thought all of us want to make sure we can track people down who are using guns to commit crimes and catch them. If you print a gun at home using a 3D printer, there is no traceable number, there is no serial number. We are not going to be able to easily track down the people who are using these guns to commit crimes.

No. 3, with plastic 3D printing, the technology we have at airports to detect metal will become ineffective.

Folks around the world, if you are a terrorist wanting to do harm, now you are going to get instructions over the internet. You are going to be able to download it as easy as you can download an iTune. With a 3D printer in your basement or around the corner in some space, you are going to be able to manufacture guns; No. 1, evading metal detectors at airports, putting the entire flying public at risk; No. 2, it is a public end-run around the criminal background check system, which is already flawed; and, No. 3, it will not allow us to trace guns used in crimes.

I thought there was a consensus in this body that we should get after people who use guns to commit crimes, whether crimes in the United States or crimes around the world. Yet what this body is doing by not allowing a vote today on the Nelson bill is saying it is OK for people to be using this technology in their basements to make guns that can evade all these systems and commit crimes and make it impossible to trace who did it.

This is a really bad day for the U.S. Senate. This is a moment where people should be acting in emergency fashion to stop this danger and risk to the American public. Instead, people are folding up their tent and allowing this to happen, starting tomorrow. It is a shameful moment.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

## ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2018

Mrs. MURRAY. Mr. President, in February, the HELP Committee passed a bill to reauthorize the animal drug and animal generic drug user fee programs at FDA. That bill was the result of months of bipartisan work. During markup, we worked together to put aside differences and adopted an amendment from Senator MURPHY increasing innovation in animal drug trial designs to advance more medicines for our pets and livestock—similar to the work we did for humans in the 21st Century Cures Act—and an amendment from Senator PAUL to clarify the regulatory process for animal feed additives.

We worked together because this bill has to pass by August 1 to avoid disruption to the hard-working employees at FDA who ensure our pets and food-producing animals have safe and effective drugs.

Last month, the House Energy and Commerce Committee took our bipartisan bill that we worked on together and added a controversial amendment that expands the conditional approval pathway for animal drugs. Currently, the FDA can conditionally approve an animal drug for a minor species or for an uncommon disease in a major species. This narrow category of drugs can be approved, for a limited time, and sold to customers while the company collects data to determine whether the drug actually works. This pathway was supposed to spur innovation, but only four drugs have ever been conditionally approved in the pathway's 14-year history, and only one of those four was actually effective and gained full approval.

That is not a very good track record. Nonetheless, the House bill expands that pathway to any difficult-to-develop animal drug that can address an unmet need and doesn't even define what qualifies as difficult.

I have been very concerned that the undefined scope of this pathway sets a terrible precedent and, more importantly, doesn't uphold the gold standard of FDA approval that our public relies on. However, today Dr. Gottlieb has made public assurances to both me and our chairman that he intends to implement this provision with additional caution and restrictions, according to congressional intent.

FDA has committed to promulgating regulations to define what it means for a study to be ''difficult.'' Importantly, FDA has publicly agreed that conditional approval is not an appropriate pathway for any human medical products or antibiotics.

Antibiotic resistance is a large and growing global public health problem, and the rampant overuse of medically important antibiotics in our food supply compounds that problem. I am very pleased this bill requires FDA to report on its work to bring all medically important antibiotics under veterinary supervision, but there is more to do.

I thank Senators WARREN, FEINSTEIN, GILLIBRAND, and BLUMENTHAL for their leadership on reducing the nonjudicious use of antibiotics in animals. On Friday, Senator WARREN sent a letter to FDA asking for additional actions and commitments to bring all medically important antibiotics under veterinary supervision and reevaluate duration limits for antibiotic abuse.

I thank Mr. Gottlieb for his quick response to Senator WARREN and his clear commitment to work with us on these issues, including greater transparency into the progress of removing unlimited durations of antibiotic use. I sincerely hope we can avoid these situations in the future, where deals struck between FDA and the industry, with little transparency, are then somehow demanded of Congress.

