be able to trust that the food they buy is accurately labeled. And manufacturers and farmers should have a level playing field where they are not facing unfair competition. If confirmed as Commissioner, I will support FDA's use of its authority provided by Congress to ensure products labeled as seafood are, in fact, seafood.

SENATOR SCOTT

Question 1.

Given FDA's numerous responsibilities and authorities, will you commit to engaging with my office and with relevant stakeholders to explore and, ideally, to address each of the following issues and opportunities for the agency?

Answer 1. I commit to you that, if confirmed, I will work with your office and other interested stakeholders on each of these important issues. I offer the following initial thoughts.

> a. PDUFA VI and the 21st Century Cures Act outlined a number of new initiatives aimed at facilitating efficient patient access to life-changing new therapeutic options. I urge you to build upon your predecessor's work in continuing to push forward with these initiatives, including patient-focused drug development, real-world evidence, and innovative clinical trial designs.

Answer a. Both PDUFA VI, enacted as part of the Food and Drug Reauthorization Act in 2017, and the 21st Century Cures Act provided FDA with significant new authorities to improve the drug development and approval process. I believe we can together build on the work underway at FDA which can be tracked at the following two sites:

https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.

https://www.fda.gov/regulatory-information/21st-century-cures-act/21st-century-cures-act-deliverables.

> b. Innovative gene and cell-based therapies have the potential to transform the treatment landscape. In the long run, they will improve quality of life for tens of millions of Americans and dramatically drive down healthy system costs. However, these products also present unique regulatory challenges and face manufacturing and logistical hurdles. I hope to work with you on ensuring that FDA has the tools and flexibilities needed to tackle the agency's recruitment and retention needs on this front, particularly given the hiring competition that the agency has likely confronted from some of the same startup biotechs that it regulates in this sphere. I also hope to work with your agency and with impacted stakeholders on ensuring that these novel treatments can overcome manufacturing and logistical barriers and reach patients.

Answer b. I agree that gene and cell-based therapies have great potential as new and innovative ways to treat disease. I also recognize that recruiting a workforce with experience in these rapidly evolving fields can be challenging, both because of the competition for the necessary skills and experience and because of bureaucratic challenges in the hiring process. As the Chief Medical Executive of University of Texas MD Anderson Cancer Center, I am familiar with these challenges and recognize that recruitment and retention must be a top priority. I commit that, if confirmed, I will focus on building and maintaining a modern workforce able to address the many issues facing innovators, such as those related to manufacturing and logistics.

> c. On the post-market side, gene therapies and over cutting-edge treatments present opportunities for innovative payment arrangements, such as value-based arrangements (VBAs), whereby manufacturers pay over time based on patient outcomes. FDA's Communication guidelines have, however, created some uncertainty on this front. While FDA updated its guidelines in 2018, additional clarity would be helpful as to what performance metrics and populations can be part of a VBA, particularly if those metrics or pa-

tient subpopulations are not specifically included in a drug's label. Because conversations between developers and payors around these arrangements often need to begin before labeling information and/or approval is available, the ability for VBAs to help facilitate adoption of these therapies may be limited. I encourage the agency to take whatever steps necessary to address remaining uncertainties and to further facilitate the communications needed for efficient and timely VBA design, development, and implementation among interested stakeholders.

Answer c. I recognize the benefits of providing clear guidance to manufacturers and other firms on their communications with different audiences. The information appropriate for sophisticated payors is different from what is appropriate for patients. I commit that, if confirmed, I will support the Agency in providing further clarity on this issue.

d. The goals of FDA's unapproved product enforcement activity are to remove unapproved prescription drugs and devices from the marketplace and to ensure that patients have access to medically necessary products that are safe and effective. In order for the agency's enforcement activity to function well, FDA must continue to encourage manufacturers of unapproved products to obtain approval to be legally marketed. Once such approval is obtained, the agency must then prevent the sale of these products by manufacturers who have not received approval. Removing these unapproved products from the market ensures that patients have access to safe and effective drugs, while also encouraging the R&D necessary to bring previously unapproved drugs up to FDA's standards. If the agency does not take steps to prevent the manufacture, marketing, and distribution of unapproved drugs and devices, patients remain at risk of adverse events. I would encourage FDA to consider taking additional steps to protect patients and uphold the integrity of the marketplace by limiting the availability of unapproved products.

