

In debating this measure over the past week, we voted on several amendments. We hope to include dozens more in a managers' package that we are working with the Democrats on that continues to evolve. We sought to achieve a fair process on this package. The bill managers have gone to great lengths to accommodate Members' interests within the framework that has allowed us to make so much progress thus far in the appropriations process.

I want to thank my colleagues. I especially thank Senator LEAHY for working together with us in a bipartisan way. We hope this will continue to be a constructive process because all of us benefit. In this light, I urge my colleagues to vote yes so we can continue to move forward on this package and build upon the momentum we have generated thus far.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. LEAHY. Mr. President, I applaud what the senior Senator from Alabama said. We worked very closely together on the weekend, yesterday, and today, and we are continuing to work on a managers' package. I also want to be able to bring up my elections security grants amendment, especially as we know that Russia and others continue to try to interfere with our elections.

I believe the Senate has to act as a coequal branch of government in defending against a threat to our democracy. The threat is very real. Our intelligence community unanimously agrees that Russia interfered in the 2016 elections. There is an imminent threat to our 2018 elections. Just last week, we learned that a Russian hacker targeted the office of a sitting Senator. We can't ignore such a threat against this Chamber or our government.

My amendment, if I bring it up, will provide \$250 million for State election security grants to protect our elections. It improves election cyber security, replaces outdated election data equipment, and undertakes other anti-cyber efforts.

In fiscal year 2018, Congress came together—Republicans and Democrats, House and Senate—and appropriated \$380 million for state election security grants. It was the first new funding for election security in years. In just a few short months since then, all the States and territories—55 in all—requested funding, and 100 percent has been committed to the states and 90 percent disbursed.

Last week, 21 State attorneys general signed a letter pleading with Congress to provide more funding to address this crisis, writing: "More funding is essential to adequately equip states with the financial resources we need to safeguard our democracy and protect the data of voting members in our states."

Securing our elections and safeguarding our democracy should not be a partisan issue. The House Republicans blocked Democrats from even

having a vote on the House floor. I am still hopeful the Senate will not make that same mistake.

Let us heed the warnings of our intelligence agencies. Of the lights blinking red. Of the appeals from the attorneys general, the secretaries of state, and the state and local election officials who are sounding the alarm. This duty has fallen to us, and we must not later be found to have been asleep at the switch, with so much at stake.

I join with Senator SHELBY on this next vote, but I do want Senators to be on notice that I will be bringing this up at some point.

The PRESIDING OFFICER. Pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The assistant bill clerk read as follows:

#### CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on Senate amendment No. 3399, to H.R. 6147, an act making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.

Mitch McConnell, Thom Tillis, Johnny Isakson, Orrin G. Hatch, John Hoeven, Bob Corker, James Lankford, Lindsey Graham, Mike Crapo, David Perdue, Mike Rounds, Steve Daines, Roger F. Wicker, John Boozman, James M. Inhofe, Roy Blunt, Jerry Moran.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on amendment No. 3399, offered by the Senator from Alabama, Mr. SHELBY, to H.R. 6147, an act making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes, shall be brought to a close?

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The senior assistant legislative clerk called the roll.

Mr. CORNYN. The following Senators are necessarily absent: the Senator from Arizona (Mr. FLAKE) and the Senator from Arizona (Mr. MCCAIN).

The PRESIDING OFFICER (Mr. HOEVEN). Are there any other Senators in the Chamber desiring to vote?

The yeas and nays resulted—yeas 94, nays 4, as follows:

[Rollcall Vote No. 175 Leg.]

#### YEAS—94

Alexander	Casey	Enzi
Baldwin	Cassidy	Ernst
Barrasso	Collins	Feinstein
Bennet	Coons	Fischer
Blumenthal	Corker	Gardner
Blunt	Cornyn	Graham
Booker	Cortez Masto	Grassley
Boozman	Cotton	Harris
Brown	Crapo	Hassan
Burr	Cruz	Hatch
Cantwell	Daines	Heinrich
Capito	Donnelly	Heitkamp
Cardin	Duckworth	Heller
Carper	Durbin	Hirono

Hoeven	Moran	Shaheen
Hyde-Smith	Murkowski	Shelby
Inhofe	Murphy	Smith
Isakson	Murray	Stabenow
Johnson	Nelson	Sullivan
Jones	Perdue	Tester
Kaine	Peters	Thune
Kennedy	Portman	Tillis
King	Reed	Udall
Klobuchar	Risch	Van Hollen
Lankford	Roberts	Warner
Leahy	Rounds	Warren
Manchin	Rubio	Whitehouse
Markey	Sanders	Wicker
McCaskill	Sasse	Wyden
McConnell	Schatz	Young
Menendez	Schumer	
Merkley	Scott	

#### NAYS—4

Gillibrand	Paul
Lee	Toomey

#### NOT VOTING—2

Flake	McCain
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The PRESIDING OFFICER. On this vote, the yeas are 94, the nays are 4.

Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

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

The PRESIDING OFFICER. Cloture having been invoked, the clerk will report the bill.

The senior assistant legislative clerk read as follows:

A bill (H.R. 6147) making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.

Pending:

Shelby amendment No. 3399, in the nature of a substitute.

Murkowski amendment No. 3400 (to Amendment No. 3399), of a perfecting nature.

The PRESIDING OFFICER. The Senator from Florida.

#### UNANIMOUS CONSENT REQUEST—S. 3304

Mr. NELSON. Mr. President, to accommodate the Senator from Utah, I will not make my remarks first, but just by way of introduction to say that tonight at midnight American national security is going to be irreversibly weakened by the actions of President Trump and his administration. That is because at midnight the administration will allow the online publication of blueprints to manufacture 3D plastic guns, and this is one example.

So to accommodate the Senator from Utah, instead of making my remarks now, I ask unanimous consent that the Senate proceed to the immediate consideration of S. 3304 submitted earlier today; that the bill be considered read a third time and passed, and the motion to reconsider be considered made and laid upon the table with no intervening action or debate.

The PRESIDING OFFICER. Is there objection?

The Senator from Utah.

Mr. LEE. Mr. President, reserving the right to object, I first saw this legislation literally moments ago; therefore, I haven't had adequate time to review it, but I will say this: Any legislation that comes from this body that begins with the following words will attract my attention and should attract the attention of anyone who is concerned about our First Amendment and other constitutional rights. It begins with the words: "It shall be unlawful for any person to intentionally publish. . . ." That ought to be concerning to us—to each and every one of us—Democrats and Republicans alike.

On that basis, I object.

The PRESIDING OFFICER. Objection is heard.

The Senator from Florida.

Mr. NELSON. Mr. President, the Senator is basing that on First Amendment rights. There are many limits on our First Amendment rights of speech. You cannot say "fire" in a crowded theater. Why in the world would you assert First Amendment rights to publish instructions to manufacture a plastic gun that someone can take through a metal detector, into a crowded theater, and start shooting in that theater—instead of shouting "fire," which is clearly an understood limitation upon our First Amendment rights of speech.

It is inexplicable that the administration is allowing this to go into effect at midnight tonight. It is dangerous. In fact, the President this morning tweeted that allowing these blueprints to go online—the President tweeted: "It doesn't seem to make sense."

I would say amen to that, Mr. President, but it is your administration that has allowed this to happen because after years of winning this issue in courts at every stage of litigation, the administration has surrendered to the crazed demands of a self-described anarchist who is going to put this on the internet. He wants to sow chaos—he said so—in our country and across the world by making these blueprints widely available.

We can make this impossible if, No. 1, the President will do it. He can stop it before midnight, and the clock is ticking. We are only talking less than 9 hours from now because 3D-printed guns, made of plastic or resin, can't be detected by metal detectors. Because they are plastic, there is not a serial number on the metal so they are untraceable, and anyone can get their hands on them, even people who are legally barred from having a gun, such as felons or domestic abusers. So after midnight, people can walk onto airplanes with a deadly weapon because they are not caught in the metal detector, and people would not know about it.

People can walk into schools. My State is the most recent for a school shooting. As a result of Parkland, people are outraged. They want to harden schools, but now are we going to render

the metal detectors useless as they try to harden the schools because somebody can get through a metal detector with this or with an AK-47 or an AR-15 that can be manufactured by these 3D printers?

Somebody could come into this building, somebody could be up in that Gallery right now, and if they have a plastic gun, including bullets that are plastic bullets, we wouldn't know about it.

So whether you are talking about schools or this Chamber or whether we are talking about airports, any public space that we try to protect is going to be useless because these 3D-printed firearms are a direct threat to our national security, and we are going to let these go up on the internet tonight at midnight.

I think some of our allies like the Israelis should be concerned about this because this is not limited to the United States. These can be printed anywhere in the world. Therefore, it can give national security apparatuses a great headache because they can't detect them.

So as I stated in the unanimous consent request, I and other Senators have introduced the legislation today to block the online publication of blueprints.

Now, as it turns out, since we can't do it here, and if the President can't do it in 8 hours 45 minutes, it is going online, and it is going to take us a long time—I mean, what Senator or Representative can object to this? So even if we can get the legislation passed, it is going to take a while because the legislative process is slow.

We have also introduced a separate bill to require every gun to have a serial number and to have a main component made of metal so it can be detected by a metal detector.