Senator ALEXANDER and I included language in this year's agricultural appropriations bill that makes clear Congress does not find this appropriate, and I hope the FDA and its regulated industries take that language seriously in future user fee negotiations.

I support moving this bill forward today, but I do plan to conduct careful oversight into the implementation of this law and hold FDA accountable for any deviations from the commitments made to me today.

Mr. President, I ask unanimous consent that the letter addressed to Senator ALEXANDER and myself from Scott Gottlieb and Steve Solomon be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. FOOD & DRUG ADMINISTRATION,
*July 31, 2018.*

Hon. LAMAR ALEXANDER, *Chairman*,
Hon. PATTY MURRAY, *Ranking Member*,
*Committee on Health, Education, Labor and Pensions, U.S. Senate, Washington, DC.*

DEAR CHAIRMAN ALEXANDER AND SENATOR MURRAY: We are writing to share with you the Food and Drug Administration's (FDA or the Agency) current views on how it would implement the proposed expanded conditional approval pathway in H.R. 5554, the ''Animal Drug and Animal Generic Drug User Fee Amendments of 2018.'' The Agency's staff were directed to review the possibility of expanding the conditional approval pathway by the previous reauthorization of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA) programs in 2013, and we are prepared to implement the expansion of the pathway as outlined in H.R. 5554, if enacted, with appropriate regulatory caution and restrictions.

FDA currently has conditional approval authority for animal drugs intended to treat a minor species or for diseases or conditions in major species that would constitute a minor use, which was granted by the addition of section 571 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 2004 by the Minor Use and Minor Species Animal Health Act (MUMS Act). To receive conditional approval, an animal drug sponsor must meet the same safety and manufacturing standards as a new animal drug for which full approval is sought under section 512. The main advantage of the conditional approval pathway for sponsors is that they can make their drug available after demonstrating a reasonable expectation of effectiveness. The pathway requires an annual review of the conditional approval to determine if the sponsor is making sufficient progress toward meeting the effectiveness standard for full approval.

FDA believes conditional approval offers a unique pathway to address specific challenges of certain aspects of veterinary medicine that human medicine does not face. Therefore, FDA does not believe this pathway would be suitable for human medical products. For example, variability in response to therapies among animals means that one product is not likely to meet the needs of all animals. Even within a single species (e.g., canine), it is well-documented that there can be significant variability among animal breeds in how drugs are metabolized (e.g., ivermectin is toxic for collies, but safe for other breeds). Despite the need, incentivizing new product development continues to be a challenge for the industry given the limited market for veterinary drugs. Based on experience, we believe this pathway would be used uncommonly, as a sponsor must make a substantial investment of time and resources to obtain the conditional approval. In addition, the sponsor

must be confident that they will ultimately be successful in meeting the substantial evidence of effectiveness standard required for full approval under section 512(b). FDA's review of its active pending animal drug products in various phases of development indicates that 16 products might qualify for the new pathway. FDA's best current estimate is that 12 to 20 animal drugs might seek conditional approval during the 10–year authorization period provided in H.R. 5554.

FDA has acted to withdraw conditional approval when sufficient progress towards meeting the effectiveness standard for full approval has not been met. For example, FDA withdrew the conditional approval of the drug Paccal Vet-CAI in 2017, after it was conditionally approved in 2014, for this reason. Since the MUMS Act was enacted in 2004, only four drugs have received conditional approval, and FDA has only granted a full new animal drug approval to one of these drugs. We want to assure you that FDA will make certain there are appropriately defined parameters for this expansion of the conditional approval pathway, which will be developed through a public process.