Answer d. As a physician, I prescribe drugs to my patients relying on FDA to ensure their safety and effectiveness. Unapproved drugs that are still on the market undermine this trust and pose a risk to patients. I commit that, if confirmed, I will support the Agency's Unapproved Drugs Program which balances the removal of unapproved drugs from the market with the need to ensure patient access to medically necessary products.

e. Under FDA's HCT/P framework, companies must self-designate the products that they believe qualify as 361 HCT/Ps. To date, guidance from FDA has left significant room for interpretation, creating regulatory uncertainty and disincentivizing innovation and investment in this area. In the interest of helping to bring important and affordable treatments to patients, there may be a need for additional certainty as to the appropriate regulatory treatment of these products.

Answer e. Advances in regenerative medicine have real potential to help patients. I recognize that industry will only invest in this area if FDA establishes clear rules to help foster innovation. I commit that, if confirmed, I will work to ensure that FDA provides the needed regulatory clarity so industry can bring innovative new human cells, tissues, and cellular and tissue-based products to market.

f. The potential for 21st century innovations such as AI applications to improve diagnostic accuracy and quality may call for revisiting existing regulatory pathways in order to ensure predictability and efficiency.

Answer f. As with any technology, advances in artificial intelligence bring new challenges along with new opportunities. Artificial intelligence has the potential to improve our ability to detect disease and improve the outcomes for patients. FDA must strike the appropriate regulatory balance to allow innovation while ensuring that diagnostic tools that use artificial intelligence are sufficiently reliable.

g. On April 5, 2018, the Surgeon General released an advisory statement, emphasizing the importance of expanding access to naloxone. In December 2018, an FDA joint advisory panel recommended the co-prescribing of naloxone with opioids. Shortly thereafter, HHS released naloxone co-prescription guidelines, calling for "co-prescribing naloxone when a patient is considered to be at high risk of an overdose," as "an essential element of our national effort to reduce overdose deaths" that "should be practiced widely." In April, CMS released the final 2020 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter, encouraging insur-

ance plans to implement co-prescribing for beneficiaries at an increased risk for an opioid overdose. In short, the Surgeon General, HHS, CDC, CMS, SAMSHA, the AMA, AAFP, ASAM, a growing number of states, and FDA's advisory committee all support increasing access to naloxone through co-prescription. I hope that you will commit to working with my office and Congress to ensure that FDA increases access to naloxone by considering the addition of labeling language recommending co-prescription of naloxone for those at increased risk of opioid overdose.

Answer g. I commit that, if confirmed, I will review FDA's efforts related to the opioid epidemic including the appropriate labeling of naloxone. Opioid misuse and abuse is an urgent public health crisis and would be one of my very top priorities as Commissioner of Food and Drugs. I understand the damage that opioid addiction causes our society. I also appreciate the current role opioids play in alleviating human suffering. I look forward to the potential opportunity to work within HHS on the comprehensive plan to combat this epidemic and appreciate your raising this issue.

h. Earlier this year, I read an article about a woman from Mississippi who has seen promising results to treat her sickle cell disease using a revolutionary treatment from a small biotechnology company. We now know that these treatments can work, but there are some estimates that this class of products might not be on the market for up to a decade, due to FDA's data requirements. Some experts have advised that FDA use biomarkers as the benchmark to approve these types of therapies, assuming that they can be aligned with clinically significant outcomes. I would urge your agency to do everything possible to speed these treatments to market, assuming that they continue to prove safe and effective for patients.