Obviously, this is all common sense. This is not a partisan issue. Everybody should be concerned about the threat posed by these deadly plastic guns.

I had intended to give these remarks before asking for unanimous consent. As an accommodation to the Senator from Utah, who had to run to an appointment, I went ahead and asked that unanimous consent. But I want my fellow Senators, who have been so great and so articulate on this issue, to be heard. I ask for them to also speak—the Senator from Utah's objection was about First Amendment rights—about why those objections don't apply here.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. BLUMENTHAL. Mr. President, I thank my colleague and friend from Florida for his leadership on this profoundly important and imminently threatening issue of safety, as well my colleague from New Jersey for his very important leadership and also Senator MARKEY from Massachusetts. We have joined together in this cause to prevent a new wave of lethal gun violence in our streets and communities resulting

from these plastic, undetectable, and untraceable, weapons. We are talking about assault rifles, pistols, and shotguns—all of them homemade. They are ghost guns. They are the new frontier and new face of gun violence in this country.

Our colleague from Utah raised a First Amendment objection. The fact is that the courts are dealing with that objection. It is the basis of a challenge brought by a group who so far has failed in the courts to stop this public health regulation.

No right is absolute. The First Amendment is not absolute. The idea of crying fire in a movie house is one example that is given time and again. Likewise, in the course of our history, we have found that the First Amendment has to yield to public safety when there is an imminent and urgent threat. Clearly, there is here.

I have supported companion legislation that would, in fact, stop the actual making of these kinds of weapons. It involves none of the First Amendment difficulties the Senator from Utah has raised, and I will be pursuing it perhaps through the same kind of unanimous consent effort in the days to come.

Today, the Senator from Florida is absolutely right to seek this body's unanimous consent in the face of this threat that is self-inflicted by the Trump administration. It has caved to the rightwing fringe group and the NRA, which are challenging this public safety regulation, and it has, in effect, snatched defeat from the jaws of victory because the litigation was on a path to prevailing against those objections. This litigation should have been permitted to run its course. It was on a path to success. But now the administration has created this emergency, beginning at midnight tonight. On August 1, plans, designs, blueprints can be published without limit on the internet, making possible the mass homemade manufacture of these ghost guns. They are a scourge, a potential source of death and injury on our streets.

Any idea that plastic is less durable or strong as a source of material for these guns is completely outmoded because we make planes from plastic. Plastic in some forms is as durable and strong as metal.

The threat here is real and urgent, and I join my colleague from Florida in asking that there be unanimous consent. I hope we will pursue this legislative effort together and that we will have bipartisan support. I stress that we must have bipartisan support. Senators who fail to step up, speak out, and act in the face of this emergency should be held accountable.

Mr. President, I yield the floor to our colleague from New Jersey.

The PRESIDING OFFICER. The Senator from New Jersey.

Mr. MENENDEZ. Mr. President, I join my colleagues on the floor, and I salute both Senator NELSON and Senator BLUMENTHAL, who represent

States whose citizens have felt the scourge of gun violence—in Newtown, in Parkland, and in the Pulse nightclub. I don't know how many more Parklands we need, but I certainly know that my colleague from Utah, who only read a part about what alarms him—that it shall not be possible to publish what? To publish the information to create a gun—a gun that is undetectable and untraceable.

Why are we spending billions to secure ourselves as we go through the airports of our country? We saw it after September 11. Now we are going to undermine all of those billions and all of that security by allowing anyone here or in the world to get access to the IP address. You download it, and all of a sudden, you can create a three-dimensional plastic gun that is as deadly as any other gun.

What draws us to the floor to ask the unusual effort of unanimous consent to ultimately bring this legislation to the floor is the failure of the administration to not allow this to happen in the first place. We won't need legislation if the President turns back the decisions of his Secretary of State and others in his administration and says: Wait. This is not in our national security interests. It is not in the national interests of the United States to allow our citizens to be exposed to an undetectable, untraceable gun that is as deadly as any other. It is not in the national interests and security interests of the United States to have our soldiers halfway around the world face terrorists who have access to a new design that will be cheaper for them and at the end of the day will allow them to attack our soldiers.

It is unconscionable. But since the administration, if anything, has acted the opposite way, we come to the floor. If the government has any specific role that rises above all others, it is to protect its citizens. That is what we are trying to do here. It should be a bipartisan request.

What is so difficult about the legislation? Nothing much. One of the two pieces of legislation simply says that you cannot permit an IP address to be published on the internet because, globally, anybody can get that, download it, and create a gun. That is the simple part of it. The other one is that any gun has to be traceable and identifiable and therefore has to have a number on it.