The proposed expansion of the pathway in H.R. 5554 would allow certain animal drugs that are not intended to treat minor species or minor uses in major species to qualify for conditional approval, but only if they meet two key requirements. The first proposed requirement is that the drug must be ''intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need.'' FDA considers serious or life-threatening diseases or conditions to be those that, if untreated, are likely to lead to an animal's death, such as congestive heart disease and lymphoma. FDA intends to define ''unmet need'' similarly to how the term is defined in FDA's Expedited Programs guidance for human medical products. FDA intends to provide more details to clearly define this first requirement in the guidance or regulation it would be required to issue.

The second key requirement for eligibility would be that ''a demonstration of effectiveness would require a complex or particularly difficult study or studies.'' FDA believes use of the conditional approval pathway should and will be limited to situations in which effectiveness is in fact particularly difficult or complex to demonstrate, and would only be granted after demonstrating a reasonable expectation of effectiveness. FDA intends to consider whether the clinical end-points of the disease or condition are particularly difficult to evaluate. FDA also intends to consider factors such as the need of a sponsor to use complex adaptive or other novel investigation designs, real world evidence, and the difficulty of enrolling trials. To clarify the limited scope of new animal drug applications for which this pathway would be available, FDA intends to issue regulation to describe the elements it would consider in determining whether an effectiveness study would be difficult or complex to complete.

The proposed conditional approval expansion requires FDA to issue guidance or regulation by September 30, 2019, to clarify these criteria; FDA expects to finalize these documents before accepting applications for the expanded conditional approval pathway. We can assure you that FDA believes this expanded pathway should be used only in very limited cases, since its goal is to bring new veterinary therapies to market for which there have not been sufficient incentives to do so through the traditional new animal drug approval pathway. FDA does not believe the age conditional approval pathway should be available to new animal drugs that easily could use the traditional new animal drug approval pathway. If H.R. 5554 is enacted, we will keep your staff closely updated on our efforts to clarify in guidance and regulation the statutory restrictions on use of the expanded conditional approval pathway.

H.R. 5554 also contains language that will provide Congress the opportunity to reconsider conditional approval. The proposed pathway will sunset after 10 years, to coincide with the reauthorization of the user fee programs in 2028. In addition, the language requires a Government Accountability Office study to be completed prior to this date so that Congress, the Agency, and stakeholders can evaluate the expanded conditional approval pathway prior to its sunset. The sunset provision would create an incentive for the Agency and stakeholders to demonstrate that this pathway's implementation is appropriately implemented and judiciously utilized. Finally, H.R. 5554 further restricts this pathway by prohibiting any drug that contains an active antimicrobial ingredient from utilizing the expanded pathway.

In closing, we want to remind you that if H.R. 5554 is not reauthorized before August 1, 2018, we must initiate the process of adjusting animal drug review activities and the personnel engaged in those activities, including identifying and notifying 115 full time equivalent federal employee positions of a reduction in force no later than 60 days prior to their expected release. This could not only result in 115 full time employees being terminated, but would disrupt work and morale—not only for hundreds of other employees at the Agency's Center for Veterinary Medicine, but for their colleagues in other Agency centers as well.

We hope that we have been able to alleviate any concerns you have with the temporary, limited expansion of the Agency's existing conditional approval pathway for animal drugs in H.R. 5554, and that you will support timely passage of this bill to avoid any reductions in force and disruptions at the Agency. Again, you have our personal commitment to keep your staff informed as we implement this provision, if it is enacted.

Sincerely,

SCOTT GOTTLIEB, M.D.,
*Commissioner of Food and Drugs.*
STEVE SOLOMON, D.V.M, M.P.H,
*Director, Center for Veterinary Medicine.*

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, in a moment, I will specifically address the comments the Senator from Washington made. First, I would like to acknowledge that she and other Members of the Senate worked with us to make sure this legislation could become law by August 1, and I thank her for that.

Sometimes the House accepts a Senate bill, as it did with the Perkins Career and Technical Education Act that the President signed today, and sometimes the Senate accepts a House bill, as I will move that we do today. One reason we are able to do that is because our committees work closely with the House to try to take as many of their good ideas as we can so we can pass each other's bill, if that became necessary. The second reason that happens is because Senator MURRAY characteristically works with me to solve problems like she is doing today, and I am grateful to her for doing that. We don't agree on everything, but we agree on a lot.