Answer h. I commit that, if confirmed, I will look for opportunities to further speed the development process and review of innovative medical products, while upholding FDA's gold standard for safety and efficacy. For example, I will review FDA's expedited programs, including accelerated approval which allows FDA to approve drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint.

i. As an advocate for the increased personalization of medicine, as evidenced, most recently, by my decision to partner with Senator Sinema to launch a bipartisan Personalized Medicine Caucus, I am deeply interested in the role that diagnostic innovation might play in helping us to detect diseases and other medical conditions earlier, as well as to better identify and thus target and combat their root causes. As some of my colleagues have begun working to modernize the regulatory framework for diagnostic tests of all types, my understanding is that FDA has been a constructive and proactive partner. I look forward to engaging with my colleagues and with the agency in this area.

Answer i. As a physician who relies on accurate diagnostic tests to treat my patients, I thank you for advocating for personalized medicine. I agree that innovation in this area will have real benefits for the public health of the Nation. I commit that, if confirmed, I will ensure FDA continues to partner with you, other members of the Personalized Medicine Caucus, and interested stakeholders to adapt FDA's framework to modernize the regulation of diagnostic tests.

SENATOR ISAKSON

Question 1.

Dr. Hahn, FDA first committed to publish separate regulations on medical gases in 1978. Congress has passed two statutory mandates that require FDA to complete the rulemaking process for medical gases by July 2017 and yet small business medical gas manufacturers are still waiting.

If confirmed as Commissioner of FDA, will you ensure that FDA complies with its statutory obligations and promulgates its overdue separate regulations for medical gases in 2020?

Answer 1. I am committed to working with your office on this issue and working to protect American patients. I look forward to working with FDA's professional staff to study this issue and understand the most efficient path forward that protects patients.

Question 2.

Georgia is one of the top olive-producing states in the country. I understand that FDA is or will soon be reviewing a standard of identity (SOI) petition that, if approved, would establish quality and purity standards for American olive oil. Such standards would provide consumers with accurate and reliable information on the products they purchase as well as ensure the authenticity of foreign imports. What is the status of FDA's review of this petition? Can you offer a timeline for when this review will conclude?

Answer 2. Although I cannot provide a specific timeline for reviewing the standard of identity for olive oil as I am not currently a part of FDA, I can commit that I will support the Agency in its next steps. I think it is important that consumers have access to accurate information about the food that they eat and that industry competes on a level playing field.

SENATOR BRAUN

Last March, the U.S. Food and Drug Administration (FDA) ordered that Aid Access, an international organization based in Austria, cease distributing abortion pill Mifeprex (Mifepristone), on demand through the mail. Despite regulations by the FDA limiting distribution of these pills through a Risk Evaluation and Mitigation Strategy (REMS) precluding the importation of these drugs, Aid Access has reportedly continued to prescribe these drugs to women in the United States and directing them to have these drugs shipped from a company in India. Aid Access has ignored the FDA's order and instead countersued them out of Idaho to strike down the existing REMS.

Question 1.

What enforcement steps could you as FDA commissioner take to address these violations of the law? Would you consider issuing an import alert—so that international mail facilities could be inspected and put on alert? Would you consider partnering with the Department of Justice to consider enforcement options such as injunctions or seizure of the illegal drugs?

Answer 1. If confirmed, I will work with Agency staff to determine what enforcement steps the FDA has at its disposal. Science, data, and the law will guide my decision making at the FDA.

In 2016, the Obama administration watered down the REMS for abortion pills, and since then, abortion groups and a former FDA chief have been pushing to make abortion pills available for do-it-yourself abortions by mail and without doctor supervision currently still required. Given the documented adverse effects of these drugs, allowing their availability without doctor supervision will be dangerous and may have detrimental, even fatal, consequences to women. Moreover, the current reporting may not entirely reflect issues with these drugs. Though the drug company that makes Mifeprex DANCO, is mandated to report complications to FDA and prescribers must report deaths, it is still optional for prescribers to report any other adverse effects to DANCO.