Even when our colleagues who are the most ardent advocates of the Second Amendment say they want to keep guns out of the hands of criminals—well, how do you keep a gun out of the hands of criminals when it isn't detectable and isn't traceable? It is pretty amazing. I have been in the Congress 26 years between the House and the Senate, and it is one of the most amazing moments for me.

Look, this country has a gun violence problem. It has a mass-shooting problem. But a do-it-yourself, downloadable gun will supercharge this

crisis, leading to more senseless tragedies. It is already too easy for criminals, extremists, and terrorists to get their hands on a gun. Now we are going to add a new concern: terrorists packing the plans for new, plastic, printable firearms. I don't care if a gun is made out of metal or plastic—if it can fire a bullet and take someone's life, then it should be regulated.

It is beyond irresponsible for the Trump administration to roll over and allow a self-described anarchist to post directions for do-it-yourself guns on a website available to anyone with an internet connection. That is what we are saying. Already, according to some news reports, the blueprints for an AR-15—the weapon used in the massacre at Parkland—were downloaded more than 2,500 times. That is 2,500 unknown individuals in an unregulated space.

As the ranking member of the Senate Foreign Relations Committee, I was appalled to find out that the State Department carried this out without notifying Congress. Last Wednesday, Secretary of State Mike Pompeo was before our committee, and he looked us in the eye and said that he was unaware of the issue and that he would look into it. That was on Wednesday. On Friday, the State Department had suspended arms export regulations specifically to allow these 3D gun blueprints to be posted on the internet—so much for looking into it.

This is a case that was proceeding through the courts where the government had won at every round. In this morning's tweet, the President made it pretty clear that instead of listening to the concerns of the American people when he has a gun question—which I would submit is not even a gun question; it is a national security question—he listens to the NRA.

The NRA may be concerned in this particular case. Why? Because plastic guns don't get built by the gun manufacturers and dealers that they represent and that fund their causes.

The posting of a 3D gun shows just how dangerous the Trump administration's regulatory effort to loosen export controls on firearms—including assault-style rifles and even sniper rifles—actually is to the safety of Americans at home, abroad, and innocent civilians across the globe.

All you have to do is go to this company's website to see it for yourself. They are proclaiming that “the era of the downloadable gun” is here. That is what they say on the website. “The era of the downloadable gun” is here. Well, we should make sure that era doesn't happen.

These are two simple but powerful commonsense pieces of legislation that can protect us. I call upon the President to stop it dead in its tracks so we don't have to wait for the legislation, but if not, we call upon this institution to protect the American people.

I hope my colleagues will consider coming back later in the day and making another unanimous consent request

so that we can actually protect the American people against the ability of anyone—anyone—with a 3D printer to create a gun that can kill a human being and ultimately defy all of our security procedures at airports and elsewhere. And it lets any terrorist in the world who wishes us harm to manufacture it in quantity. That is pretty outrageous. That is what we are talking about. I hope the administration will see the light and change their course.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Maryland.

Mr. VAN HOLLEN. Mr. President, I thank the Senator from Florida, Mr. NELSON, for introducing this legislation and also my other colleagues who have been on the Senate floor today.

This is emergency legislation, which is why there was a request for unanimous consent to move forward today. It is very disturbing that consent was not provided because we know that as a result of the Trump administration's actions, starting tomorrow, people all over the country—in fact, all over the world—are going to be able to download on their computers instructions and a whole manual on how to manufacture plastic guns with 3D printing.

This is something that has been before previous administrations. The Obama administration fought hard against this ability for people to be able to send those instructions to make 3D guns at the speed of light around the world. In fact, this administration early on opposed allowing this to happen.

Somehow, when this whole lawsuit was resolved the other day, the folks who want to send these instructions around the world were allowed to do so. In fact, Alan Gottlieb, who is with the Second Amendment Foundation that was part of this case, said:

We asked for the Moon and we figured the government would reject it, but they didn't want to go to trial. The government fought us all the way and then all of the sudden folded their tent.

Secretary Pompeo and the Trump administration folded their tent. As a consequence, Americans will be placed at much higher risk starting tomorrow. We have already seen over 1,000 people sign up to begin to receive the instructions to make AR-15s using 3D printing.

Why is this going to pose a big danger? No. 1, it is a total end-run around criminal background checks for the purchase of a handgun or any kind of weapon. We should be closing the loopholes in the existing background check system, closing things like the gun show loophole. Instead, this allows for a total runaround. If you can just download instructions and use a 3D printer to make a gun at home, you obviously aren't going to go through any kind of criminal background check.

No. 2, we have spent a lot of time and effort giving the ATF the authority to track guns used in crimes. I would have

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 iTunes. 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 non-judicious 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