I noticed in our committee hearing the other day that the Committee on Health, Education, Labor, and Pensions, of which I am chairman and she is the ranking Democrat, has approved 50 bills this Congress. Eighteen of them have been signed by the President. Some more will be signed by the President.

We are working hard on opioids legislation, which is of great interest to almost every Member of this body. Our committee has unanimously reported that to the floor, and we are working with other committees. We have been working with the House on that. We are working on getting generic drugs to market more easily, something that has needed to be done for 20 years. We have reported that out to the Senate. Pandemic legislation—dealing with epidemics and being prepared for them—is ready for the Senate to act on.

This is characteristic of the work Senator MURRAY and her staff do. As she mentioned, this bill is the last of the so-called user fee agreements. We passed four last August that dealt with about $9 billion in industry user fees to fund the Food and Drug Administration. This is another bill to do that. These bills are complicated and difficult and involve lots of discussions. In the end, they often pass by agreement, as this one will today, I believe, but that is because of the amount of work our staff and Senator MURRAY's staff and the House of Representatives have done. I thank them for that.

The FDA user fee bills provide about half the funding the Food and Drug Administration uses every year to keep the drugs we buy at our pharmacies and get at the doctor's office safe. We take it for granted, but it is the gold standard, and we work very hard to try to make sure we don't infringe on that gold standard of safety and efficacy.

The House of Representatives has passed, by unanimous consent, the bill we referred to, the Animal Drug and Generic Animal Drug User Fee Amendments, which reauthorizes user fee programs that allow the animal drug industry and the Food and Drug Administration to continue to expedite the review of safe and effective treatments for animals. These updated agreements have been carefully worked out between the Food and Drug Administration and the animal drug industry, with input from farmers and ranchers, food and feed producers, veterinarians, and other stakeholders.

If Congress doesn't do its job, as the Senator from Washington said, to reauthorize these critical programs before August 1, the Food and Drug Administration will be forced to send layoff notices to 115 employees. By our action today, we will be able to avoid that.

The review of over 2,000 animal drug applications and investigational submissions currently pending before the Food and Drug Administration will be significantly delayed if we don't act, and we intend to act. This means it

will take longer for new animal drugs and treatments to be available to farmers, ranchers, veterinarians, and families, but, fortunately, because of the cooperation today, that will not happen.

The Health, Education, Labor, and Pensions Committee, our committee, approved the Senate version of this bill on February 28 of this year by a bipartisan vote of 22 to 1. The bill passed the House in almost identical form that was approved by the HELP Committee in February, but the House bill, as Senator MURRAY said, expands conditional approval to encourage innovation and competition.

Conditional approval allows a drug to go to market once it meets the Food and Drug Administration safety standards, and then the drug company has up to 5 years to prove the drug is effective. Based on bipartisan feedback about conditional approval, the House of Representatives agreed to make three changes in its bill: No. 1, a 10-year sunset for conditional approval; No. 2, clarify the conditional approval does not require an additional fee to be paid to the Food and Drug Administration; and, No. 3, a Government Accountability Office report on conditional approval.

Senator MURRAY and I agree that we need to clarify what it means for a drug to be ''difficult to study.'' I have talked to Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration about these concerns, and he agrees. Dr. Gottlieb has agreed to quickly issue guidance and develop regulations that provide clarity on what ''difficult to study'' means and that do not change the gold standard of the Food and Drug Administration's drug approval process.

Also, conditional approval is not available for antimicrobial drugs. The language in the bill is clear, and Dr. Gottlieb understands that conditional approval is not available for antimicrobial drugs.

Congress will also conduct oversight to make sure conditional approval is achieving the goal of helping more pets and keeping our food supply safe. This bipartisan legislation will help keep animals healthy, prevent disease outbreaks, and protect our food supply.

Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 5554.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 5554) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

The PRESIDING OFFICER. Is there objection to proceeding to the measure?

Without objection, notwithstanding rule XXII, the Senate will proceed to the measure.

Mr. ALEXANDER. I ask unanimous consent that the bill be considered read a third time.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The bill was ordered to a third reading and was read the third time.

Mr. ALEXANDER. I know of no further debate on the bill.

The PRESIDING OFFICER. Is there further debate?

If not, the bill having been read the third time, the question is, Shall the bill pass?

The bill (H.R. 5554) was passed.

Mr. ALEXANDER. I ask unanimous consent that the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ALEXANDER. I yield the floor.

## INTERIOR, ENVIRONMENT, FINANCIAL SERVICES, AND GENERAL GOVERNMENT APPROPRIATIONS ACT, 2019—Continued

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Mr. President, I ask unanimous consent to speak as in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

### IMMIGRATION

Mr. DURBIN. Mr. President, from the earliest moments in the Presidential campaign, Donald Trump made it clear that immigration was an important issue to his election. You will recall statements that he made about the construction of the wall on the southern border of the United States. He called it the big, glorious, gorgeous 2,000-mile wall, and he promised us that the Mexicans would pay for it. Over and over he promised us they would pay for it. That wasn't the only reference made to immigration during the course of the campaign, so it came as no surprise, when President Trump was elected, that immigration became a major issue in his administration.

It is ironic, in a way, that this Nation of immigrants called America would have such struggles these days with the issue of immigration. Many of us can trace our origins to recent immigrants. In my own case, my mother was an immigrant to this country, and here her son turned out to have a full-time government job as a U.S. Senator.

My story is my family's story, but it is also America's story of how the sons and daughters of immigrants came here and tried to—and in many ways did—make a difference in the country we live in. Despite that fact, despite the Statue of Liberty and all of our heritage from immigrants coming to America, there has always been a political voice and a political force that has resisted more immigration.

There were people who have said: We have enough. They are going to take our jobs. They don't practice our religions. They don't speak our language. Their food smells funny. We don't like the way they dress.

Over the course of decades, if not centuries, that was always part of the American political life, but it was a minority position. With the Trump administration, immigration issues have been front and center. We have seen that many times.

Years ago, I introduced the Dream Act. The Dream Act said that if you were brought to this country, undocumented as a baby, as a child, you should have a chance to earn your way to legal status to become part of America's future. I have tried to pass that bill, and I have been successful in the Senate a few times. We have been successful in the House, but it has never made it through both Chambers to become the law of the land.

President Obama created a program called DACA, based on the Dream Act, which allowed those who qualified to have 2-year temporary, renewable status, protected from deportation, with the legal right to work.

Last year, President Trump abolished the program, and 790,000 young people who were protected—who had registered with the government, who had paid a filing fee, who had gone through a criminal background check and were going to school and working—were told their protection would go away.

Were it not for a court decision to protect them, many of them would be deported today. But that court decision can change any day, any week, any month.

We tried in February on the floor of the Senate to come up with a bipartisan approach to solving this problem, but we fell short. When a bipartisan group of Senators came up with a proposal, which I supported and which received over 50 votes, at the end of the day, the Trump administration opposed it, so it went down, and we did not answer the need for the passage of legislation.

There is a new issue before us, one most Americans are well aware of; that is, the President's announcement of what is known as the zero tolerance policy. It started at the beginning of April, and it was a policy by our government to literally arrest and charge every person who came to this border without legal status.

You could come to the United States without legal status and apply to become a person protected with asylum or a refugee. Just coming to the border itself is not a crime if you come for that purpose.

But this new zero tolerance policy said that they would charge every person who came to the border as a criminal. Well, one thing led to another because once a person has been charged as a criminal—even as a misdemeanant criminal—in most circumstances, their children, minors in their custody, are removed from them. That is exactly what happened. In 2,700 cases, our government, under the President's zero tolerance policy, forcibly removed children from their parents.