Question 2.

Would you consider strengthening the current REMS for abortion pills to improve protections for patients along the lines of the pre-2016 REMS—such as by limiting the gestational timeframe back to 49 days and restoring the requirement to require physician supervision (without allowing nonqualified health providers)? How will you better ensure complete reporting of adverse events? Would you consider requiring adverse events to be reported by prescribers, not only by the abortion pill manufacturers?

Answer 2. As a provider, I am committed to my patient's safety. If confirmed, patient safety will be my top priority and I will always be guided by science, data, and the law.

AquaBounty Technologies, which produces AquAdvantage Salmon, has a fish farming facility located in my home State of Indiana. Using biotechnology and land-based recirculating systems, AquaBounty's salmon grows year-round, reaching market weight in half the time of other farm-raised Atlantic salmon and thereby requiring less feed and water while minimizing waste and stress on our oceans.

Question 3.

On what date did AquaBounty file an Investigational New Drug Application with FDA?

Question 4.

On what date did FDA approve AquAdvantage salmon for human consumption?

Question 5.

Did FDA find that AquAdvantage salmon was safe to eat?

Question 6.

On what date did FDA approve the grow-out of the salmon in a land-based facility in Albany, Indiana?

Question 7.

If you are confirmed as our next FDA Commissioner, would you overturn or undermine FDA's previous science-based approvals and determinations for AquaBounty's salmon?

Answers to 3–7. Thank you for your questions on AquaBounty. According to public information, AquaBounty Technologies, submitted a Supplemental New Animal Drug Application on December 22, 2017, and the FDA approved the supplemental NADA on April 26, 2018. If confirmed, science, data, and the law would guide all of my decisions.

Two years ago, Congress passed the FDA Reauthorization Act of 2017 (FDARA) to adopt uniform standards around not-for-cause inspections and to improve the FDA process for inspecting medical device facilities in general. The provisions were intended to address inefficiencies and inconsistencies in the process, which include the open-ended nature of facility inspections, inconsistent communications, a lack of punctuality in FDA responses, and differing behavior in U.S. and foreign inspections. The legislation was passed in response to stakeholder calls for a more transparent, efficient and consistent process. I've heard that FDA has had dialog with industry while working to implement the provisions, and that some progress has been made but more work remains.

Question 8.

Please provide an update on FDA's plans to develop and implement facility inspection regulations and guidance that take into account stakeholder input and congressional intent.

Answer 8. I do not currently have information on FDA's plan, but if confirmed, I commit to providing you and office an update on FDA's plans to develop and implement facility inspection regulations and guidance that take into account stakeholder input and congressional intent.

Additionally, FDA has been very aggressive in issuing letters with safety concerns about particular devices or particular kinds of devices—even before they've done a full evaluation of available data or talked to the manufacturer. I'm not opposed to FDA communicating with patients, doctors, or anyone else regarding safety issues—but manufacturers should be included in the process for issuing these letters. And there should be a process for correcting the record when data show, after the fact, that there isn't an issue after-all.

Question 9.

We have heard concerns regarding FDA's implementation of the emerging signals program. How will you ensure that manufacturers are duly consulted both in the determination of a signal and in communicating the signal to the public?

Question 10.

Would you agree the agency's emerging signals program must have a process for correcting the record in instances where it is later determined that the signal is faulty?

Answers to 9–10. I appreciate you raising your concerns with FDA's implementation of the emerging signals program. If confirmed, I will work with Agency staff to consider ways to ensure the program is working for patients, providers, and manufacturers.

The FDA issued its final guidance document regarding radiopharmaceutical compounding in September 2018. This document provides important clarity about definitions of illegal compounding and counterfeiting of diagnostic radiopharmaceuticals and FDA staff have done a commendable job of raising awareness among stakeholders in the nuclear pharmacy community.

Nonetheless, there is continued evidence that a small, but potentially significant subset of nuclear pharmacies continue to exploit ambiguities in Federal and state laws and regulations to operate defacto drug manufacturing facilities, without complying with FDA regulatory protections, which raise serious concerns of illegal compounding and counterfeiting.

For instance, at least one such operation appears to be manufacturing thousands of lyophyllized (freeze-dried) kits for the preparation of diagnostic radiopharmaceuticals, which constitutes compounding copies of FDA-approved and commercially

available drugs, in anticipation of prescriptions or orders and selling and distributing these illegal copycat drugs throughout the United States. These actions seem to contradict the final FDA Guidance for Industry Compounding and Repackaging of Radiopharmaceuticals by State Licensed Nuclear Pharmacies (503A) and by Outsourcing Facilities (503B), both of which expressly prohibit compounding copies of FDA-approved and commercially available drugs.

Question 11.

How is the FDA addressing illegal compounding/counterfeiting of diagnostic radiopharmaceuticals at the Federal level, since the release of the 2018 guidance document on Compounding and Radiopharmaceuticals?

Answer 11. Since I am not at the agency, I am not familiar with how FDA is addressing illegal compounding/counterfeiting of diagnostic radiopharmaceuticals. If confirmed, I will work with FDA staff on this important issue.

Job creators in the food industry need to be able to innovate to grow, yet outdated Federal food "standards of identity" often stand in the way of companies utilizing new technologies. For instance, petitions to update the yogurt and cheese standards have been pending for 20 years. FDA's Nutrition Innovation Strategy included standards modernization as one of its key activities and recently held a public meeting on Horizontal Approaches to Food Standards of Identity Modernization. However it is unclear what specific actions and under what timetable FDA will address changes to its food standards.

Question 12.

As Commissioner what actions will you take to be more proactive and responsive to modernize dairy standards?

Answer 12. I am in favor of clear, transparent and understandable food labeling for the American people. The American people need this so that they can make the appropriate decisions for their health for their nutrition. If confirmed, I will ensure that FDA follows the scientific evidence to guide actions in this area.

FDA regulations put a high value on controlled clinical trials to provide sufficient evidence of safety and effectiveness to support market availability of new drugs. The nature of the controlled trial depends on the risks. The value of placebo controlled trials is more than questionable in patients with life threatening diseases. Placebo controlled trials are not often attempted in therapeutic cancer studies. And many cancer drugs are approved based on comparison to historical standard of care in situations where no other drugs are approved for the specific use or indication.

Question 13.

Given this, as Commissioner of FDA, would you insist on placebo controlled trials as a condition for FDA approval (conditional or full approval) for treatments intended to treat fatal diseases like DMD and ALS?

Answer 13. FDA's role is to ensure the safety and efficacy of drugs, and that standard cannot be diminished. However, I believe that big data can provide us new opportunities to design clinical trials that may not need a control arm when it is not in the best interest of patients and when the data collected from these trials allows for the best decision making regarding safety and efficacy.

In DMD and ALS, over half of the treating physicians are easily reachable, so news is able to spread quickly about a particular treatment and that treatment can be pulled from the market, or its effects studied more closely.

Question 14.

In your view, with the risks minimized by virtue of a small circle of treating physicians and vast advocacy networks, are historical controlled trials, post approval studies, and increased FDA post-market oversight appropriate to help facilitate conditional or full approval of certain treatments intended to treat fatal diseases, like DMD and ALS, with no meaningful treatment options available for patients?

Answer 14. FDA's role is to ensure the safety and efficacy of drugs, and that standard cannot be diminished. However, within that construct I hope to work with Agency staff to advance the drug approval process to make sure patients can have access to life-saving drugs, particularly in disease states where there is substantial unmet clinical need.

[Whereupon, at 12:14 p.m., the hearing was adjourned.]

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